#726

DSM Nutritional Products
Regulatory Affairs
45 Waterview Boulevard
Parsippany, NJ 07054
United States of America

August 15, 2017

Office of Food Additive Safety (HFS–200),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5001 Campus Drive,
College Park, MD 20740.

Subject: GRAS Notification – elaVida™

To whom it may concern:

DSM Nutritional Products LLC is submitting for FDA review a GRAS notification. The enclosed document provides notice of a claim that the food ingredient elaVida™, which is a polyphenol-rich preparation derived from olive fruits, described in the enclosed notification, is exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because it has been determined to be generally recognized as safe (GRAS) based on scientific procedures.

If you have any questions or require additional information, please do not hesitate to contact the undersigned at your convenience.

Sincerely yours,

(b) (6)

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Summary of Information Supporting the Generally Recognized As Safe (GRAS) Status of elaVida™ (A Polyphenol Preparation From Olive Fruits) for Use as an Ingredient in Selected Foods

- Final -

Prepared for: DSM Nutritional Products, LLC
45 Waterview Boulevard
Parsippany, New Jersey
07054

August 15, 2017

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Summary of Information Supporting the Generally Recognized As Safe (GRAS) Status of elaVida™ (A Polyphenol Preparation From Olive Fruits) for Use as an Ingredient in Selected Foods

1.0 STATEMENTS AND CERTIFICATION

1.1 Compliance with 21 C.F.R. § 170.30

DSM is hereby submitting a GRAS notice in accordance with 21 CFR 170.30.

1.2 Name and Address of Notifier

DSM Nutritional Products, LLC.
45 Waterview Blvd.
Parsippany, New Jersey, 07054, USA

Tel: 973-257-8500
www.DSM.com

1.3 Name and Address of Manufacturer

C/ Antonio Belmonte Abellán, 3-5
30100 Murcia,
Spain

Tel.: +34 968 307 250
www.probelte.es

1.4 Name and Address of Exclusive Distributor

DSM Nutritional Products, LLC.
45 Waterview Blvd.
Parsippany, New Jersey, 07054, USA

1.5 Name of the Notified Substance

DSM Nutritional Products LLC (DSM hereafter) has undertaken an independent safety evaluation of a polyphenol preparation from olive fruits, to be sold under the trade name of elaVida™.

1.6 Intended Conditions of Use and Technical Effects of the Notified Substance

The purpose of the initial evaluation was to ascertain whether the direct addition of elaVida™ to certain specified foods intended for the general U.S. population at a use level of 12.5 mg/serving up to 25 mg/serving, depending on the food use application, was Generally Recognized as Safe (GRAS) through scientific procedures. A self-determination of GRAS status would make the proposed use of elaVida™ exempt from the definition of "food additive" and thus from the premarket approval requirements outlined in section 201(s) of the Federal Food, Drug, and Cosmetic Act.

DSM's olive derived product, elaVida™ is self-affirmed generally Recognized as Safe (GRAS) for use in eleven broad food categories: bakery products; beverages; dairy products and substitutes; desserts; fats and oils; fruit juices and nectars; dry seasoning mixes for meat, poultry and fish; chewing gum; sauces, dips, gravies and condiments; snacks; and vegetable juices to deliver 5 to10 mg of hydroxytyrosol per serving of food.

1.7 Basis for GRAS Determination

In the present GRAS dossier, DSM provides detailed information about the intended foods and use levels, ingredient manufacturing, specifications, and batch analyses, along with a summary discussion of the safety of elaVida™ and an assessment of consumer exposure. In determining whether the use of elaVida™ in human foods would be GRAS, DSM has considered that hydroxytyrosol from olives is a non-novel dietary component with an estimated average intake in some Mediterranean countries of 12 mg/day and a high-level intake of up to 30 mg/day. In this document, the safety information pertaining to elaVida™ 40% is assessed. The safety evaluation involves the assessment of the pivotal safety studies with extract from the process used to make H40. To fulfil the "common knowledge" element of a Generally Recognized As Safe (GRAS) determination, the studies regarded as pivotal, the genotoxicity studies and a 90-day rat study in the rat are published (Kirkland *et al.,* 2015; Heilman *et al.,* 2015). Safety data for other olive extracts, including a less concentrated form of elaVida™ 15% (or H15), plus studies looking specifically at hydroxytyrosol, are presented in this dossier as supporting information.

To make its GRAS determination, DSM sought the opinion of a panel of scientific experts specifically convened to assess whether: (1) the available information is sufficient in quantity and quality to demonstrate to a reasonable certainty that no harm will result from the proposed use of elaVida™; and (2) there is a basis to conclude there is publicly available information that is sufficient to enable a conclusion that the technical evidence of safety is generally well known and accepted. The Expert Panel opinion statement is attached as Appendix 1.

1.8 Exemption from Premarket Approval

DSM Nutritional Products LLC believes that the notified substance, elaVida™ is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on our conclusion that the notified substance is GRAS under the conditions of its intended use.

1.9 Availability of Information for FDA Review

Data and information that are the basis for DSM's GRAS conclusion are available to the FDA.

1.10 Copying

The FDA can review and copy the data and information that were used to conclude that elaVida™ is GRAS during customary business hours at:

DSM Nutritional Products, LLC.
45 Waterview Blvd.
Parsippany, New Jersey, 07054, USA

1.11 Accessibility to Raw Data

DSM will provide for FDA's evaluation a complete copy of the data and information used as a basis for the GRAS conclusion either in an electronic format or on paper.

1.12 Exemption From Disclosure

The data and information in Parts 2 through 7 of this GRAS notice are not exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552.

1.13 Certification

The undersigned certifies that to the best of their knowledge, this GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to DSM Innovation and pertinent to the evaluation of the safety and GRAS status of the use of elaVida™.

(b) (6)

July 23, 2017

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Date

2.0 Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

2.1 Identity: elaVida™ (A Polyphenol Preparation From Olive Fruits)

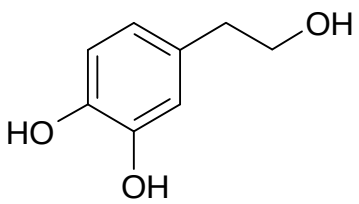
elaVida™ is made from olive fruits using a proprietary, solvent-free process. elaVida™ has a standardized content of the main olive phenol and anti-oxidant, hydroxytyrosol (HT), which is the defining characteristic component of the commercial product undergoing GRAS Notification. elaVida™ containing no less than 40% HT content may also be referred to as H40.

Hydroxytyrosol (CAS number: 10597-60-1; IUPAC name: 4-(2-hydroxyethyl)-1,2-benzenediol; other names include: 3-hydroxytyrosol 3,4-dihydroxyphenylethanol (DOPET), 4-hydroxytyrosol, as well as the abbreviation 'HT') is the major phenolic component of olives, which originates from the hydrolysis of another olive component, oleuropein, during the maturation of olives, during the storage of olive oils, and also during the preparation of olives for consumption (Granados-Principal *et al.,* 2010). The oleuropein component loses glucose to form the aglycone, which then converts to hydroxytyrosol and elenolic acid. The chemical structure of hydroxytyrosol is shown in Figure 2-1.

elaVida™ 40% (H40) is an olive extract The olive fruit extraction process used to produce H40 is precisely defined and is performed under food grade standards and current Good Manufacturing Practice (cGMP). The preparation of elaVida™ from H40 involves addition of an inert matrix, maltodextrin. Different grades of extract from the process used to produce H40, based upon HT content, are possible. These vary by the hydroxytyrosol / water ratio. H40 is the extract nominally containing 40% hydroxytyrosol. H35 is an extract from the same process that has also been used for safety tests. H35 contains approximately 35% hydroxytyrosol, due to a shorter final water evaporation step.

Hydroxytyrosol is a phenylethanoid, a type of phenolic phytochemical believed to be one of the most powerful natural antioxidants. Having three hydroxyl groups it is often referred to as a polyphenol, although it is quite a small molecule in comparison to many other natural polyphenols. Pure hydroxytyrosol is clear, colorless, and liquid and mixes with either aqueous or fatty matrices (Soni *et al.,* 2006).

Figure 2-1 Chemical structure of hydroxytyrosol



2.2 Manufacturing and Specifications

The olive fruit extraction process used to produce H40 is precisely defined and is performed under food grade standards and cGMP. There are two variations in the initial steps of the manufacturing process. H40 can be derived either from extraction from the olive pomace, or from the vegetation water obtained from the olives, as defined within the Manufacturing process documentation. An evaluation of potential by-products in H40 has also been made.

2.2.1 Manufacturing

The manufacturing process of elaVida™ (H40), is a simple aqueous extraction of the polyphenolic compounds (i.e. hydroxytyrosol) from olive fruit pomace. Alternately, the vegetation water co-produced during olive oil production in the absence of organic solvents may be used as source material. A pair of schematic diagrams describing the manufacture of elaVida™ from either source material are presented below in Figure 2-2 and Figure 2-3, respectively.

When the starting material is olive pomace, the material is fed into a stirred glass lined reactor at the same time that hot demineralized water is fed into the tank, while stirring is maintained so that the olive pomace is homogeneously dispersed in water. Sulfuric acid is added to produce acidic conditions. The olive pomace is then subjected to a thermal treatment under acidic conditions at a temperature not exceeding 100°C, preferably within the range from 70°C to 100°C at a residence time within the range of 2 to 4 hours. The purpose of this thermal treatment is similar to the treatment of table olives, which are consumed after processing for removal of their natural bitterness. Hence, thermal treatment is undertaken in order to complete they hydrolysis of oleuropein, ligstroside and their aglycons in olive flesh, giving rise to hydroxytyrosol and tyrosol. In parallel, the thermal treatment also inactivates enzymes within the fruit to avoid oxidation and preserve the product from microbial degradation.

The crude olive extract is next pH adjusted with NaOH, forming very water-soluble salts. Once the acid is neutralized, the crude olive extract is pumped through a heat exchanger and into stirring tanks for homogenization and to allow any remaining water-soluble compounds in the olives to pass from the fruit into the water. The crude olive extract then undergoes centrifugal separation to separate the solid fraction formed by the exhausted olive paste, and from the liquid phase containing the water soluble aqueous compounds extracted from the olive fruit. For such centrifugal separation, in the case of olive pomace as the starting material, a primary centrifugal decanter removes the exhaust olive paste, followed by a second clarification centrifuge to eliminate fine solid particulates in suspension that had not been decanted in the previous step.

In an alternative manufacturing process where vegetation water is used as starting material, separation starts directly by the clarification centrifuge step. Vegetation water is produced by physical means (centrifugal), during olive processing for olive oil production. After separation from the olive pomace, the vegetation water is concentrated by evaporation and stored in stainless

steel tanks, to be used for the production of elaVida™ (H40). Manufacture from olive vegetation water does not involve an initial heating process (up to 100°C) in acidic conditions and is therefore referred to occasionally as occurring under Mild Process Conditions or MPC. Previously described steps in the manufacture of aqueous olive pomace extract are not needed when the starting material is vegetation water.

Upon completion of the clarification centrifuge step, the H40 production process becomes identical when either olive pomace or vegetation water are used as starting material. In both cases, the clarified liquid phase containing aqueous olive extract enters stirred tanks for a second homogenization step. This liquid phase is then loaded in a chromatographic resin column. Olive polyphenols and other compounds retained in said chromatographic column are then eluted with demineralized water.

The water-eluted solution from the first column is passed through membrane filters, which effectively remove water. Then, the olive extract is concentrated by tangential flow filtration (TFF-I) and is loaded in a second column of chromatographic resin. The product retained in this second column is again eluted with demineralized water, obtaining a purified olive extract rich in hydroxytyrosol and substantially free from sugars and salts, including the salts formed during the neutralization step.

This concentrated liquid extract, which is substantially free from sugars and salts, is again passed through membrane filters. The olive extract is again concentrated by tangential flow filtration (TFF-II) and is then subjected to a thermal treatment (pasteurization) at a temperature not to exceed 100°C, preferably within the range from 70°C to 100°C, at a residence time within the range of 1 second to 120 seconds. Then, the pasteurized olive extract is further concentrated by vacuum evaporation, to further remove water and produce an olive concentrate in liquid form containing 40 % hydroxytyrosol, and is hereafter referred to as H40. The product is then further homogenized by stirring into a mixing tank, pumped through a filter, and filled into aseptic bags. Finally, the bags are labeled and packed manually in cardboard boxes, and stored at the warehouse. The finished product is stable in storage at 15°C for 18 months and at 40°C and 75% relative humidity for 6 months (See Section 2.3). The trade name for the finished commercial product is called elaVida™.

Figure 2-2 elaVida™ Manufacturing process (Option 1)

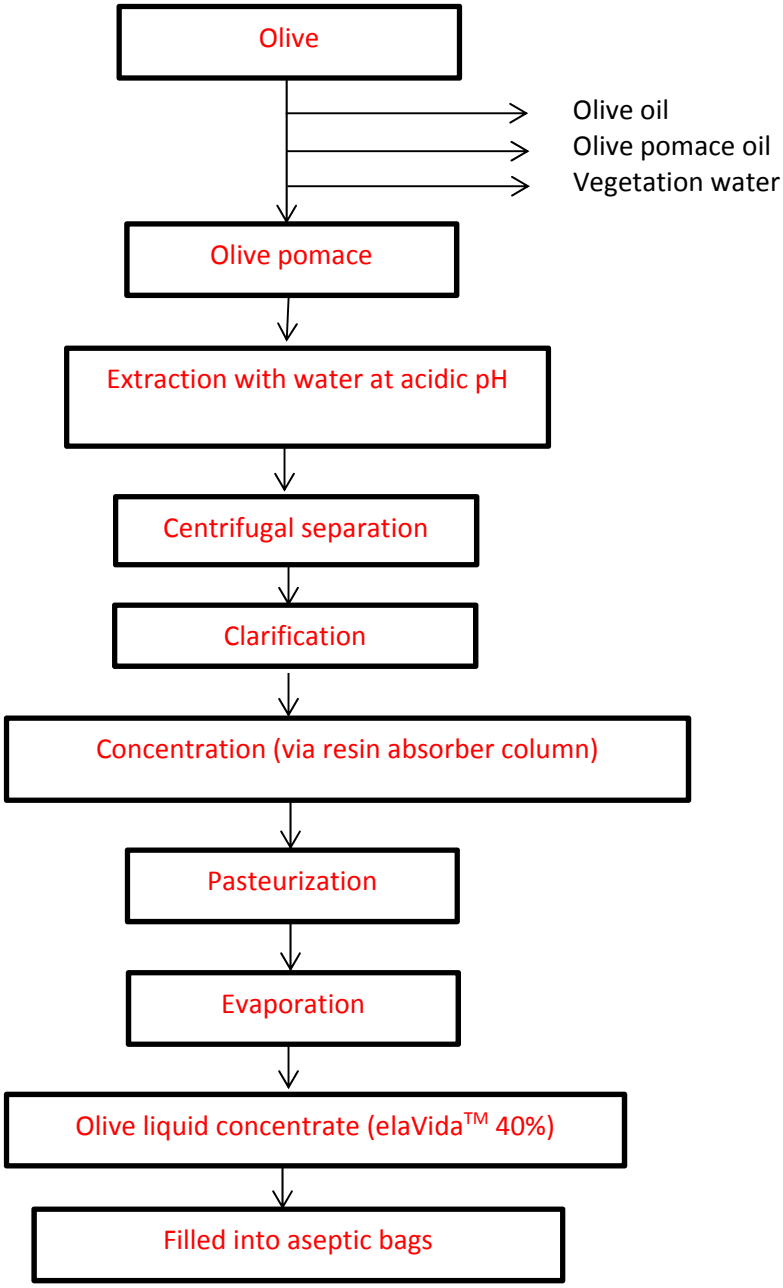
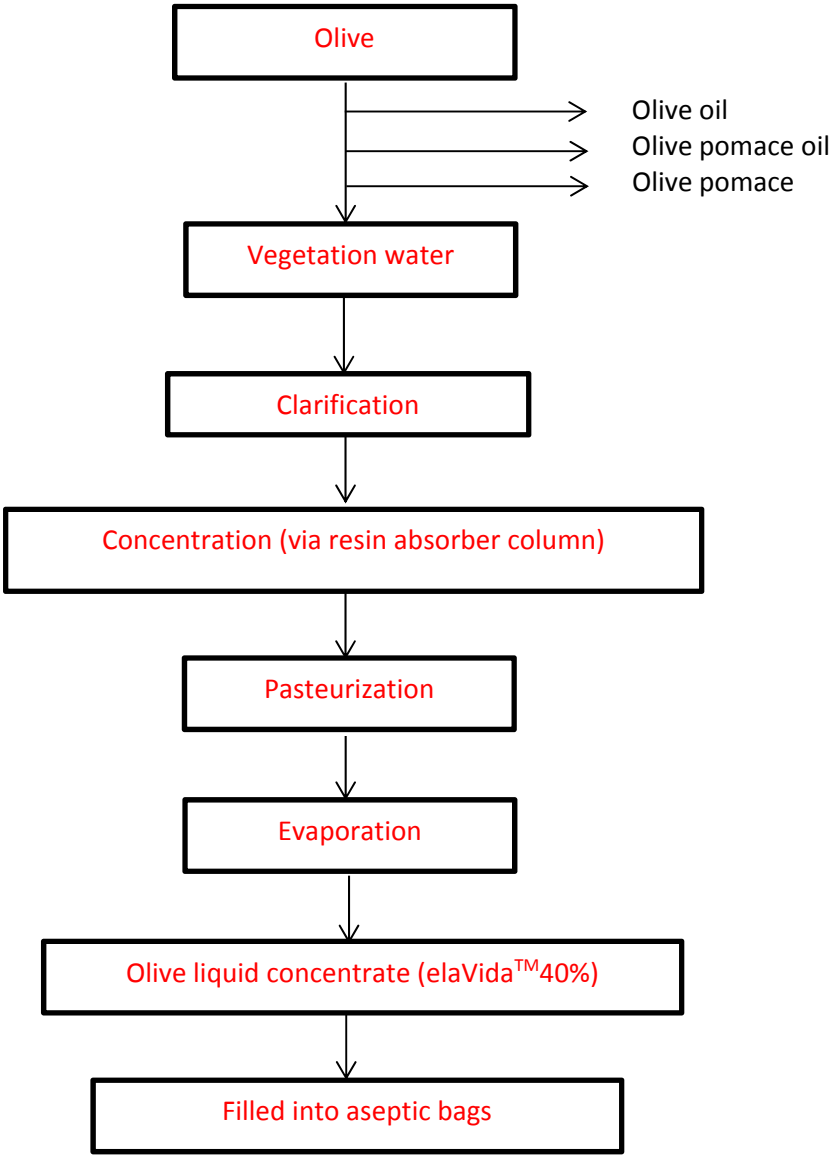


Figure 2-3 elaVida™ Manufacturing process (Option 2)



2.2.2 Specifications and Analyses

Specifications for elaVida™ are presented in Table 2-1.

Table 2-1 Chemical and microbiological specifications for elaVida™ (H40)

Parameter	Specification elaVida 40%	Method
Appearance	Viscous liquid	Visual
Color	Yellow to dark brown	Visual
Identity	Corresponds	HPLC
Hydroxytyrosol	Min. 40% w/w	HPLC-UV
Minor Polyphenols	Max. 8% w/w	HPLC-UV
Tyrosol	Max. 1:58 w/w of hydroxytyrosol content, i.e. tyrosol is <= 1.75% of hydroxytyrosol content	HPLC-UV
Oleuropein	Max. 1:230 w/w of the hydroxytyrosol content, i.e. oleuropein is <= 0.43% of hydroxytyrosol content	HPLC-UV;
Total ash	Max. 3.0 %	Ph. Eur- 2.4.16
pH of an aqueous solution containing 50 % (w/w) of the extract and 50 % (w/w) of distilled water	2.5 to 4.0	pH-Meter
Dispersibility in water 20°C	n/a	
Loss on drying	n/a	USP 35 <921> water determination, Method III (Gravimetric)
Lead	Max. 1.0 ppm	Heavy metals Ph. Eur. 2. 4.27 (examined by AAS 2.2.23) and total Ph. Eur. 2.4.8, method A
Mercury	Max. 0.1 ppm	
Cadmium	Max. 0.5 ppm	
Arsenic	Max. 1.0 ppm	
Total Heavy metals	Max. 10 ppm	
Total aerobic plate count	max 10^3 cfu/g	Ph. Eur. 2.6.12 and 2.6.13 and Ph. Eur. 2.6.31
Total yeast and mold	max 10^2 cfu/g	
Enterobacteria	<10 cfu/g	
Salmonella spp.	Negative in cfu/25g	
Escherichia coli	Negative in cfu/10 g	
Staphylococcus aureus	Negative in cfu/10 g	
Pseudomonas aeruginosa	Negative in cfu/10 g	
Clostridia	Negative in 1 g	Ph. Eur. 2.6.13

Several lots were analyzed to verify that the manufacturing process produced a consistent product within the product specifications. Summaries of the batch-to-batch reproducibility of chemical and microbiological product analyses of three non-consecutive lots are presented in Table 2-2. Actual certificates of analysis are attached as Appendix 2.

Table 2-2 Confirmatory analyses for 3 lots of elaVida™ (H40)

	Specification	Lot Results		
		EV17032201	EV17032202	EV17032203
Item				
Appearance	Viscous liquid	Complies	Complies	Complies
Colour	Yellow to dark brown	Brownish	Brownish	Brownish
Identity	Corresponds	Complies	Complies	Complies
Hydroxytyrosol	Min. 41.5 % w/w	48.3%	42.5 %	45.2 %
Minor phenols	Max. 8 %	4.2%	3.8 %	4.9 %
Tyrosol	Max. 1:58 w/w of hydroxytyrosol content	1:71.4	1:91.1	1:107.5
Oleuropein	Max. 1:230 w/w of hydroxytyrosol content	N.D. (oleuropein not detected)	N.D. (oleuropein not detected)	N.D. (oleuropein not detected)
Total Ash	≤ 3.0 %	1.8 %	2.7 %	2.2 %
pH of an aqueous solution	pH 2.5 to 4.0	3.7	3.8	3.8
Heavy metals				
- Lead	max. 1.0 ppm	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm
- Mercury	max. 0.1 ppm	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm
- Cadmium	max. 0.5 ppm	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm
- Arsenic	max. 1.0 ppm	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm
- Heavy metals	max. 10 ppm	< 1.0 ppm	< 1.0 ppm	< 1.0 ppm
Microbiological purity				
- total aerobic plate count	below 10^3 CFU / g	Complies	Complies	Complies
- Total yeasts and moulds count	below 10^2 CFU /g	Complies	Complies	Complies
- Enterobacteria	below 10 CFU	Complies	Complies	Complies
- *Pseudomonas aeruginosa*	negative in 10 g	Complies	Complies	Complies
- *Staphylococcus aureus*	negative in 10 g	Complies	Complies	Complies
- *Escherichia coli*	negative in 10 g	Complies	Complies	Complies
- Salmonella species	negative in 25 g	Complies	Complies	Complies
- Clostridia	negative in 1 g	Complies	Complies	Complies

2.3 Compositional analysis of elaVida™

For the scope of regulatory clearance of elaVida™ in North America analytical data on its composition was requested. Two representative elaVida™ H40 batches were selected for compositional analysis. They were produced in 2013 in the production plant of the supplier Probelte Biotechnología in Murcia, Spain. Analysis of hydroxytyrosol, other olive phenols and moisture were performed at DSM Nutritional Products analytical research center.

2.3.1 Methods

Nutritional values have been determined by means of accepted food standards. Hydroxytyrosol has been assayed by a validated internal HPLC method. Other Phenols have been identified and quantified by HPLC-UV-MS. The moisture content was determined by means of a halogen moisture analyzer according to the QC release method of the supplier. Total carbohydrate has been calculated by the difference method according to the formula 100-(weight in grams [protein + fat + water + ash + hydroxytyrosol + other phenols] in 100g of food).

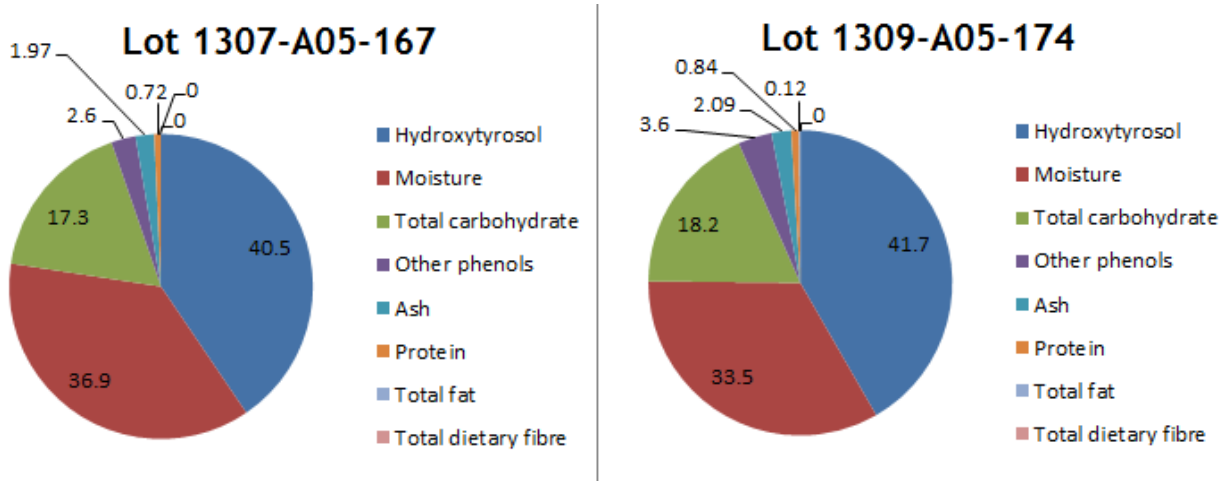
2.3.2 Analytical results

Composition of two H40 olive extract batches are shown in Table 2-3 and Figure 2-4 below.

Table 2-3 Data on chemical composition of two elaVida™ batches (g/100g)

	Lot 1307-A05-167	Lot 1309-A05-174	Method
Hydroxytyrosol	40.5	41.7	HPLC (280 nm)
Moisture	36.9	33.5	Halogen moisture analyzer
Total carbohydrate	17.3	18.2	SLMB/FAO difference method
Other phenols	2.60	3.60	HPLC-UV-MS (280 nm)
Ash	1.97	2.09	ISTISAN 1196/34 pag. 77, gravimetric
Protein	0.72	0.84	MI 2272 rev 01/2013, Dumas
Total fat	< 0.1	0.12	ISTISAN 1996/34 pag. 41, gravimetric
Total dietary fibre	< 0.2	< 0.2	AOAC 991.43 enzymatic-gravimetric

Figure 2-4: Graphical presentation of the chemical composition of two elaVida batches (g/100g)



In olives only a minor part of hydroxytyrosol is available in free form. The majority is present as chemically bound in ester form in its precursor molecules oleuropein, demethyloleuropein verbascoside and other secoiridoids. Other polyphenols present in elaVida™ H40 include: oleuropein (<0.17%), tyrosol (<0.69%), oleuropein aglycone (trace) and gallic acid (trace). Another group of constituents are the flavonoids (luteolin, apigenin, querecetin and others) which are present mainly as mono-, di- and tri-saccharides (Obied et al., 2007; Neveu et al., 2010; Rothwell et al., 2013). Specific endogeneous esterases and glycosidases are present in the fruit which are activated upon malaxation of the fruits. Both enzymatic and non-enzymatic processes lead to the cleavage of these constituents thereby releasing the sugar moieties, phenolic compounds and other olive typical non-phenolic transformation products (Obied et al., 2008; Capozzi et al., 2000).

A comprehensive HPLC-UV-MS analysis was undertaken by DSM to further characterize the phenolic and non-phenolic products in elaVida™ (Gössl *et al.,* 2015) In this investigation, the phenolic constituents were quantitated and their content in total (without hydroxytyrosol) was between 2.6 g/100g and 3.6 g/100g in the observed elaVida™ batches. The most abundant phenolic compound with a content of approximately 1 g/100g in both samples was decarboxymethyl oleuropein aglycon (3,4-DHPEA-EDA). 3,4-DHPEA-EDA is considered as an oleuropein transformation product and is a known constituent of extra virgin olive oil (Neveu et al., 2010; Rothwell et al., 2013). The non phenolic-products were characterized by means of the acquired MS spectra wherein the dlaldehydic form of decarboxymethyl elenolic acid was identified as the most abundant constituent. This compound is a direct breakdown product of 3,4-DHPEA-EDA and was described in olive products earlier (Obied et al., 2008; Christophoridou et al., 2005). Due to the lack of a standards it was not possible to perform a quantitation but by comparison of the MS signal with that of 3,4-DHPEA-EDA it was estimated that the content of this compound in elaVida™ was approximately 0.5 g/100g.

The carbohydrates were calculated according to the difference method. The method was modified such that the measured contents of the phenolic compounds were taken into account in order to produce meaningful data. It should be noted that slight errors occur from the fact that the non-phenolic products as well as some very minor phenolic peaks could not be quantitated. Based on the evaluation of the MS signals, it can be estimated that this error is below 2% and was therefore accepted.

2.3.3 Other phenols

For the purpose of setting a minor phenolic content specification, three batches of Elavida 40% were analyzed for phenolic constituents by means of UHPLC-DAD-QTOF-MS analysis. The content of Hydroxytyrosol as measured by the quality control (QC) release of the manufacturer was 42.5 %, 45,2% and 48.3% in. The content of minor phenolic compounds as quantified by UHPLC-DAD-QTOF-MS was found to be 3.9 %, 4.9 % and 4.2 % in these three batches.

Table 2-4 below is summarizing the analytical results. The individual chromatogram reports, the recorded UV spectra and QTOF-MS data are attached in Appendix 3 (Gössl *et al.,* 2017).

Table 2-4 Results from UHPLC-DAD-QTOF-MS analysis of three elaVida™ batches

RRT*	m/z**	λ_{max} [nm]	Formula	Assignment	Concentration [%]		
					EV17032201	EV17032202	EV17032203
0.86	305.103	283	$C_{16}H_{18}O_6$	Dimeric phenylethanoid	0.54	0.30	0.30
1.00	153.056	280	$C_8H_{10}O_3$	3,4-DHPEA (Hydroxytyrosol, HT)	48.3	42.5	45.2
1.26	137.061	276	$C_8H_{10}O_2$	4-HPEA (Tyrosol)	0.31	0.22	0.20
1.82	337.129	282	$C_{17}H_{22}O_7$	Hydrated form of 3,4-DHPEA-EDA	0.37	0.39	0.46
2.16	337.129	280	$C_{17}H_{22}O_7$	Hydrated form of 3,4-DHPEA-EDA	0.32	0.31	0.36
2.45	349.129	281	$C_{18}H_{22}O_7$	Other Phenol	0.60	0.47	0.45
2.24	321.134	282	$C_{17}H_{22}O_6$	Other phenol	0.28	0.12	0.10
2.28	279.124	281	$C_{15}H_{20}O_5$	Other phenol	0.30	0.54	0.76
2.55	319.118	281	$C_{17}H_{20}O_6$	3,4-DHPEA-EDA	1.20	1.30	1.92
3.15	473.181	281	$C_{25}H_{30}O_9$	Other phenol	0.26	0.26	0.40
				Sum of phenols [%]	52.5	46.4	50.1
				Non-HT phenols (minor phenolic compounds) [%]	4.2	3.9	4.9

* Relative retention time (retention time of phenolic compound divided by retention time of HT)

** Mass-to-charge ratio of detected pseudomolecular ions $[M-H]^-$

There are a large number of phenolic and related substances in extra virgin olive oil (EVOO) and table olives seen in Table 2-5 below (Lozano-Sánchez *et al.,* 2013). The occurrence of these trace substances in the extract is likely to be influenced by the precise extraction method. In the HPLC-UV-MS analyses of formulated elaVida™ 40% batches, several minor phenolic peaks were detected. These were mainly hydrolysis and transformation products of oleuropein. Several individual phenolic species have been tentatively identified. The most predominant ones are decarboxymethyl oleuropein aglycon (3,4-DHPEA-EDA) and decarboxymethyl elenolic acid dialdehyde (EDA), which are known constituents of extra virgin olive oils. As in olive oils (Lozano-Sánchez *et al.,* 2013), a range of very minor phenolic peaks was also observed.

Table 2-5 Proposed phenolic compounds and their derivatives and storage by-products by HPLC (Lozano-Sánchez *et al.*, 2013)

Phenolic and other polar compounds					EVOO			Waste		
Peak	Compound	Molecular formula	T_r (min)	*m/z* calcd	*m/z* exptl	Error	mSigma	*m/z* exptl	Error	mSigma
1	Quinic acid	$C_7H_{12}O_6$	2.1	191.0561	191.0561	0.1	10.4	191.0592	4.8	2.3
2	Oxidized hydroxytyrosol	$C_8H_8O_3$	3.9	151.0401	151.0409	−4.9	5.9	151.0410	−5.3	32.7
3	Uk1	$C_9H_{14}O_6$	5.0	217.0718	ND[a]			217.0727	−4.6	24.6
4	Uk2	$C_7H_{10}O_4$	6.7	157.0506	ND[a]			157.0516	−3.7	7.1
5	Hydroxytyrosol	$C_8H_{10}O_3$	8.1	153.0557	153.0560	1.7	13.4	153.0546	−2.1	24.1
6	Hydrated product of the dialdehydic form of decarboxymethyl-elenolic acid	$C_9H_{14}O_5$	8.3	201.0768	ND[a]			201.0778	4.5	22.3
7	Hydroxylated product of the dialdehydic form of decarboxymethyl-elenolic acid	$C_9H_{12}O_5$	9.2	199.0618	ND[a]			199.0615	1.7	37.7
8	Tyrosol	$C_8H_{10}O_2$	9.9	137.0608	137.0608	0.1	11.0	137.0599	−2.9	25.5
9	Decarboxylated form of hydroxy-elenolic acid	$C_{10}H_{14}O_5$	10.4	213.0768	213.0758	4.8	13.9	213.0768	0.4	40.6
10	Uk3	$C_{20}H_{24}O_9$	10.7	407.1348	ND[a]			407.1352	−1.0	10.2
11	Dialdehydic form of decarboxymethyl-elenolic acid	$C_9H_{12}O_4$	11.0	183.0663	183.0664	−0.7	15.4	183.0676	2.5	33.1
12	Hydroxy-decarboxymethyl oleuropein aglycone or isomer (I)	$C_{17}H_{20}O_7$	12.0	335.1136	335.1119	5.0	11.7	335.1121	3.9	15.9
13	Uk4	$C_{17}H_{18}O_6$	12.2	317.1031	ND[a]			317.1040	−3.0	16.6
14	Dehydro-oleuropein aglycone or isomer (I)	$C_{19}H_{20}O_8$	12.6	375.1085	375.1080	1.4	32.9	375.1103	−5.2	26.6
15	Uk5	$C_9H_{14}O_2$	13.5	153.0921	ND[a]			153.0935	−4.9	19.0
16	Aldehydic form of decarboxymethyl-elenolic acid	$C_{10}H_{16}O_5$	14.0	215.0925	ND[a]			215.0945	4.3	11.8
17	Hydroxytyrosol acetate	$C_{10}H_{12}O_4$	14.4	195.0663	195.0659	1.7	49.8	ND		
18	Uk6	$C_{11}H_{16}O_6$	14.7	243.0874	ND[a]			243.0892	−5.4	13.6
19	Uk7	$C_{11}H_{16}O_6$	15.2	243.0874	ND[a]			243.0891	−5.2	25.7
20	Elenolic acid	$C_{11}H_{14}O_6$	15.4	241.0718	241.0726	3.4	28.5	241.0727	3.6	19.7
21	Hydroxylated form of elenolic acid	$C_{11}H_{14}O_7$	15.9	257.0667	257.0666	0.1	9.6	257.0667	0.1	9.7
22	Decarboxymethyl oleuropein aglycone	$C_{17}H_{20}O_6$	16.6	319.1187	319.1169	4.7	1.8	319.1167	5.4	11.6
23	Hydroxy-decarboxymethyl oleuropein aglycone or isomer (II)	$C_{17}H_{20}O_7$	16.9	335.1136	335.1125	3.3	16.1	335.1120	4.7	25.2
24	Syringaresinol	$C_{22}H_{25}O_8$	18.2	417.1555	417.1519	5.3	8.5	417.1533	3.9	21.0
25	Uk8	$C_{12}H_{18}O_6$	18.8	257.1031	ND[a]			257.1044	−3.4	22.3
26	Pinoresinol	$C_{20}H_{22}O_6$	18.9	357.1344	357.1324	5.8	3.1	ND[a]		
27	Decarboxymethyl-ligstroside aglycone	$C_{17}H_{20}O_5$	19.2	303.1229	303.1221	4.8	2.1	ND[a]		
28	Acetoxypinoresinol	$C_{22}H_{24}O_8$	19.4	415.1398	415.1382	5.7	2.4	415.1395	3.4	14.7
29	Ligstroside aglycone or isomer	$C_{19}H_{22}O_7$	19.9	361.1293	361.1279	4.6	10	ND[a]		
30	Ligstroside aglycone or isomer	$C_{19}H_{22}O_7$	20.4	361.1293	361.1276	4.7	14.2	ND[a]		
31	Ligstroside aglycone or isomer	$C_{19}H_{22}O_7$	20.7	361.1293	361.1277	4.5	10.4	ND[a]		
32	Uk9	$C_{28}H_{30}O_{11}$	21.4	541.1715	ND[a]			541.1716	−0.1	8.8
33	Dehydro-oleuropein aglycone or isomer (II)	$C_{19}H_{20}O_8$	21.6	375.1085	375.1081	1.2	51.2	ND[a]		
34	Uk10	$C_{19}H_{24}O_8$	22.7	379.1398	ND[a]			379.1412	−3.5	28.4
35	10-Hydroxy-oleuropein aglycone	$C_{19}H_{22}O_9$	22.9	393.1191	393.1178	3.2	19.4	ND[a]		
36	Oleuropein aglycone or isomer	$C_{19}H_{22}O_8$	23.1	377.1242	377.1242	0.1	5.8	377.1221	5.2	35
37	Luteolin	$C_{15}H_{10}O_5$	23.8	285.0405	285.0407	1	42.3	285.0419	6.0	35.8
38	Oleuropein aglycone or isomer	$C_{19}H_{22}O_8$	24.3	377.1242	377.1249	−2.5	10.3	377.1242	−2.7	13.7
39	Oleuropein aglycone or isomer	$C_{19}H_{22}O_8$	24.9	377.1242	377.1240	0.4	22.1	ND[a]		
40	Ligstroside aglycone or isomer	$C_{19}H_{22}O_7$	25.5	361.1293	361.1284	2.4	14.0	ND[a]		
41	Apigenin	$C_{15}H_{10}O_5$	25.8	269.0455	269.0451	1.5	16.6	269.0449	5.0	19.5
42	Methyl oleuropein aglycone	$C_{20}H_{24}O_8$	26.0	391.1398	391.1389	2.4	17.3	ND[a]		

[a] ND, compounds no detected.

2.4 Stability

Stability testing was performed on multiple lots of elaVida™ 40% (H40).

Table 2-6 Stability Data in Multiple Batches of elaVida™ (H40)

elaVida™ (H40) Lot Number	Storage temperature	Retention in % per month								
		0	1	3	6	9	12	18	24	36
EV13071801	4° C	100	95.5	99.8	98.7	98.7	96.0	97.3	89.9	95.5
EV13092001		100	98.6	100.0	99.8	97.3	96.2	96.8	92.1	96.8
EV13071801	25° C	100	99.6	98.2	98.1	95.3	93.1	94.5	86.9	93.0
EV13092001		100	99.9	98.9	98.1	94.5	94.2	94.5	87.8	93.0
EV13071801	30° C	100	99.4	97.2	95.7	92.6	92.0	94.0	85.5	90.7
EV13092001		100	98.9	97.6	93.9	95.4	92.2	93.2	87.0	90.7
EV13071801	40° C	100	98.3	95.2	95.2	92.2	90.4	91.1	84.1	90.7
EV13092001		100	96.1	96.1	95.7	92.6	90.4	90.5	82.5	88.0

2.5 Acrylamide

Although the standard test for genotoxic impurities is the Ames test, it has been shown this test is not sensitive to acrylamide (does not give a clear positive) (Bull et al., 1984). Additional analyses were undertaken and showed that the content of acrylamide in H40 was very low (Table 2-7).

An initial analysis conducted by DSM showed a low level of 27 ppm of acrylamide in an H40 sample. This level is low in comparison to the level in various food products and is not higher than published information for content in table olives (EFSA, 2011; Casado et al., 2008). Further analyses of 4 batches of H40 showed acrylamide levels in the range of 74 to 95 ppb (Table 2-7). These values are significantly lower than the initial 27 ppm measurement.

Table 2-7 Acrylamide Content in 4 batches of elaVida™ H40

Sample	Acrylamide Content (µg/kg)
elaVida™ H40, Batch 1106-A05-121	95
elaVida™ H40, Batch 1107-A05-125	74
elaVida™ H40, Batch 1109-A05-132	91
elaVida™H40, Batch 1109-A05-135	94

JECFA defined a NOAEL for acrylamide of 0.2 mg/kg bw/day for neurotoxicity and a lowest BMDL10 (benchmark dose lower confidence limit for a 10% response) of 0.18 mg/kg bw/day for carcinogenicity. These data can be used in conjunction with human intake data to show the margin of safety from normal intake in the diet. EFSA in their most recent evaluation (EFSA, 2015) have published acrylamide intake information in Europe for different age categories and recommend that companies should try to reduce acrylamide content in food products as far as possible.

Based on the data for these four batches, all of which were produced using the manufacturing process starting with pomace, there is no safety concern for the acrylamide content in elaVida™ H40, as the measured levels were comparatively low. Therefore, it can be concluded that based on the analytical data, there is no evidence to suggest any concerns related to acrylamide in H40.

2.6 Polyaromatic Hydrocarbons

Analytical results for the content of Polyaromatic hydrocarbons (PAHs) in dried olive pomace (3 batches) consistently demonstrate that these are below the limit of detection (LOD). The LOD was less than 0.5 ppb. If a single marker for PAH contamination is used (e.g. sum of benzo(a)pyrene, benzo(a)anthracene, benzo(b)fluoranthene and chrysene) there is the possibility to miss a single PAH contamination. Therefore, in addition to the data provided by Probelte, DSM performed a broader GC/MS screening targeting 13 PAH markers. This confirmatory analysis, shown below in Table 2-8, further confirmed the levels of PAHs, if present, were very low or below the detection limit of 0.5 ppb.

Table 2-8 PAH profile of elaVida™ H40 (Batch 1105-A-05-114) determined by GC/MS

Sample	Concentration (µg/kg)
Anthracen	<0.5
Benzo(a)pyren	<0.5
Benzo(g,h,i) perylen	<0.5
Benz(a)anthracen	<0.5
Benzo(b)fluoranthen	<0.5
Benzo(k)fluoranthen	<0.5
Chrysen	<0.5
Dibenz(a,h)anthracen	<0.5
Fluoranthen	<0.5
Fluoren	<0.5
Ind'(1,2,3,c,d) pyren	<0.5
Phenanthren	<0.5
Pyren	<0.5

2.7 Physical or Technical Effect

No specific physical or technical effects are proposed for elaVida™ at this time.

3.0 Intended Food Uses and Projected Dietary Exposure

3.1 Proposed food uses

Hydroxytyrosol is naturally occurring polyphenol found in olives and processed olive products such as olive oil. DSM's olive extract product, elaVida™ H40, containing 40% hydroxytyrosol, is proposed for use in 11 broad food categories: bakery products; beverages; dairy products and substitutes; desserts; fats and oils; fruit juices and nectars; dry seasoning mixes for meat, poultry and fish; chewing gum; sauces, dips, gravies and condiments; snacks; and vegetable juices to deliver 5 to10 mg of hydroxytyrosol per serving of food. Based on the FDA reference amounts customarily consumed per eating occasion (RACC) outlined in 21 Code of Federal Regulations (CFR) 101.12[1], the use of elaVida™ H40 imparts 5 to 10 mg of hydroxytyrosol per serving for each of the 11 food categories, as summarized in Table 3-1. Information on the intended food uses and use levels was used to estimate consumer intakes, which are discussed further below. The full intake assessment report is attached as Appendix 3.

[1] Exception: for the food category "meat, poultry, and fish coating mixes, dry; seasoning mixes, dry" the RACC for dry seasoning mixes was estimated to be 4.5 g dry spice rub (i.e., 2 teaspoons per serving) based upon publicly available food recipes for mixed dishes containing dry seasonings and rubs from McCormick Spices (http://www.mccormick.com/Grill-Mates/Recipes). This is the lowest value, which would provide a worst case scenario for estimating exposure to a food additive in dry seasonings and rubs.

Table 3-1 Summary of all proposed foods and use levels

Food Category	Use Level (mg/serving)		RACC [d] (g/serving)	Use Level elaVida[b] (ppm)
	HT[a]	elaVida[b]		
Bakery Products				
Crackers that are usually used as snacks	5	12.5	30	417
Croutons	5	12.5	7	1786
Grain-based bars with or without filling or coating (e.g., breakfast bars, granola bars, rice cereal bars)	10	25	40	625
Protein based, meal replacement and energy bars	10	25	40	625
Beverages				
Sport drinks, energy drinks, milk-based meal replacements, flavoured waters and fruit-flavoured drinks	5	12.5	240	52
Dairy Products and Substitutes				
Yogurt	10	25	225	111
Desserts				
Frozen yogurt	10	25	120	208
Fats and Oils				
Butter, margarine, oil and shortening	5	12.5	15	833
Dressing for salads	5	12.5	30	417
Mayonnaise, sandwich spreads, mayonnaise-type dressings	5	12.5	15	833
Fruit and Fruit Juices				
Fruit juices and fruit nectars	5	12.5	240	52
Miscellaneous				
Meat, poultry, and fish coating mixes, dry; seasoning mixes, dry (e.g., chilli seasoning mixes, pasta salad seasoning mixes)[d]	5	12.5	4.5	2778
Chewing gum	10	25	3	8333
Sauces, Dips, Gravies, Condiments				
Major main entree sauces (e.g., spaghetti sauce)	5	12.5	125	100
Minor main entree sauces (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g. gravy, white sauce, cheese sauce), cocktail sauce	5	12.5	60	208
Major condiments: catsup only	5	12.5	15	833
Barbecue sauce, hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa)	5	12.5	30	417
Snacks				
All varieties, chips, pretzels, popcorns, extruded snacks, fruit-based snacks (e.g., fruit chips), grain-based snack mixes	5	12.5	30	417
Vegetable Juices				
Vegetable juice	5	12.5	240	53

[a] Hydroxytyrosol

[b] DSM's elaVida contains 40% hydroxytyrosol

[c]. U.S. FDA reference amounts customarily consumed (RACC) refers to Reference Amounts Customarily Consumed per eating occasion – 21 CFR §101.12 (CFR, 2014). When a range of values is reported for a particular food-use, particular foods within that food-use may differ with respect to their RACC.

[d] The estimated RACC for dry seasoning mixes was estimated to be 4.5 g dry spice rub (i.e., 2 teaspoons per serving) based upon publicly available food recipes for mixed dishes containing dry seasonings and rubs from McCormick Spices (http://www.mccormick.com/Grill-Mates/Recipes). This is the lowest value, which would provide a worst case scenario for estimating exposure to a food additive in dry seasonings and rubs.

3.2 Available data and methods

3.2.1 Consumption data

The U.S. population's consumption of hydroxytyrosol, the defining component in DSM's elaVida™ H40, from existing and proposed uses was based on food consumption records collected in the What We Eat in America (WWEIA) component of the National Health and Nutrition Examination Surveys (NHANES) conducted in 2007-2008 and 2009-2010 (2007-2010). This continuous survey is a complex multistage probability sample designed to be representative of the civilian U.S. population (NCHS 2013a-b). The NHANES datasets provide nationally representative nutrition and health data and prevalence estimates for nutrition and health status measures in the U.S. To produce reliable statistics, NHANES over-samples adults 60 years of age and older, African Americans and Hispanics. Statistical weights are provided by the National Center for Health Statistics (NCHS) for the surveys to adjust for the differential probabilities of selection. As part of the examination, trained dietary interviewers collect detailed information on all foods and beverages consumed by respondents in the previous 24-hour time period (midnight to midnight). A second dietary recall is administered by telephone 3 to 10 days after the first dietary interview, but not on the same day of the week as the first interview. The dietary component of the survey is conducted as a partnership between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). The DHHS is responsible for the sample design and data collection, and the USDA is responsible for the survey's dietary data collection methodology, maintenance of the databases used to code and process the data, and data review and processing. A total of 16,244 individuals in the survey period 2007-2010 provided 2 complete days of dietary recalls.

Consumption data in the NHANES are reported on an "as consumed basis". That is, if a survey participant consumed an apple pie, the consumption amount reported in the survey for that subject would be for the amount of pie consumed, and not for the ingredients (flour, butter, apples, sugar, etc.) used to make that pie.

In cases where the food of interest is a component of mixed dish, (e.g., oil component in a casserole, mayonnaise component of a sandwich, spaghetti sauce in pasta noodles with sauce, catsup on a hamburger, etc.) Exponent, working on behalf of DSM, utilized USDA's Food and Nutrient Database for Dietary Studies (FNDDS), version 5.0 (USDA, 2012), that translates the food as consumed into its corresponding ingredients (and gram amounts) or recipes. The list of NHANES food codes (and their description) that was captured in determining the foods with hydroxytyrosol from the proposed uses is provided in the full intake assessment report.

The NHANES and USDA FNDDS recipes database do not include food codes for either the whole food or the portion of foods containing meat, poultry, and fish dry coating mixes, or dry seasoning mix (i.e., dry seasoning mixes). Exponent calculated the portion of mixed dish recipes (mainly

meat, poultry and fish) containing dry seasonings and rubs based upon publicly available food recipes from McCormick Spices (http://www.mccormick.com/Grill-Mates/Recipes). These recipes indicated that 1 to 3% of the mixed dish was dry seasoning mix. Based upon this range, Exponent made a conservative assumption that 5% of mixed dishes contain dry seasonings or rubs. The portion of meat based mixed dishes that noted seasoning in the nomenclature (e.g., taco seasoning) including frozen meals were included in the analysis. Most meat and poultry dishes were assumed to contain dry seasoning mixes with the exception of the following categories: baby food, organ meats, hot dogs/sausages, cold cuts, meat spreads, bacon, canned meats (not usually prepared with rub/spices), meat or fish used in soups, and any meats/fish that indicated "no coating" in the food description.

3.2.2 Existing dietary sources

Hydroxytyrosol is naturally occurring in olives and processed olive products such as olive oil. Exponent conducted a literature search to determine the levels of hydroxytyrosol in olives and olive oil. The search included a review of multiple sources including: 1) the U.S. Food and Drug Association (FDA) inventory of Generally Recognized as Safe (GRAS) notices using any of the following key words [hydroxy, tyrosol, 3,4-DHEPA, olive, hydrox, hytolive, polyphenol], 2) pubmed scientific literature search [hydroxy, tyrosol, 3,4-DHEPA, olive, hydrox, hytolive, polyphenol], 3) European Food Safety Authority (EFSA) opinions using the key words [olive, hydroxy, tyrosol, hydroxytyrosol].

The FDA GRAS notice inventory included one GRAS notice related to olive pulp extract (GRN 459); however, at the notifiers request, the FDA ceased to evaluate the notice (FDA, 2013). A review of the cited references in GRN 459 resulted in one article which provided measured hydroxytyrosol levels in olives (Blekas et al., 2002).

The Pubmed search resulted in two articles that provided measured hydroxytyrosol levels in various types of olives and olive oils (Mazzottia *et al*., 2012; Romero and Brenes, 2012).

The EFSA published scientific opinions on the substantiation of health claims related to polyphenols in olives and various measures of health (EFSA, 2011; EFSA, 2012). One particular claim (Claim ID 1638) related to the antioxidant properties of the food constituents, polyphenols from olive (olive fruit, olive mild waste waters or olive oil), was approved under the following conditions of use: 20 g of an olive oil with a polyphenol content of 200 mg/kg or a minimum of 2 mg/day of hydroxytyrosol. This implies that approximately 100 mg hydroxytyrosol /kg olive oil would be a reasonable quantity to occur naturally in olives or olive oil. The EFSA data were not used in Exponent's analysis.

Exponent summarized the reported hydroxytyrosol concentration in olives and olive oil from three literature sources and calculated the average hydroxytyrosol concentration per broad food category (Table 5-2) (Blekas et al., 2002; Mazzottia et al., 2012; Romero and Brenes, 2012). A listing of the data derived from the three individual sources is summarized in the full report.

Table 3-2: Average hydroxytyrosol concentration of olives and olive oil[a]

Food	Average hydroxytyrosol concentration (mg/kg)
All Olives	**315.1[b]**
Black Olives	312.5
Green Olives	320.6
All Olive Oil	**66.0 [b]**
Extra Virgin Olive Oil	74.2
Other Olive Oil	8.5

[a] Blekas et al., 2002; Mazzottia et al., 2012; Romero and Brenes, 2012

[b] Bolded values are the average of the sub-categories

Based on NHANES 2007-2010 in combination with the USDA FNDDS recipes database, the following olive and olive oil ingredients are available and included in the intake assessment:

4053 Oil, olive, salad or cooking

9193 Olives, ripe, canned (small-extra large)

9194 Olives, ripe, canned (jumbo-super colossal)

9195 Olives, pickled, canned or bottled, green

The average concentration of hydroxytyrosol (315.1 ppm for olives, and 66 ppm for olive oil, see Table 3-2) were used.

3.2.3 Dietary supplement uses

The NHANES also contains a Dietary Supplement Database (NHANES-DSD) that includes detailed information on the dietary supplements reported by survey participants since NHANES 1999. The NHANES-DSD consists of three datasets which contain information on products (i.e., product label database); Dietary Supplement Product Information (DSPI), Dietary Supplement Ingredient Information (DSII), and Dietary Supplement Blend Information (DSBI). These files incorporate all products that have been reported by respondents since 1999. NCHS attempts to obtain a product label for all dietary supplements or antacids reported by NHANES participants from sources such as the manufacturer or retailer, the Internet, company catalogs, and the

Physician's Desk Reference. Selected label information is then entered into the product label database including, but not limited to: supplement name; manufacturer and/or distributor; serving size; form of serving size; and ingredients and amounts. The ingredient information entered into the database is taken directly from the supplement facts box on the dietary supplement label or carton.

Starting in 1999, NHANES collected information on respondent's 30-day supplement use during the household interview component. Participants who indicated they reported taking one or more supplements in the past month were asked to show the interviewer the supplement container for all reported products, which was recorded. In cases where a container was not provided, the interviewer asked the participant to record the name of each supplement consumed. For each supplement reported to be consumed, participants were asked to report how long they had been taking the supplement, how many times they took it in the past 30 days, and how much they typically consumed daily on the days they had taken it.

Exponent searched the database for any dietary supplements containing the ingredient "hydroxytyrosol" (10007639 hydroxytyrosol). One dietary supplement in the database was reported to contain hydroxytyrosol as an ingredient; however, there were no reported consumers of this dietary supplement (Nature's Plus Herbal Actives Oliceutic-20 standardized olive leaf 250 MG 20-25% oleuropein).

The database was also searched for any dietary supplement containing the ingredient "olive" which resulted in 11 ingredients.

10000275	OLIVE OIL
10000406	OLIVE LEAF EXTRACT
10002604	OLIVOL OLIVE EXTRACT
10005098	HIDROX (OLIVE EXTRACT 6%) (FRUIT)
10005121	NEW CHAPTER BROCCOLIVE PLUS PROPRIETARY BLEND
10005478	POLYPHEN-OIL OLIVE FRUIT EXTRACT
10006167	OLIVE LEAF POWDER (LEAF)
10006478	OLIVE JUICE EXTRACT (FRUIT)
10006581	OLIVE EXTRACT (FRUIT)
10006749	OLIVOL (OLIVE EXTRACT FRUIT)
10007622	BENOLEA OLIVE EXTRACT (LEAF)

A total of 25 dietary supplements contained these 11 ingredients. The total combined estimated usual intake of these ingredients based on 30-day recall data resulted in a total of 25 reported consumers out of a total of 15,994 respondents, representing 0.2% of the U.S. population, in the NHANES 2007-10.

Due to the limited reported users of olive and hydroxytyrosol-containing dietary supplements, this potential exposure from dietary supplements was not included in the analysis.

3.2.4 Analysis

Using the WWEIA consumption data, Exponent estimated the daily intake of foods with existing and proposed uses of hydroxytyrosol on a *per capita* and *per user* basis. In this analysis, a user is anyone who reported consuming any of the existing or proposed foods on either of the survey days (USDA's user definition), as appropriate. We identified each participant who reported consuming the foods of interest on either of the survey days, and we used that individual's responses for both survey days. Zero consumption days are included in calculating that individual's average daily intake. For example, if someone reported consuming 15 grams of olives on day 1 and 0 grams of olives on day 2, the consumer's 2-day average olive consumption would be 7.5 grams ([15+0]/2). The current analysis was limited to individuals who provided two complete and reliable dietary recalls as determined by NCHS. The 2-day average intakes by each individual were estimated using Exponent's Foods and Residues Evaluation Program (FARE® version 10.06) software. Exponent uses the statistically weighted values from the survey in its analyses. The statistical weights compensate for variable probabilities of selection, adjust for non-response, and provide intake estimates that are representative of the U.S. population.

For the existing dietary exposure to hydroxytyrosol from olives and olive oil, the 2-day average intake of hydroxytyrosol was estimated by multiplying the reported intake of foods from the 24-hr recall with the hydroxytyrosol concentration derived from the literature and the cumulative sum over the two 24-hr recalls was divided by two. Estimates were also derived on a body weight basis based on each participant's reported body weight.

For the proposed uses of DSM‘s elaVida in foods, the reported intake of foods from the 24-hr recall was multiplied by the proposed use level of DSM‘s elaVida™ (containing 40% HT). The EDI of elaVida™ is then multiplied by 40% to estimate the EDI for HT.

The cumulative estimated daily intake (CEDI) for hydroxytyrosol was calculated by summing at the individual level the EDI from existing dietary sources with the EDI from proposed uses of DSM's elaVida™ H40.

3.3 Results

3.2.1 Existing Dietary Exposure

The estimated daily intakes of hydroxytyrosol from existing dietary sources (i.e. olives and olive oil) in units of mg/day and mg/kg-bw/day are provided in Table 3-3 for the U.S. population ages 2 years and older and four subpopulations. The highest 90th percentile *per user* reported intake of hydroxytyrosol from existing dietary sources was 1.2 mg/day (0.01 mg/kg-bw/day) among adults ages 19 years and older. The existing EDI at 90th percentile *per user* for U.S. population 2 years and older was 1.0 mg/day (0.01 mg/kg-bw/day). Approximately 50% of the U.S. population ages 2+ years reported eating a food containing hydroxytyrosol.

Table 3-3 U.S. Population ages 2+ years average daily hydroxytyrosol intake from olives and olive oil (NHANES 2007-2010)

			2 Day Average (mg/day)				2 Day Average (mg/kg-bw/day)			
			Per Capita		Per User		Per Capita		Per User	
Subpopulation	N[a]	%User	Mean	90th	Mean	90th	Mean	90th	Mean	90th
Children 2-5 y	649	47.2%	0.1	0.05	0.2	0.1	0.005	0.003	0.01	0.006
Children 6-12 y	1010	44.0%	0.1	0.1	0.2	0.4	0.003	0.002	0.008	0.009
Teens 13-18 y	685	40.6%	0.1	0.1	0.3	0.5	0.002	0.002	0.005	0.009
Adults 19+ y	5540	54.1%	0.3	0.4	0.6	1.2	0.004	0.005	0.007	0.01
U.S. population 2+ y	7884	51.5%	0.3	0.3	0.5	1.0	0.004	0.004	0.007	0.01

[a] Unweighted number of users; % user, per capita and per user estimates derived using the statistical weights provided by the National Center for Health Statistics (NCHS).

3.3.2 Proposed uses

The estimated daily intake of elaVida™ from its proposed uses in 11 broad categories of food in units of mg/day and mg/kg-bw/day are provided in Table 3-4 for the U.S. population ages 2 years and older and in four sub populations. The highest 90th percentile *per user* EDI of elaVida was 136.8 mg/day among teenagers ages 13 to 18 years (2.1 mg/kg-bw/day). The 90th percentile *per user* EDI of elaVida for U.S. population 2 years and older was 129.8 mg/day (2.2 mg/kg-bw/day). Nearly everyone 2 years and older in the U.S. population reported eating a food with proposed uses of elaVida™ H40.

Table3-4 Estimated daily intake of elaVida™ H40 from proposed uses in foods[a] (NHANES 2007-2010)

Population	N[b]	%User	2 Day Average (mg/day)				2 Day Average (mg/kg-bw/day)			
			Per Capita		Per User		Per Capita		Per User	
			Mean	90th	Mean	90th	Mean	90th	Mean	90th
Children 2-5 y	1374	99.8%	48.9	82.2	49.0	82.2	2.9	5.0	2.9	5.0
Children 6-12 y	2127	99.9%	60.6	97.8	60.7	97.8	1.8	3.2	1.8	3.2
Teens 13-18 y	1563	100%	76.2	136.8	76.2	136.8	1.2	2.1	1.2	2.1
Adults 19+ y	9950	99.8%	76.1	133.9	76.3	133.9	1.0	1.7	1.0	1.7
U.S. Population 2+ Years	15014	99.9%	73.1	129.7	73.2	129.8	1.2	2.2	1.2	2.2

[a] DSM's elaVida™ is proposed for use in 11 broad food categories including bakery products; beverages; dairy products and substitutes; desserts; fats and oils; fruit juices and nectars; dry seasoning mixes for meat, poultry and fish; chewing gum; sauces, dips, gravies and condiments; snacks; and vegetable juices.

[b] Unweighted number of users; % user, per capita and per user estimates derived using the statistical weights provided by the National Center for Health Statistics (NCHS).

The estimated daily intake of hydroxytyrosol from the proposed uses in 11 broad categories of food in units of mg/day and mg/kg-bw/day are provided in Table 3-5 for the U.S. population ages 2 years and older and in four sub populations. The highest 90th percentile *per user* EDI of hydroxytyrosol was 54.7 mg/day among teenagers ages 13 to 18 years (0.9 mg/kg-bw/day). The 90th percentile *per user* EDI for U.S. population 2 years and older was 51.9 mg/day (0.9 mg/kg-bw/day).

Table 3-5 Estimated daily intake of hydroxytyrosol exclusively from proposed uses of elaVida™ [a, b] (NHANES 2007-2010)

Population	N [c]	%User	2 Day Average (mg/day)[a, b]				2 Day Average (mg/kg-bw/day)[a,b]			
			Per Capita		Per User		Per Capita		Per User	
			Mean	90th	Mean	90th	Mean	90th	Mean	90th
Children 2-5 y	1374	99.8%	19.6	32.9	19.6	32.9	1.2	2.0	1.2	2.0
Children 6-12 y	2127	99.9%	24.3	39.1	24.3	39.1	0.7	1.3	0.7	1.3
Teens 13-18 y	1563	100%	30.5	54.7	30.5	54.7	0.5	0.9	0.5	0.9
Adults 19+ y	9950	99.8%	30.5	53.6	30.5	53.6	0.4	0.7	0.4	0.7
U.S. Population 2+ Years	15014	99.9%	29.3	51.9	29.3	51.9	0.5	0.9	0.5	0.9

[a] Based upon use rates of elaVida™ containing 40% hydroxytyrosol equating to 5-10 mg hydroxytyrosol per serving of food.

[b] DSM's elaVida™ is proposed for use in 11 broad food categories including bakery products; beverages; dairy products and substitutes; desserts; fats and oils; fruit juices and nectars; dry seasoning mixes for meat, poultry and fish; chewing gum; sauces, dips, gravies and condiments; snacks; and vegetable juices

[c] Unweighted number of users; % user, per capita and per user estimates derived using the statistical weights provided by the National Center for Health Statistics (NCHS).

3.3.3 Cumulative estimated intake of hydroxytyrosol

The cumulative estimated daily intake (EDI) of hydroxytyrosol from existing dietary sources and DSM's proposed uses of elaVida™ H40 (to deliver 5 to 10 mg/serving of hdyroxytorosol in 11 food categories) in units of mg/day and mg/kg-bw/day are provided in Table 3-6 for the U.S. population ages 2 years and older and in four sub populations. The highest 90th percentile *per user* cumulative estimated dietary intake (CEDI) of hydroxytyrosol was 55.1 mg/day among teenagers ages 13 to 18 years (0.9 mg/kg-bw/day). The 90th percentile *per user* CEDI for the U.S. population 2 years and older was 52.4 mg/day (0.9 mg/kg-bw/day).

Table 3-6 Cumulative estimated daily intake (CEDI) of hydroxytyrosol from existing dietary exposure plus proposed uses from elaVida™ H40 (NHANES 2007-2010)

			2 Day Average (mg/day)[b, c]				2 Day Average (mg/kg-bw/day)[b, c]			
			Per Capita		Per User		Per Capita		Per User	
Population	**N[a]**	**%User**	**Mean**	**90th**	**Mean**	**90th**	**Mean**	**90th**	**Mean**	**90th**
Children 2-5 y	1374	99.8%	19.6	33.0	19.7	33.0	1.2	2.0	1.2	2.0
Children 6-12 y	2127	99.9%	24.4	39.9	24.4	39.9	0.7	1.3	0.7	1.3
Teens 13-18 y	1563	100%	30.6	55.1	30.6	55.1	0.5	0.9	0.5	0.9
Adults 19+ y	9950	99.8%	30.8	53.9	30.8	53.9	0.4	0.7	0.4	0.7
U.S. Population 2+ Years	15014	99.9%	29.5	52.4	29.5	52.4	0.5	0.9	0.5	0.9

[a] Unweighted number of users; % user, per capita and per user estimates derived using the statistical weights provided by the National Center for Health Statistics (NCHS).

[b] Cumulative EDI of hydroxytyrosol based upon existing uses of hydroxytyrosol in olive and olive oil and proposed uses of DSM's elaVida containing 40% hydroxytyrosol in 11 broad food categories including bakery products; beverages; dairy products and substitutes; desserts; fats and oils; fruit juices and nectars; dry seasoning mixes for meat, poultry and fish; chewing gum; sauces, dips, gravies and condiments; snacks; and vegetable juices at a use rate of 5-10 mg of hydroxytyrosol per serving of food.

Information on the intended food uses and use levels was used to estimate consumer intakes, which are discussed further below. The full intake assessment report is attached as Appendix 5.

Estimates for the intake of astaxanthin in the U.S. have been determined based on the proposed food uses and use levels for astaxanthin, in conjunction with food consumption data obtained from the U.S. National Center for Health Statistics' (NCHS) National Health and Nutrition Examination Surveys (NHANES) 2011-2012 (USDA, 2014; CDC, 2015). Calculations for the mean and 90th percentile all-person and all-user intakes were performed for each of the individual proposed food uses of astaxanthin, and the percentage of consumers was determined. Similar calculations were used to estimate the total intake of astaxanthin resulting from all proposed food-uses of astaxanthin combined. In each case, the estimated per person (mg/person/day) and per kilogram body weight (µg/kg bw/day) intakes were reported for the following population groups:

Infants and young children, aged up to 3 years;
Children, ages 4 to 11;
Female teenagers, ages 12 to 19;
Male teenagers, ages 12 to 19;
Female adults, ages 20 and up;
Male adults, ages 20 and up; and
Total population (all age and gender groups combined).

The results of the intake estimate are summarized in Tables 3-2 and 3-3. Table 3-2 provides the estimated total intake of astaxanthin on a mg/person/day basis, and Table 3-3 presents these data on a µg/kg bw/day basis.

All-person intake refers to the estimated intake of astaxanthin averaged over *all* individuals surveyed, regardless of whether they potentially consumed food products for which astaxanthin is intended, and therefore includes individuals with "zero" intakes (*i.e*., those reporting no intake of foods like those for which astaxanthin is intended, during the 2 survey days). All-user intake refers to the estimated intake of astaxanthin by individuals that reported consuming food products like those for which astaxanthin is intended. Individuals were considered *users* if they consumed 1 or more food products containing astaxanthin on either Day 1 or Day 2 of the survey.

The percentage of users was high among all age groups evaluated; more than 83.4% of the population consisted of users of food products for which astaxanthin is intended. Since nearly all participants were identified as users, all-person consumption estimates were nearly identical to the all-users estimates. In terms of food sources, bottled, enhanced, and carbonated water, yeast breads and rolls, and carbonated beverages were consistently among the top contributors to mean daily astaxanthin intakes across all population groups, on both an absolute and a per kg bw basis (see Appendix 5 for further details). In evaluating these intake estimates, however, it is important to consider that this constitutes a worst-case exposure estimate, and actual astaxanthin intakes are likely to be lower.

As Tables 3-2 and 3-3 show, the estimated mean and 90th percentile intakes for the total U.S. population were 0.72 mg/person/day (11.3 µg/kg bw/day) and 1.25 mg/person/day (19.9 µg/kg bw/day), respectively. Among the individual groups, male adults had the greatest projected mean and 90th percentile all-user intakes on an absolute basis (0.87 and 1.47 mg/person/day, respectively); infants and young children had the lowest absolute mean and 90th percentile estimated intakes, 0.30 and 0.55 mg/person/day, respectively. As might be expected, astaxanthin intake estimates on a per kg body weight basis were greatest among younger (*i.e*., smaller) individuals. Specifically, infants and young children (≤ 3 years old) had the greatest projected intakes per body weight (22.1 and 38.9 µg/kg bw/day for the mean and 90th percentile, respectively). Female teenagers had the lowest mean and 90th percentile projected intakes on a per kg bw basis (9.5 and 14.9 mg/kg bw/day, respectively).

4.0 SELF LIMITING LEVELS OF USE

In keeping with § 170.240 Part 4 of a GRAS notice, in circumstances where the amount of the notified substance that can be added to food is limited because food containing levels of the notified substance above a particular level would become unpalatable or technologically impractical must be described, including data and information on such self-limiting levels of use.

DSM is unaware of any specific physical or technically impractical effects for elaVida™ at this time. The intended uses and use levels for elaVida™ are intended exclusively as commercial products in the United States.

5.0 EXPERIENCE BASED ON COMMON USE IN FOOD BEFORE 1958

5.1 Scientific Procedures

In keeping with § 170.245 Part 5 of a GRAS notice, the statutory basis for DSM's conclusion of GRAS status is not through experience based on common use in food use by a significant number of consumers prior to January 1, 1958. A self-affirmation of GRAS status by DSM was instead based upon scientific procedures including the application of scientific data (including, data from human, animal, analytical, or other scientific studies), information, and methods, whether published or unpublished, as well as the application of scientific principles, appropriate to establish the safety of a substance under the conditions of its intended use.

5.2 Natural occurrence and benefit

Hydroxytyrosol and tyrosol are respectively the most abundant and second most abundant phenolic compounds present in raw olive flesh, predominantly occurring as esters. Hydroxytyrosol and tyrosol are structurally similar, hydroxytyrosol possessing an extra hydroxy group in the meta position. Both also occur as esters, a notable example being the glycoside oleuropein. Oleuropein is an ester consisting of hydroxytyrosol and elenolic acid.

Levels of hydroxytyrosol in raw olives, including that present in conjugated forms, are of the order of up to 1,800 mg/kg (Tennant, 2013). However, raw olives are rarely consumed and the fruit undergoes extensive processing to produce the forms most commonly consumed – table olives and olive oil. Hydroxytyrosol levels in table olives vary according to the source and specific type of treatment and can range from 400 mg/kg up to 1000 mg/kg for certain variants. Processing reduces hydroxytyrosol levels in olive oil so that they are in the range 15 – 20 mg/kg. Average consumption of table olives is over 10 g/day in some Mediterranean countries and individual consumption could be as high as 30 g/day. Consumption of olive oil in the same countries is on average about 70 g/day and could be as high as 200 g/day for high level consumers. Combining these occurrence levels and consumption data results in estimates of average intakes of hydroxytyrosol in some Mediterranean countries of 12 mg/day, with the potential for high level intakes to exceed 30 mg/day (Tennant, 2013). Thus, the average combined hydroxytyrosol intake in some Mediterranean countries for a 60 kg adult is 0.2 mg/kg bw/day (12 mg/day) and for a high level consumer 0.5 mg/kg bw/day (30 mg/day).

Although historically, the healthful properties of virgin olive oil were attributed to a high proportion of monounsaturated fatty acids (MUFAs), namely oleic acid, several seed oils (e.g. sunflower) also rich in MUFA have been demonstrated to be ineffective in beneficially altering chronic disease risk factors. Virgin olive oil contains a minor, yet significant phenolic component that other seed oils lack. This, the phenolic fraction of virgin olive oil, has generated much interest regarding its health promoting properties. Various studies (human, animal, *in vivo* and *in vitro*) have

demonstrated that olive oil phenolics have positive effects on certain physiological parameters, possibly reducing the risk of chronic disease development (Cicerale *et al.,* 2009).

The benefits of hydroxytyrosol consumption have been noted in the literature and include claims of a diverse set of positive health effects. Such activities include as protection low density lipoprotein (LDL) from oxidation (Wiseman *et al.,* 1996), for which the European Food Safety Agency (EFSA) has concluded that the cause effect relationship has been established (EFSA Panel on Dietetic Products, 2011). Oxidized LDLs are an emerging risk factor for cardiovascular disease. It is clear from in vitro studies that hydroxytyrosol acts as a direct free radical scavenger. DPPH (2,2-diphenyl-1-picryhydrazyl) antioxidant assays contracted by DSM show that elaVida™ and HT react positively, thereby demonstrating direct radical savaging (Bulbarello, 2015). Studies investigating an indirect action, e.g. via theKeap1/Nrf2/ARE signaling axis, did not show activity. A recent study, with one-week administration of hydroxytyrosol (5 or 25 mg/d), did not significantly modify Phase II enzyme expression in peripheral blood mononuclear cells (Crespo *et al.,* 2015).

Moreover, hydroxytyrosol has anti-inflammatory activity (Raederstorff, 2009), supports mitochondrial function (Hao *et al.,* 2010) and metabolic balance improvements such as increased insulin sensitivity (de Bock *et al.,* 2013).

6.0 NARRATIVE SAFETY

6.1 Forms of olive extract or hydroxytyrosol tested for safety

elaVida™ 40% (H40) is a polyphenol preparation made from olive fruits using a proprietary, solvent-free process. elaVida™ 40% has a standardized minimum content of 40% of hydroxytyrosol (typical range 41 to 47%), the main olive phenol and anti-oxidant.

H35 is an olive extract derived via a very similar process to that used in the manufacture of H40. H35 contains approximately 35% hydroxytyrosol, due to a shorter final water evaporation step. DSM does not plan to develop H35 commercially. However, at the time of study initiation, a final determination of what the standardized hydroxytyrosol concentration in the commercial product had not yet been established. A decision was therefore made to proceed with testing of H35. It remains DSM's position that safety testing using the H35 formulation derived through a largely identical manufacturing process is sufficient to establish overall product safety of elaVida™ (H40).

elaVida™ 15% (H15) is a less concentrated version of H40 that DSM has developed for commercialization. However, the preparation of elaVida™ 15% from H40 is by addition of an inert matrix, food-grade maltodextrin. Separate determination of GRAS status of elaVida™ 15% is therefore not considered necessary.

DSM has also undertaken a separate toxicology package with an extract preparation (Hydroxytyrosol 15% SD) containing 15% hydroxytyrosol in a maltodextrin matrix. The manufacturing process of the Hydroxytyrosol 15% SD prototype was different to that for H40 and is not related to the plan to commercialize an elaVida 15% (H15). It was eventually determined that DSM would proceed with commercialization of the H40 product in conjunction with Probelte Biotechnological rather than the Hydroxytyrosol 15% SD product. However, these study results also contribute to the total weight of safety evidence for the elaVida™ product. Nevertheless, when standardized for hydroxytyrosol content, the dosages of HT achieved in the Hydroxytyrosol 15% SD safety study were much higher than those reported in support of safety for the commercially available HIDROX product. These results are therefore considered relevant to the safety evaluation of elaVida™.

There are also safety studies that have been performed with other olive extracts. In the scientific literature, there is a publication reporting on safety studies undertaken with an olive extract formulation (HIDROX, Hydrolyzed Aqueous Olive Pulp Extract; OPE) containing approximately 2.4% hydroxytyrosol (Christian *et al.,* 2004). Moreover, published studies with chemically pure hydroxytyrosol have also been considered in establishing the safety of elaVida™ H40. A tabulation of tested extracts, or other hydroxytyrosol forms, is given below in Table 6-1.

Table 6-1 Summary tabulation of safety-tested olive extracts

Material	Respective safety studies
elaVida™ 40%	H40 (or H35) extract, 40% (or 35%) nominal HT content
Hydroxytyrosol 15% SD	Hydroxytyrosol 15% SD (Formulation of another extract, 15% HT content)
HIDROX	HIDROX (Extract with low hydroxytyrosol content, ca. 2.4%)
pure hydroxytyrosol	Pure hydroxytyrosol (synthetic)

The current safety assessment is focused on the safety evaluation of elaVida™ 40% and the main phenolic component hydroxytyrosol and the supportive data contained in this dossier.

6.2 Absorption, Distribution, Metabolism and Excretion (ADME) of polyphenols focused on hydroxytyrosol

6.2.1 Summary of published ADME data of hydroxytyrosol in mammals

A large amount of literature is publicly available on animal and human studies investigating the bioavailability and metabolism of (pure) hydroxytyrosol or "olive phenolics" from olive oil or other olive-derived products (fruits, olive extracts, olive cake, olive leaf extracts, *etc*.). An overview on these *in vitro* and *in vivo* animal and human studies on absorption, distribution, metabolism and excretion (ADME) of olive oil phenolic compounds, with special focus on hydroxytyrosol is available (Beck, 2014).

In summary, the ADME data indicate that hydroxytyrosol as pure substance or as component of olive oil or olive extracts is rapidly and dose-dependently absorbed in man and the rat (Bai *et al.,* 1998; Christian *et al.,* 2004; Visioli *et al.,* 2000, 2001; Miro-Casas *et al.,* 2001, 2003; Tuck and Hayball 2002; Covas *et al.,* 2006; Gonzalez-Santiago *et al.,* 2010; Kotronoulas *et al.,* 2013). Rapid and broad tissue distribution has been reported in rats, with no preference for a specific organ or tissue. A decrease in plasma and tissue levels is also rapid, and there is no indication of any accumulation in the body (D'Angelo *et al.,* 2001; Serra *et al.,* 2012).

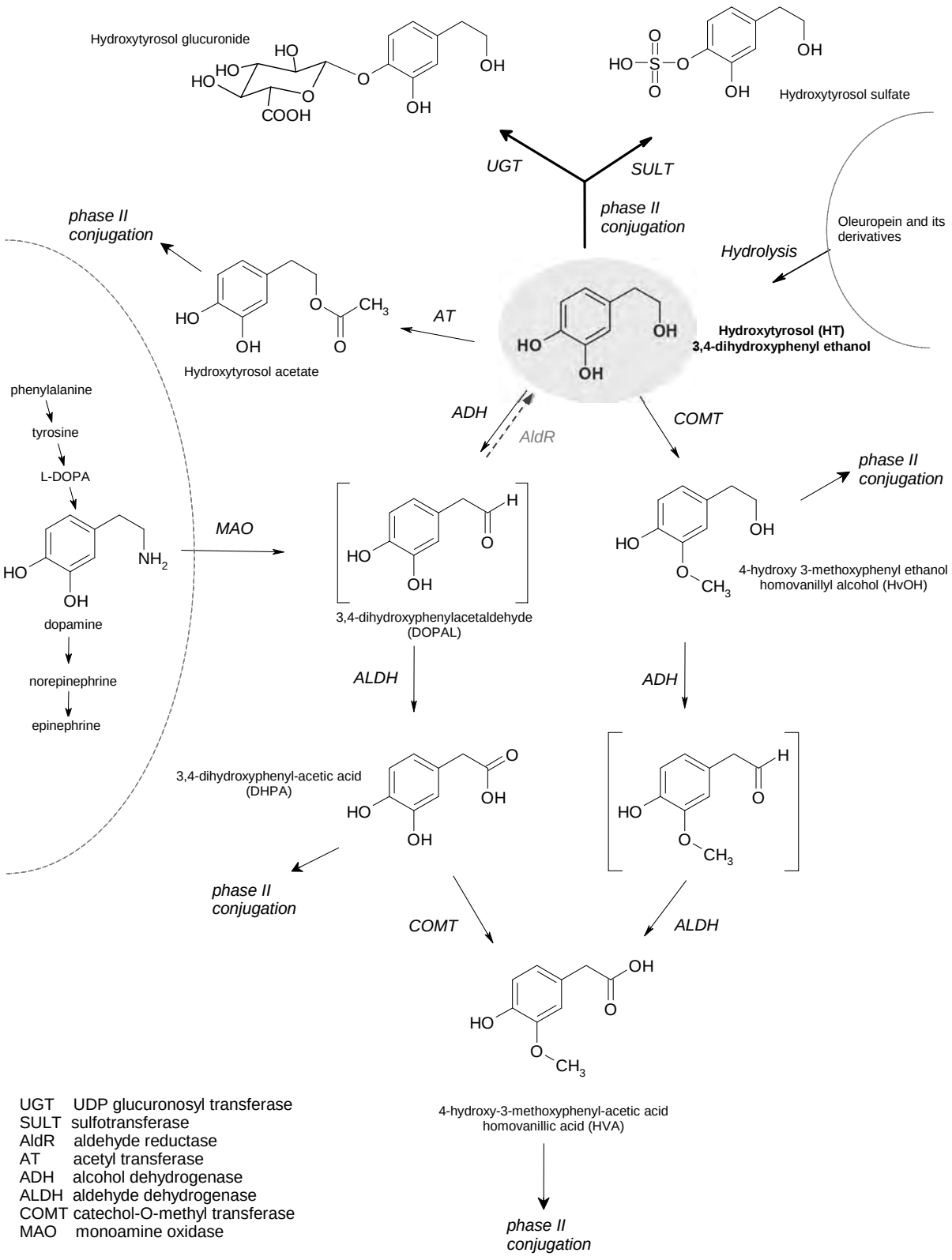
The metabolism of hydroxytyrosol has been studied in some detail (Tuck *et al.,* 2001, 2002; D'Angelo *et al.,* 2001; Visioli *et al.,* 2000, 2003; Caruso *et al.,* 2001; Vissers *et al.,* 2002; Miro-Casas *et al.,* 2001; Rubio *et al.,* 2012a). An overview of the metabolic pathways of hydroxytyrosol is shown schematically in Figure 6-1 below. Only a minor portion (<6%) of unchanged hydroxytyrosol is found in plasma or urine, and the majority of hydroxytyrosol and its metabolites are present in conjugated form (glucuronides and sulfates). Besides direct phase II conjugation of hydroxytyrosol, a major metabolic transformation is found to be the methylation (via catechol-O-methyl transferase, COMT) leading to homovanillyl alcohol, which is subsequently oxidized to homovanillic acid. Intestinal phase II conjugation and COMT activity contribute to the high first pass elimination observed. Oxidation of hydroxytyrosol to 3,4-dihydroxyphenyl acetic acid

(DHPA) via 3,4-dihydroxyphenyl acetaldehyde before methylation and/or phase II conjugation has also been observed. A further metabolite identified in human plasma and urine after olive oil ingestion is hydroxytyrosol acetate sulfate.

As mentioned above, several investigators studied hydroxytyrosol bioavailability in rats and humans after oral administration of olive oil or other olive-derived food products (humans) or pure hydroxytyrosol (rats). These studies demonstrate the presence of hydroxytyrosol and its metabolites in blood and urine. Hydroxytyrosol precursors such as oleuropein and its aglycones also present in olive oil are hydrolyzed to hydroxytyrosol in the gut to a high degree (Corona *et al.,* 2006; Pereira-Caro *et al.,* 2012; Mosele *et al.,* 2014) and thereby contribute to its high absorption (Visioli *et al.,* 2003; Serra *et al.,* 2012; Kendall *et al.,* 2012). In the majority of the studies with olive oil, levels of hydroxytyrosol in the oil were not given (only "total phenolics" content), and it is difficult to estimate how much hydroxytyrosol is formed as a result of hydrolysis of absorbed oleuropein or oleuropein derivatives. Hydroxytyrosol is rapidly absorbed and reaches a plasma maximum within minutes (5-30 min) after intake (Bai *et al.,* 1998; Miro-Casas *et al.,* 2003; Gonzalez-Santiago *et al.,* 2010; Suarez *et al.,* 2011; Rubio *et al.,* 2012b). Elimination from plasma is also rapid mainly due to high first pass metabolism in the intestine and liver. The major pathway of excretion is via urine. Urinary excretion rate (including all metabolites) is highest within the first 8 hrs. (D'Angelo *et al.,* 2001; Tuck *et al.,* 2001; 2003, Visioli *et al.,* 2000, 2001; Miro-Casas *et al.,* 2001; Kountouri *et al.,* 2007). Estimations of bioavailability by recovery of hydroxytyrosol and its metabolites in urine reach levels >90% in rats (D'Angelo *et al.,* 2001, Tuck *et al.,* 2001), and range from 30-75% in human studies (Visioli *et al.,* 2000; Vissers *et al.,* 2002; Miro-Casas *et al.,* 2001; Weinbrenner *et al.,* 2004a/b).

Besides olives and olive-derived products, red wine has been shown to be a natural source of hydroxytyrosol (de la Torre *et al*. 2006, Fernandez-Mar *et al* 2012). More importantly, the oxidized hydroxytyrosol metabolite 3,4-dihydroxyphenyl aldehyde is also a well-known dopamine catabolite (called DOPAL) formed by activity of monoamine oxidase (MAO) from dopamine (Meiser *et al.,* 2013). DOPAL usually is oxidized by aldehyde dehydrogenase to 3,4-dihydroxyphenyl acetic acid (DOPAC=DHPA), but can also be reduced by aldehyde/aldose reductase to hydroxytyrosol (DOPET=HT). Therefore, endogenous equivalents of hydroxytyrosol and all its metabolites (from methylation, oxidation, phase II conjugation) are present in virtually all biological matrices of human and animal origin. Innumerable modulating parameters of dopamine metabolism are known, including alcohol (Mardh and Vallee, 1986; Schroeder *et al.,* 2009; Perez-Maña *et al.* 2015)], nicotine (Foulds, 2006), tyramine present in wine and cheese (Hiroi *et al.,* 1998) as well as in food in general (Epstein and Leddy 2006). For example, de la Torre et al. (2006) were not only the first group to report that red wine is a natural source of hydroxytyrosol, they also showed that red wine can promote endogenous hydroxytyrosol generation via dopamine metabolism induced by the alcohol. Alcohol as an indirect promoter of endogenous hydroxytyrosol generation was later confirmed in additional human studies (Schroeder *et al.,* 2009; Perez-Maña *et al.,* 2015).

Figure 6-1 Metabolic pathways of hydroxytyrosol



Therefore, analysis of the metabolites of olive-derived phenols in biological matrices (e.g. plasma and urine) is challenging, and as a consequence so is the estimation of bioavailability of hydroxytyrosol and its metabolites. Inter-individual variability in hydroxytyrosol absorption and metabolism further complicates a quantitative assessment of bioavailability, and consequent biological activity/efficacy of olive polyphenols.

As indicated earlier, aside from dietary intake from current foods, hydroxytyrosol occurs naturally at a low level in animals as a breakdown product of the neurotransmitter dopamine. However, hydroxytyrosol is not an intermediate in the well documented biosynthesis pathway of dopamine.

6.2.2 Potential drug interactions

The *in vitro* CYP450 inhibition potential has been studied for an olive extract, and for its two major constituents, hydroxytyrosol and tyrosol (Beck *et al.,* 2009). The olive extract (Olive II) used was a water-soluble extract with a high hydroxytyrosol content (>50%) and tyrosol (>10%). The inhibitory potential of the test items on the activity of human CYP450 isoenzymes (CYP1A2, 2C9, 2C19, 2D6, and 3A4) was investigated. Inhibition potential of Olive II was very weak, and half maximal inhibitory concentrations (IC_{50}) of the extract necessary for inhibition of the studied isoenzymes ranged from 9.1 µg/mL (CYP2C19) to 66.5 µg/mL (CYP1A2). The single compounds, hydroxytyrosol and tyrosol, also showed extremely weak or no inhibition potential, with IC_{50}>200 µM for all isoenzymes studied. The concentrations in this *in vitro* assay are much higher (by two orders of magnitude or more) than those expected in human plasma. In humans, plasma concentrations of hydroxytyrosol after intake of pure hydroxytyrosol at a dose of 2.5 mg/kg bw (ca 150 mg for a 60 kg person) peaked after approximately 13 minutes and ranged from 0.47 to 2.24 µM. Hydroxytyrosol was undetectable in plasma 2 hours. after the administration (Gonzalez-Santiago *et al.,* 2010). Based on the *in vitro* results and the expected maximum plasma concentrations after oral ingestion of hydroxytyrosol at up to the ADI derived from the 90-day rat study (150 mg/day hydroxytyrosol), no relevant interactions are expected in man for hydroxytyrosol and tyrosol with concomitantly consumed medicinal drugs metabolized by CYP1A2, CYP2C9, CYP2C19, CYP2D6, or CYP3A4.

6.2.3 Plasma data from safety studies

Within the 90-day rat study with H35 extract (see Section 6.3.3), Toxicology studies with olive extracts and hydroxytyrosol), and also in a 90-day rat study with Hydroxytyrosol 15% SD (support study in section 6.3.3.3) samples for analysis of hydroxytyrosol content were taken 30 minutes after dosing at three-time point (weeks 4, 8 and 12).

In both studies, plasma data for hydroxytyrosol showed its presence in plasma after dosing but no evidence of hydroxytyrosol accumulation with time. The plasma levels, determined in samples taken 30 minutes after dosing, at the respective dosages and time point (weeks 4, 8 and 12), were stable. These data confirm other previous data indicating there is efficient elimination of

hydroxytyrosol and no evidence of continuous bio-accumulation with repeated intake. Published data for hydroxytyrosol indicate there is efficient elimination.

Within the rat micronucleus studies with H40, plasma samples taken 30 minutes after dosing confirmed that significant levels of free and total HT were present in plasma, and therefore the bone marrow was exposed. The levels of free and total HT were much higher than in either the 4-week study with Hydroxytyrosol 15% SD or the 90-day study with H35, consistent with the higher dosage that was used in the micronucleus studies (2000 mg/kg bw).

6.3 Toxicology studies with olive extracts and hydroxytyrosol

6.3.1 Acute toxicity studies

A tabular summary is presented below in Table 6-2 of various acute toxicological studies provides additional support for the safe intended use of elaVida™.

Table 6-2: Summary table of acute toxicity studies

Reference	Study type	Route	Duration	Doses (mg/kg bw)	GLP	Results
Study with olive extract from process used to make H40 (H35)						
Escario *et al.*, 2009	Mouse acute OECD Guideline 420	Oral (gavage)	Single dose, 14 days	5, 50, 300 or 2000 (pilot plant extract)	Yes	LD50 > 2000 mg/kg pilot plant extract ≥ 13 mg/kg hydroxytyrosol
Other studies with olive extracts from different sources (HIDROX)						
Christian *et al.*, 2004	Rat acute	Oral (gavage)	Single dose, 14 days	limit dosage of 2000 mg/kg in terms of HIDROX	-	LD50 value for hydroxytyrosol ≥ 48 mg/kg
Christian *et al.*, 2004	Mouse acute	Oral (gavage)	Single dose, 14 days	limit dosage of 2000 mg/kg in terms of HIDROX	-	LD50 value for hydroxytyrosol ≥ 48 mg/kg
Other studies: pure hydroxytyrosol						
D'Angelo *et al.*, 2001	Rat acute	Oral (gavage)	Single dose, 14 days	2000	n.i.	LD50 > 2000 mg/kg bw pure hydroxytyrosol well tolerated

n.i. not indicated

6.3.1.1 Acute oral toxicity study in mice with pilot plant extract

An acute toxicological evaluation of an early pilot plant extract (lot 0811-A10-001, hydroxytyrosol content 0.66 %) was carried out by Biolab S.L., on behalf of Probelte Biotechnologica in 2009 (Escario *et al.,* 2009). The study was conducted in accordance with OECD directive "Good Laboratory Practice" (GLP). The method performed was based on OECD Guideline 420 for the testing of chemicals: Acute oral toxicity – Fixed dose procedure.

Male and female Crl:NMRI mice were administered the extract by oral gavage at levels of 5, 50, 300 or 2000 mg/kg bw in terms of total extract. However, the high dose in terms of hydroxytyrosol was low (13.2 mg/kg bw).

The conclusion of the test was that the LD50 in mice of the extract is greater than 2000 mg/kg bw and the extract was classified according to the Globally Harmonized System (GHS) in category 5 (low acute toxicity).

6.3.1.2 Acute oral study in the mouse and rat with HIDROX

The acute oral toxicity profile of HIDROX (Hydrolyzed Aqueous Olive Pulp Extract; OPE, containing 2.4% hydroxytyrosol), has been characterized in a series of toxicology studies (Christian *et al.,* 2004). A limit dosage of 2000 mg/kg in terms of HIDROX produced no toxicity in mice (acute oral NOAEL: ≥ 2000 mg/kg). Also in rats, an acute oral NOAEL of ≥ 2000 mg/kg in terms of HIDROX was established. Based on these studies, and assuming a 2.4% hydroxytyrosol content, the acute oral LD50 value for hydroxytyrosol is ≥ 48 mg/kg.

6.3.1.3 Acute oral study in the rat with pure hydroxytyrosol

The acute toxicology of pure hydroxytyrosol has been investigated (D'Angelo *et al.,* 2001).

Materials and Methods

The study was carried out using young adult Sprague-Dawley rats by RBM-Laboratories & Clinics Group (Colleretto Giacosa, Italy). Six male and six female rats, about 3-months old and weighing 210 to 262 g, were used for the experiment. They were acclimatized at least 5 days before starting the test and fasted about 16 h before the experiment. A single dose of 2 g/kg bw. pure hydroxytyrosol was administered by gavage. The hydroxytyrosol was chemically synthesized.

Three hours after treatment, diet was made available "ad libitum". During the study period, rats were housed under controlled environmental conditions. The rats were observed and weighed daily, after administration of hydroxytyrosol until day 14. At the end of the test, rats were sacrificed, and gross pathological changes in main organs were evaluated. Toxicity was determined from the death/survival ratio of treated animals.

Results

During the study period, no death occurred in the treated animals; the only clinical sign observed in males and females was piloerection, which started 2 h after gavage and disappeared within 48 h from treatment. Body weight did not vary after substance administration, and the autoptic analysis failed to show appreciable macroscopic alterations of internal organs.

Conclusion

The acute oral LD50 value for hydroxytyrosol is greater than 2000 mg/kg bw.

6.3.2 Repeat Dose Toxicity

A tabular summary of the sub-acute toxicological studies reviewed in this dossier is presented below in Table 6-3.

Table 6-3: Summary table of sub-acute toxicity studies

	Study type	Route	Duration	Animals (sex/group) Doses (mg/kg bw/day)	GLP	Results NOAEL in terms of hydroxytyrosol
Studies with other olive extracts (HIDROX or Hydroxytyrosol 15% SD)						
Christian *et al.*, 2004	Rat sub-acute	Gavage	29 days	5 /sex/group 5000, HIDROX extract	Yes	Tolerated after single and repeat dosing
Pappa 2010	Rat preliminary	Gavage	2 weeks	10 /sex/group 1500 and 3000 15% HT formulation In feed and by gavage	No	450 mg/kg bw/day High dose in feed and by gavage well tolerated
Edwards *et al.*, 2010a	Rat sub-acute	Gavage	4 weeks	5 /sex/group, plus recovery animals 0, 0 (placebo), 333, 1000 and 3000, DSM 15% HT extract 0, 0, 62, 187 and 561 as HT	Yes	561 mg/kg bw/day

6.3.2.1 Sub-acute toxicity with olive extract from H40 manufacturing process

A sub-acute study with olive extract from the manufacturing process for H40 has not been performed. Such a study was not considered necessary based on existing data, which enabled the determination of appropriate dosages for a 13-week study.

6.3.2.2 4-week rat study (satellite phase) with HIDROX

The safety testing program for HIDROX (Christian *et al.,* 2004) included a repeat dosing phase to rats by oral gavage at 5000 mg/kg bw/day, in terms of olive pulp extract (OPE). A 4-week satellite phase of the 13-week rat study (Discussed in Section 6.3.2.4)) was primarily used for micronucleus (MN) evaluation purposes. With a 2.4% hydroxytyrosol content, this OPE dosage of 5000 mg/kg bw/day represented a dosage of 120 mg/kg bw/day in terms of hydroxytyrosol.

The treatment was well tolerated and results are discussed with the sub-chronic studies (see further). The MN results of the 4-week genotoxicity study phase are discussed in the publication Kirkland *et al.,* 2015. There was no increase in MN induction by HIDROX.

6.3.2.3 2-Week preliminary study in the rat with Hydroxytyrosol 15% SD

An unpublished 2-week preliminary toxicology study in the rat with Hydroxytyrosol 15% SD was undertaken to establish dosages for a 4-week study (Pappa, 2010). Gavage and feed application were compared. The study included blood sampling for toxicokinetic evaluation.

There were no treatment- or application type-related body weight differences between the treatment groups. The high dose (ca. 450 mg/kg bw/day in terms of hydroxytyrosol and 3000 mg/kg bw/day in terms of Hydroxytyrosol 15% SD) was well tolerated and plasma level data indicated satisfactory exposure by the oral route. Based on the plasma kinetics of hydroxytyrosol (higher C_{Max} values), gavage application was considered to give higher systemic absorption when compared to feed admix application and was therefore recommended for future toxicology studies.

6.3.2.4 28-Day rat study with Hydroxytyrosol 15% SD

A guideline-conforming repeat dose toxicology study with Hydroxytyrosol 15% SD with hydroxytyrosol from a different olive source was undertaken.

Table 6-4: Summary of a 28-Day rat study with Hydroxytyrosol 15% SD

DSM / External + Ref.	Edwards *et al.,* 2010a, DSM RDR No. 00003941 / MDS Study number AA77928
Type	4-week oral (gavage) toxicity study in the rat followed by a 2-week treatment-free period (including a micronucleus test)
Guideline + deviations	OECD 407
GLP	Yes
Test substance / Batch	Hydroxytyrosol 15% SD / Batch CFF29003/bv5, containing 18.7% hydroxytyrosol
Species / sex	Rat / M, F
Strain	Han Wistar
Route of administration	Oral gavage
Period of administration	28 days
Frequency of administration	once per day
Post-exposure period	2-week
Doses males	0, 0 (placebo control), 333, 1000 and 3000 mg/kg bw/day in terms of spray- dried test substance 0, 0, 62, 187 and 561 mg/kg bw/day in terms of hydroxytyrosol 5 rats/sex/group (excluding satellite animals) Additional cyclophosphamide positive control group for micronucleus (MNT) genotoxicity element
Doses females	As males
Control group	Yes
Remark	Study design included additional end-points of plasma level monitoring for exposure and an MNT element
Date	6 May 2010
Result	NOAEL in terms of hydroxytyrosol was ≥560 mg/kg bw/day

Materials and Methods

Dose levels for this study (Edwards *et al.,* 2010a) were selected subsequent to a 2-week non-GLP preliminary study (Pappa, 2010) in which the nominal high dose of 450 mg/kg bw/day, in terms of hydroxytyrosol, was well tolerated. This dosage (3000 mg/kg bw/day in terms of spray-dried test substance) corresponded to the approximate maximum practical dosage.

The 4-week toxicity study in the rat was carried out following OECD guideline 407 and GLP. The dosages administered via gavage were 0, 0 (placebo control) 333, 1000 and 3000 mg/kg bw/day, corresponding in terms of hydroxytyrosol to 0, 0, 62, 187 and 561 mg/kg bw/day, respectively. The study included a micronucleus (MN) phase, with a positive control for this genotoxicity endpoint. Samples were also taken for bio-analysis of hydroxytyrosol in liver, and for both hydroxytyrosol and the hydroxytyrosol metabolite homovanillic acid (HVA) in plasma.

Results

There was no effect on food consumption or weight gain. Hypersalivation after dosing was observed at 187 and 561 mg hydroxytyrosol/kg bw/day. Also at the high dose a slight increase in mean alanine aminotransferase (ALAT) activity was observed on day 28 at 561 mg hydroxytyrosol/kg bw/day (+42% and +17% in males and females, respectively). This variation was not considered to be of toxicological relevance owing to its small magnitude and the effect was reversible over the 2-week treatment-free period. Also at the high dose there was a decrease in mean urinary pH (males and females), which was also reversible.

Terminal and histopathological data showed that absolute and relative mean liver weights were non-significantly increased in males given 3000 mg/kg bw/day, when compared with controls (both control groups), but these values did not reach a statistical significance. In two males from this group (2/5) a minimal centrilobular hepatocellular hypertrophy was seen. Females were unaffected. This change of minimal centrilobular hepatocellular hypertrophy in the absence of other histopathological changes is considered adaptive in nature. The degree of the change was very minor, the change is typically reversible and the finding can also occur occasionally in control animals of this age. Also, 4/5 males at the high dose group showed a minimal level of vacuolation in the adrenal cortex. The degree of vacuolation was only just distinguishable from the degree of vacuolation which is found normally in the cytoplasm of adrenal cortical cells. The change was considered not to be of toxicological importance. Therefore, the histopathological findings were consistent with the high dosage being a NOAEL.

Hydroxytyrosol and the metabolite homovanillic acid were detected in plasma from all treated groups. Plasma levels of free (unconjugated) and total (conjugated plus unconjugated) hydroxytyrosol, and also free and total HVA, increased with dose but not in a clear dosage related fashion. As expected, the proportion of free to total hydroxytyrosol was relatively low and was less than 1% of total at the low dose and between 5 and 10% at the high dosage. The samples taken after one and three weeks of treatment were generally similar at both time points (no clear evidence of bio-accumulation with time). There were no consistent gender differences for plasma exposure between the different dose groups for total hydroxytyrosol, but free hydroxytyrosol was slightly higher in females than in males in the low- and mid-dose groups. Plasma exposure was similar within each dose group on days 7 and 21. At the end of the treatment-free period, there was no quantifiable hydroxytyrosol plasma exposure in the high dose group. As expected, low background levels of HVA were seen in control plasma.

In liver at the end of the treatment period, total hydroxytyrosol was detected in all treated groups, whereas free hydroxytyrosol was only measurable in the high dose group. For both total and free hydroxytyrosol, liver exposure was higher in females than in males.

The MN results of this study phase are included and discussed in the publication Kirkland *et al.,* 2015. There was no evidence of bone marrow toxicity and no statistically or biologically significant increases in MN frequencies as result of hydroxytyrosol 15% SD treatment. In this study, significant systemic exposure to HT was demonstrated.

Conclusion

The findings are consistent with the high dosage being the no-observed-adverse-effect-level (NOAEL). Therefore, in this 28-day study with Han Wistar rats the NOAEL in terms of hydroxytyrosol was ≥ 560 mg/kg bw/day (3000 mg/kg bw/day in terms of spray-dried test substance, Hydroxytyrosol 15% SD).

6.3.3 Pivotal Subchronic Toxicity Studies

A summary of the pivotal subchronic toxicological studies reviewed in this dossier is presented below in Table 6-5.

Table 6-5: Summary table of pivotal subchronic toxicity studies

Reference	Study type	Route	Duration	Animals (sex /group) Doses (mg/kg bw/day)	GLP	Results NOAEL in terms of HT (hydroxytyrosol)
Study with olive extract H35						
Heilman *et al.*, 2015	Rat sub-chronic with H35	Gavage	90 days plus 28 day treatment-free period	10 /sex/group, plus recovery animals 0, 345, 691 and 1381 in terms of H35 0, 125, 250 and 500 as HT	Yes	Based on results excluding MNT phase: 250 mg/kg bw/day (slight reduction in male weight at 500 mg/kg bw/day)
Other studies with other olive extracts (HIDROX or Hydroxytyrosol 15% SD)						
Christian *et al.*, 2004	Rat sub-chronic with HIDROX	Gavage	90 days	20 /sex/group 0, 1000, 1500 and 2000, HIDROX 0, 24, 36 and 48 as HT	Yes	48 mg/kg bw/day (change in stomach at 48 mg/kg bw/day considered non-adverse / secondary)
Edwards *et al.*, 2010b	Rat sub-chronic with Hydroxytyrosol 15% SD	Gavage	90 days plus 28 day treatment-free period	10 /sex/group, plus recovery animals 0, 750, 1500 and 3000, Hydroxytyrosol 15% SD 0, 126, 252 and 504 as HT	Yes	252 mg/kg bw/day (possible adverse effect of lower sperm motility at 504 mg/kg bw/day)
Studies with hydroxytyrosol						
Auñon-Calles *et al.*, 2013	Rat sub-chronic	Gavage	90 days	10 /sex/group, plus recovery animals) 0, 5, 50 and 500 pure HT	Yes	500 mg/kg bw/day (minor changes observed were considered not-adverse)

6.3.3.1 90-Day study with H35 olive extract

Table 6-6: 90-Day study with H35 olive extract

DSM / External + Ref.	Publication: Heilman *et al.*, 2015
Type	13-week oral (gavage) toxicity study in the rat followed by a 4-week treatment-free period
Guideline + deviations	OECD 408
GLP	Yes
Test substance / Batch	olive extract H35, batch no. 1107-A05-124
Species / sex	Rat / M, F
Strain	Wistar (RccHan: WIST)
Route of administration	Oral gavage
Period of administration	90 days
Frequency of administration	once per day
Post-exposure period	4-week
Doses males	0, 345, 691 and 1381 mg H35 /kg bw/day 0, 125, 250 and 500 mg/kg/day in terms of hydroxytyrosol 10 rats/sex/group (plus recovery animals)
Doses females	As males
Control group	Yes
Remark	Study included additional elements: Neurobehavioral observations, seminology, estrous cycling, MNT genotoxicity element
Date	3 April 2014
Result	Based on endpoints of the OECD 408 design, the NOAEL was 250 mg/kg bw/day when standardized in terms of hydroxytyrosol

Materials and Methods

Due to unavailability of H40 at the time of study initiation, it was decided to proceed with a very similar test article containing 35% hydroxytyrosol (H35). The H35 used for the 13-week rat study was produced by the same manufacturing process as H40 from olive pomace used except that the final water evaporation phase was slightly shorter, giving a slightly lower hydroxytyrosol content. H35 was administered orally (gavage) to Wistar rats for 13 weeks, followed by a 4-week treatment-free period, at doses of 0, 345, 691 and 1381 mg /kg bw/day, which were equivalent to doses of 0, 125, 250 and 500 mg/kg/day in terms of hydroxytyrosol. The study was performed following OECD guideline 408 and GLP. The study included additional elements in addition to the standard OECD guideline 408 endpoints. These included neurobehavioral observations, seminology, estrous cycling and a MNT genotoxicity element.

Also, blood samples were collected 30 minutes after dosing one day in weeks 4, 8, and 13 for hydroxytyrosol analysis.

Results

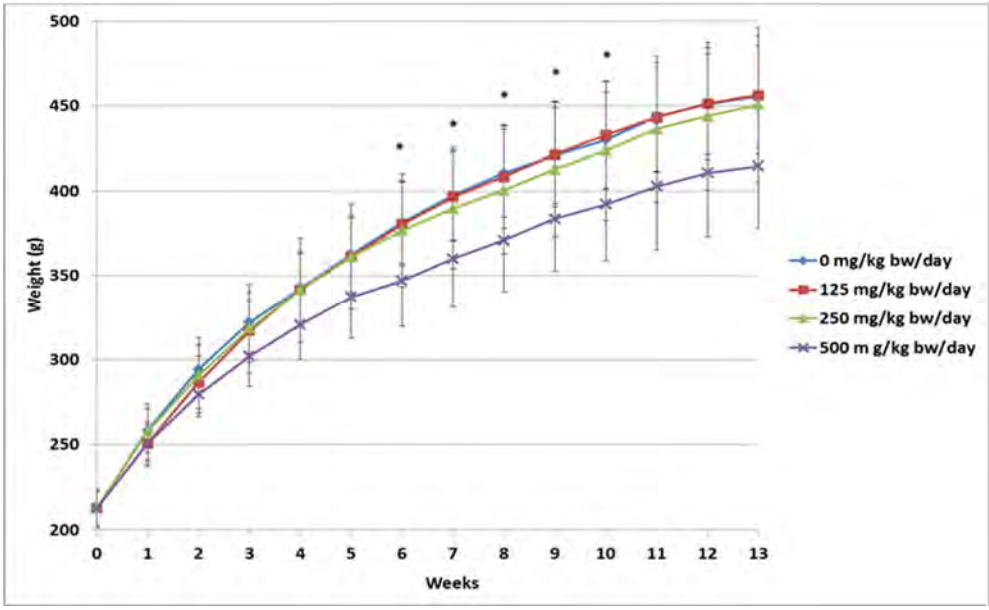
The MN results of this study phase are included and discussed in the publication Kirkland *et al.,* 2015. There was an increase in MN at high dosages but it was concluded that the validity of the results was questionable.

With respect to end-points in the main OECD 408 phase, no mortality or morbidity was observed during the study period. Animals from the high dose group showed signs of mild to moderate salivation intermittently from weeks 1 to 13. Similarly, in the intermediate dose group salivation was observed during weeks 2 to 13 in 3 to 5 animals. The observation of salivation occurred beginning at approximately 15 minutes post-dosing and persisted for approximately 40 to 50 minutes. This effect was considered to be related to the test article but not an adverse treatment-related effect.

A statistically significant lower body weight was observed during weeks 6 to 10 in males of the high dose group compared with controls ($P<0.05$). The body weight deficit in the high dose group males was approximately 9% at 13 weeks compared to control males.

No significant changes were observed in body weight and percent body weight change for male or female rats in the low and intermediate dose groups, except for a statistically significant decrease in body weight gain ($P<0.01$) observed during the first week of treatment for the low dose group males compared to controls. This difference quickly recovered and by the second week, animals were gaining weight at a rate not statistically different from control animals.

Figure 6-2: Body weights of males, significantly lower at high dose for weeks 6 to 10 (P<0.05) compared with controls. Dosages are in terms of hydroxytyrosol



In females, a statistically significant decrease in body weight (P<0.05) was observed during week 2 in the high dose recovery group when compared with the control recovery group, while in all other weeks of the treatment period, reductions in body weight in both the high dose and high dose recovery groups were not statistically significant.

The reduction in body weight at 13 weeks of study in the high dose males was considered treatment-related, and it corresponded with a reduction in body weight gain (17%) which also showed statistical significance.

No significant changes in mean food consumption were observed for treated males or females when compared with controls during the treatment phase.

Statistically significant increases in MCV, MCH, neutrophil count and platelet count were observed in high dose male animals compared to corresponding controls as well as a statistically significant reduction in lymphocyte count. Increases in MCV and MCH values were observed in female rats of the intermediate dose group, and these changes were also statistically significant. However, there was no apparent dose-response and the changes did not reach significance in the low- and high- dose groups. A statistically significant increase in WBC count was observed in female rats of the low- and high-dose groups, however significance was not achieved in the intermediate dose group. Platelet counts were significantly increased in females at the high dose compared to controls and significant decreases in HCT, MCV, MCH and platelet counts were observed, along with an increase in MCHC in male rats of the high dose recovery group when compared with the

control recovery group. All hematological variations observed following treatment with H35 at any dose level and during recovery were inconsistent without dose- response apart from minor differences in males of the high dose group. The observed variations were not considered toxicologically significant.

Compared to controls, increased serum albumin levels were observed with statistical significance in all dose groups tested and significant increases in total serum protein levels were observed in males at the low- and high-dose groups, but not in the intermediate-dose group. Serum phosphorus was significantly increased in males at the intermediate- and high-doses compared to controls, and serum chloride and sodium were decreased significantly in females of the low- and high-dose groups. In high-dose females, serum alkaline phosphatase was significantly increased compared to controls, and in males of the high-dose recovery group, serum triglyceride levels were significantly increased compared to the level in the recovery high- dose males. Alterations in clinical chemistry parameters were determined to be unrelated to treatment due to their lack of dose dependence, spontaneous nature, and their concordance with historical control ranges.

Urine volume was significantly increased and urine pH significantly decreased for males in the high-dose group compared to controls, and urine pH was significantly decreased in males of the intermediate-dose group compared to controls. Urine pH was also significantly decreased in females at the high dose, and increased in females of the high-dose recovery group. All noted observations in urinalysis parameters were without dose-response, spontaneous in nature, and within historical control range, and were therefore considered not to be of toxicological relevance.

Macroscopic external examination of animals of both sexes and across dose groups did not reveal any treatment-related abnormalities of pathological significance. Spontaneous observations that were not determined to be treatment-related included instances of enlargement of the spleen, hydronephrosis/distended pelvis in kidney, small-sized testes and epididymides, and distension of uterus and oviduct.

Microscopic examination of tissues collected revealed various minimal lesions, not related to treatment and within historical control ranges, present in the liver, kidneys, spleen, thymus, pituitary, eye, Harderian gland, heart, vagina, testes, epididymis, thyroid, adrenals and oviducts. Although some instances of lesions were observed with greater frequency in the high dose group, for example, in the spleen, extramedullary hematopoiesis (EMH) and hemosiderosis occurred in 3/10 females at the high dose, while EMH only occurred in control females at an incidence of 1/10 animals, none of the observations were considered treatment-related as all were within normal historical control ranges. Similarly, adrenal lipidosis occurred at a higher incidence (4/10) in high dose group males than controls (0/10), however, lipidosis is to some extent a normal finding which is increased with stress, and lesions were minimal and without corresponding changes in other parameters, thus the finding was considered spontaneous and not treatment-related.

Significant decreases in absolute weights of the thymus were observed in females of the intermediate-dose group compared with controls and a significant increase in absolute kidney weight was observed in females of the high dose group compared to controls. For males in the high dose group, significant increases in relative weights of the liver, heart, spleen and kidneys were observed, and a significant increase in relative weight of the kidneys was observed in male rats of the intermediate dose group compared to control animals. Similar to the findings in high dose males, a significant increase in relative weights of the liver, heart and kidneys was observed in female rats of the high dose group compared with controls. A significant decrease in the relative weight of the thymus was observed in female rats of the intermediate dose group compared with control females.

The significant increase in relative weights of liver, thymus, kidneys and spleen of the high dose group which appeared to occur with a dose-response, could be considered treatment-related effects. However, in the absence of any corresponding or related clinical, gross or microscopic lesion, this could not be explained pathologically, and these effects could be considered non-adverse.

Neurobehavioral observations conducted weekly in the home cage, during handling and in the open field did not reveal any test item-related abnormality in treated animals. Neurobehavioral observations made during removal and handling of animals did not reveal any abnormalities related to treatment. Normal gait and mobility were observed during open field observations in all treated groups and controls, and there were no alterations observed in rearing, or urination and defecation counts for treated males and females compared to controls.

In the high dose recovery group males, a significant increase in rearing count was observed during week 8 and week 11, however, this was not considered treatment-related and it did not correspond to any other findings of toxicological significance.

Likewise, no alterations were observed in mean grip strength values in groups treated with H35 compared with controls, except for a significant decrease in forelimb grip strength was observed in male rats of the high dose recovery group when compared with the control recovery group. This finding was not considered treatment-related in absence of further supportive findings.

Ophthalmological examinations conducted as part of the neurological testing set for the study did not reveal any abnormalities in any treatment groups compared to controls.

In male rats, there no apparent treatment related effects on sperm motility, percent abnormal sperm and no significant changes in Homogenisation Resistant Spermatid count from testicular and cauda epididymis samples of treated male rats compared with respective controls.

Estrus cycle length and pattern of all treated female rats were comparable with female rats of the control group.

Recovered plasma hydroxytyrosol concentrations (unconjugated or “free” HT) ranged from approximately 1543 to 2635 ng/mL in the low-dose group, 2623 to 5096 ng/mL in the mid- dose group and 5535 to 7229 ng/mL in the high-dose group. Plasma concentration of hydroxytyrosol did not differ significantly within same dose levels at different occasions of blood collection (weeks 4, 8, and 13). Total plasma hydroxytyrosol (after enzymatic de-conjugation) was not measured.

Conclusion

Daily oral administration of H35 to male and female Wistar rats for a period of 90 days did not induce any effect on body organs that could be regarded as toxicologically relevant. No reduction in food consumption was observed to explain the slightly lower weight gain in the high dose male rats (500 mg/kg bw/day). Based on the reduction in body weight gain in the high dose males, it was concluded that the NOAEL of H35 is 250 mg hydroxytyrosol/kg bw/day (equivalent to 691 mg H35/kg bw/day).

The high dose, equivalent to 500 mg hydroxytyrosol/kg bw/day, can also be considered to be the lowest observed adverse effect level (LOAEL).

6.3.3.2 Published 90-day rat study with olive pulp extract (HIDROX)

Table 6-7: Published 90-day rat study with olive pulp extract (HIDROX)

DSM / External + Ref.	External (Christian *et al.,* 2004)
Type	90-day gavage study in the rat
Guideline + deviations	OECD 408
GLP	Yes
Test substance / Batch	HIDROX® (hydrolysed aqueous olive pulp extract containing 2.4% hydroxytyrosol) / Mixture of 12 production lots, batch number/s not stated
Species / sex	Rat / M, F
Strain	Sprague Dawley Crl:CD(SD)IGS BR VAF/Plus
Route of administration	Oral gavage
Period of administration	90 days
Frequency of administration	once per day
Post-exposure period	No recovery phase
Doses males	0, 24, 36 and 48 mg/kg bw/day in terms of hydroxytyrosol 0, 1000, 1500 and 2000 mg/kg bw/day in terms of olive pulp extract (OPE) 20 rats/sex/group (excluding satellite animals)
Doses females	As males
Control group	Yes
Remark	Study included additional satellite animals for toxicokinetic sampling, MNT genotoxicity element (after 4 weeks treatment) and a single dose acute phase at 5000 mg/kg bw in terms of olive pulp extract
Date	2004, year of publication
Result	NO(A)EL was 48 mg/kg bw/day in terms of hydroxytyrosol

Materials and Methods

In this 90-day study, 20 rats/sex/group (excluding satellite animals) of the Sprague Dawley (CD-1) strain were administered HIDROX® (hydrolysed aqueous olive pulp extract; OPE) by oral gavage at 1000, 1500 and 2000 mg/kg bw/day; corresponding to dosages in terms of hydroxytyrosol to 24, 36 and 48 mg/kg bw/day, respectively (Christian *et al.,* 2004). The study was performed following international guidelines including OECD 408 requirements and in accord with GLP.

The study included a micronucleus (MN) evaluation and an acute phase element.

Blood samples (from 6/sex/group) were collected on day 90, prior to dosing and at 0.5, 1, 2, 4 and 8 h post-dose for hydroxytyrosol measurement.

Results

The MN results of this study phase are included and discussed in the publication Kirkland *et al.,* 2015. There was no evidence of bone marrow toxicity and no statistically or biologically significant increases in MN frequencies.

Daily oral dosages of 1000, 1500 and 2000 mg/kg bw/day for 90 days produced small decreases in body weight gains at 2000 mg/kg bw/day in the male rats and in all groups of female rats. Feed consumption was comparable to controls. There were no adverse effects upon clinical, hematologic, biochemical, organ weight or gross necropsy parameters.

Focal, minimal or mild hyperplasia of the mucosal squamous epithelium of the limiting ridge of the forestomach occurred in some rats at 2000 mg/kg/day; this change was attributed to local irritation by repeated intubation of large volumes of viscous, granular dosing suspension.

In the acute phase element at 5000 mg/kg, there were no deaths or clinical signs of toxicity.

Plasma data for hydroxytyrosol (see ADME section) indicated that hydroxytyrosol was rapidly absorbed. Mean concentrations were measurable through 1 to 4 hours (t_{last}) at 1000 and 1500 mg/kg/day and through 8 hours (t_{last}) at 2000 mg/kg/day. AUC_{last} and C_{max} were similar for males and females at the corresponding dosages.

Conclusion

A NOAEL at the high dose of 2000 mg HIDROX/kg/day, or 48 mg/kg/day in terms of hydroxytyrosol, was established for the 90-day study, based on the lack of significant adverse effects.

6.3.3.3 90-day rat study with Hydroxytyrosol 15% SD

Table 6-8: 90-day rat study with Hydroxytyrosol 15% SD

DSM / External + Ref.	Edwards *et al.*, 2010b. DSM RDR No. 00003942 / MDS Study number AA77929
Type	13-week oral (gavage) toxicity study in the rat followed by a 4-week treatment-free period
Guideline + deviations	OECD 408
GLP	Yes
Test substance / Batch	Hydroxytyrosol 15% SD / Batch B.2009.S1-04, containing 16.8% hydroxytyrosol
Species / sex	Rat / M, F
Strain	Han Wistar
Route of administration	Oral gavage
Period of administration	90 days
Frequency of administration	once per day
Post-exposure period	4-week
Doses males	0, 750, 1500 and 3000 mg/kg bw/day in terms of spray dried test substance (Hydroxytyrosol 15% SD) 0, 126, 252 and 504 mg/kg bw/day in terms of hydroxytyrosol 10 rats/sex/group (plus recovery animals)
Doses females	As males
Control group	Yes
Remark	Study design included additional end-points relating to fertility, behavior and plasma level monitoring for steady state determination.
Date	12 May 2010
Result	NOAEL was 252 mg/kg bw/day in terms of hydroxytyrosol

A guideline toxicology study with hydroxytyrosol from a discontinued olive-extract product.

Materials and Methods

Hydroxytyrosol 15% SD was administration orally (gavage) to Wistar rats for 13 weeks (Edwards *et al.*, 2010b), followed by a 4-week treatment-free period, at doses of 750, 1500 and 3000 mg/kg bw/day, equivalent to doses of 126, 252 and 504 mg/kg bw/day, respectively, in terms of hydroxytyrosol. The study was performed following OECD guideline 408 and GLP.

Results

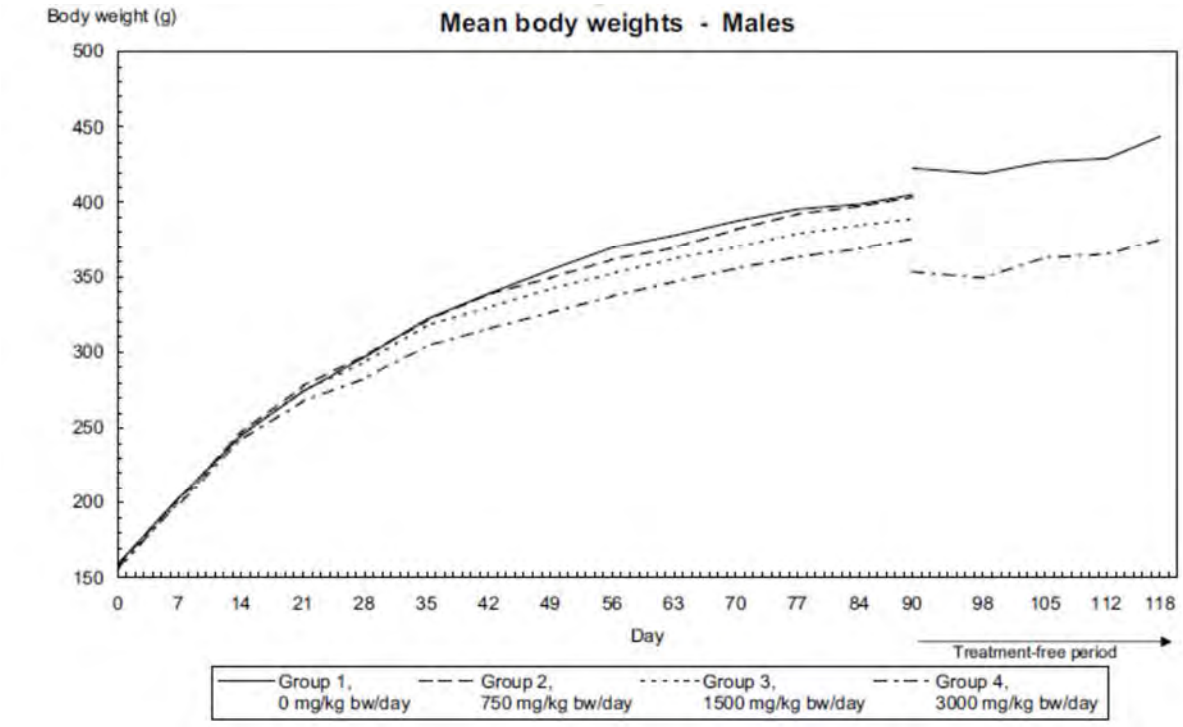
Dose dependent hyper salivation was observed, typically occurring at dosing in a proportion of animals for 5 minutes. Later in the study, among high dose rats, salivation was even noticed to start immediately before dosing. Timing at dosing suggests that hyper salivation may be more to

do with taste than a systemic effect. Elevated tail (Straub tail) also seen at dosing for 5 minutes in a proportion of animals since week 5, in the mid- and high-dose groups. The timing suggests that it is linked to the taste / hyper salivation response.

A slightly lower body weight gain was noted during the treatment period for males at 1500 mg/kg bw/day and to a greater extent at 3000 mg/kg bw/day. At 3000 mg/kg bw/day differences in absolute mean body weight at 13 weeks were between 5 and 9% lower from controls, and significantly lower, from day 28 through day 90. The reduction in males at 13 weeks at the high dose in terms of body weight gain at 13 weeks was approximately 17%.

In repeat dose 90-day oral toxicity studies in rodents, the highest dose level, if below a maximum limit dosage (1000 mg/kg/body weight) should be chosen with the aim to induce toxicity but not severe effects (OECD 408). In the context of body weight effects in long-term studies, evidence of toxicity may be provided by a depression of body weight gain of approximately 10% (OECD 451).

Figure 6-3; Doses: 750, 1500 and 3000 mg/kg bw/day, equivalent to 126, 252 and 504 mg/kg bw/day, respectively, in terms of hydroxytyrosol (Edwards *et al.*, 2010b)



Changes in urinary parameters and renal weight were noted at all dose levels and were consistent with the urinary elimination of the test item or metabolites. The increased hepatic weight, with or without centrilobular hypertrophy, noted for females given 1500 or 3000 mg/kg bw/day was considered to be adaptive. All the above findings were reversible at the end of the 4-week

treatment-free period and were considered not to be adverse. Microscopic findings were also noted in the adrenals (cortical vacuolation) for males from the dose of 1500 mg/kg bw/day. At 3000 mg/kg bw/day, this change was partially reversible after the recovery period and was considered not to be adverse.

The only potential adverse effect was a lower value for sperm motility parameters recorded at the end of the treatment period in males given 3000 mg/kg bw/day. This effect was reversible at the end of the 4-week treatment-free period.

Plasma concentrations of hydroxytyrosol and its conjugates increased dose-dependently and were quantitatively similar for both genders. Concentrations of total hydroxytyrosol were always much higher than for free (unconjugated) hydroxytyrosol indicative for efficient conjugation even at high doses. The ratio of free to total analyte was around 2% in the low-dose group and increased with the dose to ~3% (mid-dose) and 5.9% in the high dose group. No indication for accumulation in plasma was observed during the 13-week treatment. There were no measurable plasma levels of hydroxytyrosol in the high-dose group during weeks 2 and 4 of the treatment-free period. Liver samples were also taken for bio-analysis. Both plasma and liver data provided evidence of dose-dependent hydroxytyrosol absorption, rapid conjugation, and efficient elimination with no evidence of bioaccumulation with time.

Conclusion

The intermediate dose of 1500 mg/kg bw/day (252 mg/kg bw/day in terms of hydroxytyrosol) was considered as a No Observed Adverse Effect Level (NOAEL).

6.3.3.4 90-day rat study with pure hydroxytyrosol

Table 6-9: 90-day rat study with pure hydroxytyrosol

DSM / External + Ref.	Published study: Auñon-Calles *et al.*, 2013 (Seprox Biotech)
Type	13-week oral (gavage) toxicity study in the rat followed by a 4-week treatment-free period
Guideline + deviations	OECD 408
GLP	Yes
Test substance / Batch	Pure hydroxytyrosol / not reported
Species / sex	Rat / M, F
Strain	Han Wistar, RccHan™: WIST
Route of administration	Oral gavage
Period of administration	90 days
Frequency of administration	once per day
Post-exposure period	4-weeks
Doses males	0, 5, 50 and 500 mg/kg bw/day, pure hydroxytyrosol 10 rats/sex/group (excluding recovery animals)
Doses females	As males
Control group	Yes
Remark	None
Date	Publication available online 1 February 2013
Result	NO(A)EL was 500 mg/kg bw/day in terms of pure hydroxytyrosol

Materials and Methods

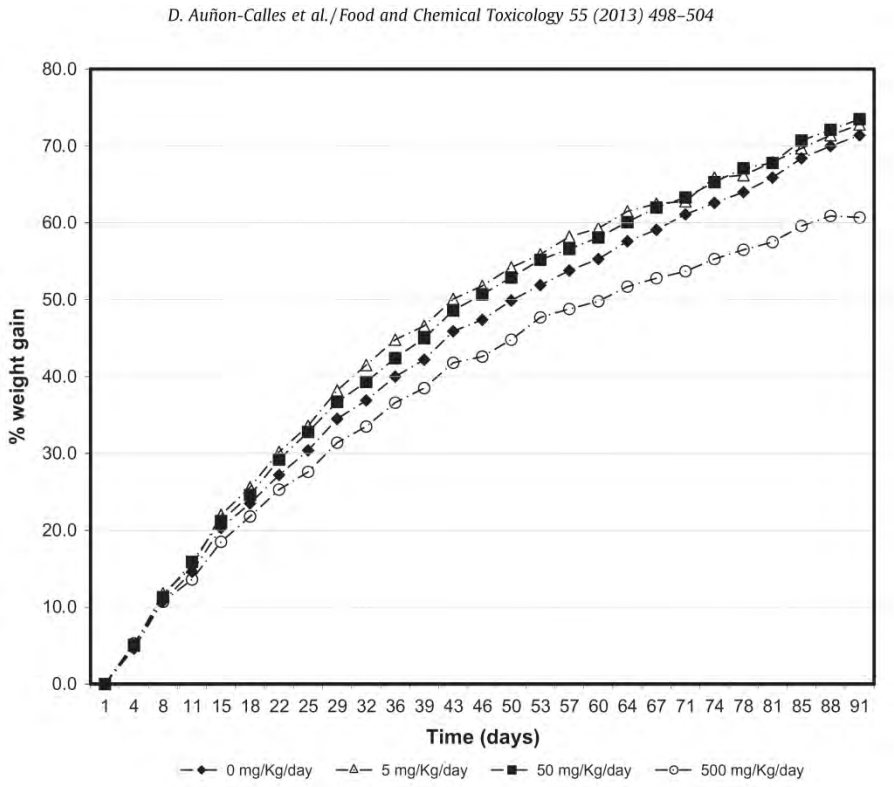
This study (Auñon-Calles *et al.*, 2013) was performed in accordance with internationally accepted guidelines and OECD Guideline 408, and GLP. Hydroxytyrosol was administered orally daily by gavage to 10 rats/sex/group for a 13-week period at dose levels of 0, 5, 50, and 500 mg/kg/day to rats (Wistar Hannover RccHan™: WIST, from Harlan Laboratories, B.V.). Five additional animals per sex in groups 1 and 4 were used for a four-week recovery period. The test material is stated as being pure hydroxytyrosol without further information.

Results

The oral administration of hydroxytyrosol to rats once a day for 13 weeks at dosages up to 500 mg/kg bw/day did not lead to any death or to micro- and macroscopic alterations. Salivation was recorded in all animals treated at the high dose and sporadically in some animals from groups treated at the intermediate- and low-doses. This phenomenon was attributed to the bitter taste of hydroxytyrosol and/or the physical characteristics of the formulation (slightly oily and dense).

Because the effects on body weight and body-weight gain in males and females treated at the high dose level were modest and a recovery was observed after four treatment-free weeks, these outcomes were not considered by the authors as toxicologically relevant. However, there was a lower weight gain in males at the high dosage of 500 mg/kg bw/day, which was similar to the lower weight gain in males at 500 mg/kg bw/day in the 90-day study with H35 (JRF 2013).

Figure 6-4: Body weight gain (%) of male rats with synthetic hydroxytyrosol (Auñon-Calles *et al.*, 2013)



Some hematological and biochemical changes were recorded and included higher MCV and MCH in females treated at the high- and intermediate-doses; higher HFR and WBC values in females treated at the high dose; lower creatinine and higher albumin values in males treated at the high dose; and higher calcium values in males treated at intermediate- and high-doses.

Although higher kidney weights were observed in males and females from the 500 mg/kg group, no alterations in this organ were observed on histopathological examination; therefore, this finding was not considered to be toxicologically relevant.

Conclusion

Based on the results obtained, daily oral administration of hydroxytyrosol to rats for a period of 13 weeks did not induce effects that can be considered of toxicological relevance. Consequently, the authors proposed the dose of 500 mg/kg bw/day as the No Observed Adverse Effects Level (NOAEL).

6.3.4 Genotoxicity / Mutagenicity

Summary

Genotoxicity studies with olive extracts are presented and discussed in the publication by Kirkland *et al.,* 2015.

An *in vitro* study for mutagenic potential (Ames test) performed on extract H35 was clearly negative, indicating the absence of mutagenic potential at the gene level. This was a robust study; performed with and without S9, was GLP-compliant and conformed to OECD guidelines. Ames test data are also available for two other olive extracts and for pure hydroxytyrosol, and are generally indicative of the absence of mutagenic potential.

In vitro studies for chromosome damage (clastogenic and or aneugenic potential) have produced positive results. However, it has been established that hydroxytyrosol, like some other polyphenols, can produce hydrogen peroxide via chemical reaction with culture medium, so these data are unreliable as indicators of *in vivo* activity.

Contrary to what was expected, an *in vivo* micronucleus (MN) test at the end of a 13-week rat study with extract H35 (produced from olive pomace) showed MN induction. An increase in micronuclei was observed at the high dosage group in males, namely 500 mg hydroxytyrosol/kg bw/day. In females, an increase was seen at the mid-dose group, 250 mg/kg bw/day, and there was a lesser increase in the high dosage group. This was not consistent with previous negative *in vivo* MN data obtained in the rat after 4-weeks of treatment for two other olive extracts. The contradictory positive MN result was suggested to be potentially related to chromosomal damage.

To attempt to elucidate these unexpected findings, two further acute *in vivo* MN tests were carried out on H40 samples under robust conditions and at higher doses than in the 13-week study. In these two *in vivo* MN tests, test item samples from standard H40 and H40 derived under Mild Process Conditions (MPC) were used.

The results from two rat acute MNT studies with both extracts (normal and mild process form) were contrary to the data from the 13-week toxicity study, and showed no dose-related increases in micronuclei up to a high dosage of 2000 mg hydroxytyrosol/kg bw. The study was considered robust. Plasma samples from the rat acute MNT studies also showed that the high dosage used (2000 mg/kg bw) was also associated with a ca. 3-fold higher plasma concentration of

hydroxytyrosol in comparison to the high dosage (500 mg/kg bw/day) in the 13-week toxicity study.

It is important to note that the inclusion of MN phases at the end of a 13-week study is an infrequent occurrence and the interpretation of the data from this study is hampered by various shortcomings including the absence of appropriate historical control data at the laboratory where the study was performed. Also, a staining method that is no longer recommended for rat bone marrow was used, and there was a lack of any positive control treatments or slides within the study.

Although slight effects on red cell parameters, possibly indicating increased erythropoiesis, occurred in the 13-week studies with olive extracts and hydroxytyrosol, they were considered insufficient to explain (as a non-genotoxic mechanism secondary to erythropoiesis) the possible MN positive result in the 13-week study with H35 olive extract.

However, various significant factors were identified (robustness of the negative acute *in vivo* MN studies with the Probelte Biotechnologica Olive extracts at high dosages, shortcomings in the only *in vivo* study (the 13-week study) with a positive result, absence of evidence of chromosomal damage in other robustly conducted *in vivo* MN studies with other olive extracts, absence of evidence of mutagenic potential, or other supporting analytical data) that influence the weight-of-evidence assessment.

Based on these factors, it was considered possible to reliably conclude there is no clear evidence that H35 extract has genotoxic potential *in vivo* as there is overwhelming data showing the absence of activity. In addition, the negative results from the high dose acute *in vivo* MN studies, and the available supporting analytical data, indicate there is no safety basis to differentiate the two forms of H40.

The pivotal genotoxicity studies have been published (Kirkland *et al.,* 2015) and provide a conclusion of lack of genotoxic concern on a Weight of Evidence basis. Based on the overall genotoxicity evaluation, it was concluded that for olive extracts in general, the specific olive extract from the process used to make H40, and for the main olive polyphenol (hydroxytyrosol), that any genotoxic risks for human consumers are negligible. Negligible risk is usually regarded as the lowest level of risk (risk levels: high, unacceptable, medium, low, acceptable, minimal, negligible).

Since the Kirkland *et al.,* 2015 paper went to press in 2014, an *in vivo* chromosome aberration test in rats (Dolan *et al.,* 2014) was published. At the oral limit dose of 2000 mg/kg bw, hydroxytyrosol also did not induce chromosome aberrations in bone marrow cells.

6.3.4.1 *In vitro* studies for mutation (Ames tests)

Table 6-10: In vitro studies for mutation

Reference	Test	Test system/	Strain(s) /Target Cells	Hydroxytyrosol (HT) concentration/ Dose	GLP	Results
Study with H35						
Kirkland *et al.*, 2015 (Internal report, Rana, 2013)	Ames test (Bacterial reverse mutation test)	S. typhimurium	TA98, TA 100, TA1535, TA1537 and TA 102	Liquid olive extract H35 tested up to 5000 µg/plate in terms of HT, in the presence (S9 at 5% and 10%) and absence of metabolic activation	Yes	Non-mutagenic
Other studies with hydroxytyrosol from different sources						
Christian *et al.*, 2004	Ames test with HIDROX extract	S. typhimurium and E coli	TA97, TA98, TA100, TA1535, and E. coli strain WP2 uvrA	up to 5 µL/plate (5000 µg/plate) in the presence and absence of metabolic activation	Yes	TA98 and TA100 “equivocal ” other strains negative
Pappa and Chalendard, 2010	Ames test with Hydroxytyrosol 15% SD	S. typhimurium (Plate incorporation and Pre-incubation methods)	TA98, TA100, TA1535, TA1537 and TA 102	Both up to 5000 µg/plate in the presence and absence of metabolic activation	Yes	Non-mutagenic
Auñon-Calles *et al.*, 2013b	Ames test with pure Hydroxytyrosol	S. typhimurium and E coli	TA 100, TA98, TA1535, TA1537 and E. coli strain WP2 pKM101	up to 5 µL/plate (5000 µg/plate) in the presence and absence of metabolic activation	Yes	Non-mutagenic

H35 extract

The Ames test conducted with H35 for mutagenic activity was clearly negative. (Kirkland *et al.,* 2015; Rana, 2013). The study was robust, was performed following OECD guidelines and done under GLP. The study included concentration analysis of the formulation in terms of hydroxytyrosol.

Based on the results of the cytotoxicity test, test concentrations of 156.25, 312.5, 625, 1250, 2500 and 5000 µg/plate of hydroxytyrosol both in the absence and presence of metabolic activation (5% v/v S9 mix) were selected for Trial I. Trial I did not show any positive mutagenic responses when compared with the negative control at any of the tested concentrations in any of the 5 strains.

Trial II was conducted to confirm the negative results of Trial I with concentrations separated by 2.5 fold i.e., 51.2, 128, 320, 800, 2000 and 5000 µg/plate of active ingredient hydroxytyrosol both in the absence and presence of metabolic activation (S9 concentration was increased to 10% v/v). No mutagenic responses were observed in Trial II confirming the results of Trial I. The efficiency of the test system was demonstrated by clear increases in numbers of revertant colonies observed with the positive controls both in the absence and presence of metabolic activation in both trials.

The formulation concentrations tested were confirmed analytically. The active ingredient hydroxytyrosol was found to be within an acceptable range of ± 10 % in sterile reverse osmosis water at the tested concentrations of 1562 and 50003 µg/mL (stock solutions from which 0.1 mL was added to each plate) during the main study (Trial I). Average recoveries were 99% and 100% at these test concentrations, respectively.

Therefore, the doses complied with the presence of test item for claimed concentration (± 10%) of active ingredient. The results of this study with H35 were clearly negative, without any indication of gene mutation potential.

HIDROX extract

With respect to genotoxic potential in general, Christian *et al* (2004) also described an Ames test (for mutagenic potential) in which positive responses were seen at relatively high concentrations in two of the five strains tested (TA98 and TA100), particularly in the presence of S9. The authors dismissed these results because of the high concentrations, but the mutagenic responses were quite large and unlikely to be due to impurities. A subsequent publication supporting the safety of HIDROX was published (Soni *et al.,* 2006) in which the responses in strains TA98 and TA100 were described as “equivocal”. Whether use of this term is correct is perhaps debatable. It is unclear why positive responses were observed in this study when other Ames tests on hydroxytyrosol-containing preparations have given negative results.

Based on the negative *in vivo* MN studies (no MN induction) with HIDROX the product was granted GRAS (self-GRAS) status and marketed.

DSM Hydroxytyrosol 15% SD extract

In this study, the test item, Hydroxytyrosol 15% SD, was evaluated as a spray-dried formulation of the extract in maltodextrin. The content of hydroxytyrosol was approximately 15% and the concentrations used in the study were defined in terms of hydroxytyrosol content. The study was performed in accord with OECD guidelines and GLP (Pappa and Chalendard, 2010).

The dosages tested were up to 5000 µg/plate of active ingredient hydroxytyrosol. The Study Director concluded that under the experimental conditions and according to the criteria of the test study plan, when tested up to the maximum recommended dose level of 5000 µg/plate in terms of active component hydroxytyrosol, using both the plate incorporation and the pre-incubation methods, the test item Hydroxytyrosol 15% SD did not induce biologically significant increases in the number of revertants in the five *Salmonella typhimurium* strains used (TA98, TA100, TA1535, TA1537 and TA102), both with or without metabolic activation. Although some weak or borderline increases in revertant numbers were observed, they did not achieve levels considered biologically significant and the overall conclusion of the Study Director is considered appropriate.

Pure hydroxytyrosol (HT)

This test (Auñon-Calles *et al.,* 2013b) was performed in accordance with international guidelines and GLP.

Salmonella typhimurium strains TA 100, TA98, TA1535, and TA1537 and *Escherichia coli* strain WP2(pKM101) were exposed to pure HT at 5 concentrations (5 µL/plate down to 0.06 µL/plate) with and without S9 under the direct incorporation (main study) and the pre-incubation (confirmatory study) procedures.

None of the concentrations assayed for HT were stated by the authors to show an increase in the revertant counts relative to control (R value), either with or without S9 metabolic activation, regardless of the procedure. No dose-response for HT was observed in any of the tested bacterial strains. Therefore, there was no indication of mutagenic potential.

6.3.4.2 *In vitro* micronucleus and chromosomal aberration tests

The following overview table shows the results from the various *in vitro* cytogenetic (MN and chromosomal aberration) studies.

Interpretation of the results of the *in vitro* studies is complicated due to changes in methodology and also due to the known impact of phenols in *in vitro* incubation systems, which can result in positive results due to hydrogen peroxide production. *In vivo,* there are natural antioxidant

mechanisms (e.g. catalase) against hydrogen peroxide production. Therefore, such positive *in vitro* results are commonly considered for phenols to be of dubious *in vivo* relevance. For completeness sake, the various *in vitro* studies have been tabulated in the table below. The studies have also been reviewed in the publication of Kirkland *et al.,* 2015.

Studies have also been performed to show that there is hydrogen peroxide production with hydroxytyrosol *in vitro* and these are also summarized here and were also reviewed in the publication of Kirkland *et al.,* 2015.

Table 6-11: *In vitro* micronucleus and chromosomal aberration tests

Reference	Test	Test system/	Strain(s) /Target Cells	Hydroxytyrosol (HT) concentration/ Dose	G LP	Results
Study with H35						
Wöhrle and Fehr, 2011	MNT screening assay	CHO cells	with/without metabolic activation	Without S9: 0.002 to0.200 µL/mL With S9: 0.039 to 5.000 µL/mL	No	Positive in absence of S9 Equivocal, in presence of S9
Other studies with hydroxytyrosol from different sources						
Christian *et al.*, 2004	HIDROX Chromosome aberration test	CHO cells	with/without metabolic activation	With and Without S9: Up to 1000 µg/mL	Yes	Positive in presence of S9
Wöhrle and Török, 2009a	Hydroxytyrosol 15% SD MNT screening assay	CHO cells	with/without metabolic activation	Without S9: Up to 200 µg/mL With S9: Up to 1000 µg/mL	No	Positive or borderline in absence of S9
Wöhrle and Török, 2009b	pure Hydroxytyrosol MNT screening assay	CHO cells	with/without metabolic activation	With and Without S9: Up to 200 µg/mL	No	Positive or borderline in absence of S9
Auñon-Calles *et al.*, 2013b	pure Hydroxytyrosol Chromosome aberration test	Human lymphocytes	with/without metabolic activation	With and Without S9: Up to 1540 µg/mL	No	Positive in absence and presence of S9

6.3.4.3 Hydrogen peroxide (H_2O_2) formation

A positive *in vitro* MNT result can occur artifactually in culture media due to the reaction of polyphenols with culture medium components leading to hydrogen peroxide (H_2O_2) formation (Long *et al.,* 2007). Such H_2O_2 formation, occurring in the absence of cells or metabolic activation mixture, is a possible mechanistic explanation for positive *in vitro* MNT results, particularly when observed in the absence of S9. Therefore, *in vitro* investigations were undertaken, and showed that H_2O_2 formation does occur with Hydroxytyrosol 15% SD (Wöhrle and Török, 2009c) and with 3'-hydroxytyrosol (Wöhrle and Török, 2009d).

Table 6-12: H_2O_2 formation occurance with Hydroxytyrosol 15% SD

Reference	Test	Test system	Strain(s) / Target Cells	Hydroxytyrosol (HT) concentration/ Dose	GLP	Results
Study with Hydroxytyrosol 15% SD						
Wöhrle and Török, 2009c	H_2O_2 production in the Hams F-12 culture medium	CHO cells	without metabolic activation	CHO cells incubated with 50, 100, 200 and 400 µg/ml Hydroxytyrosol 15 % SD (equivalent to 9.35, 18.7, 37.4 and 74.8 µg/ml in terms of Hydroxytyrosol)	No	Hydroxytyrosol 15 % SD produced H_2O_2 *in vitro* in F-12 medium
Study with 3'-hydroxytyrosol						
Wöhrle and Török, 2009d	H_2O_2 production in the Hams F-12 culture medium	CHO cells	without metabolic activation	CHO cells incubated with 12.5, 25, 50 and 100 µg/ml 3'-HT for 30 and 60 min	No	3'-HT produced H_2O_2 *in vitro* in F-12 medium

H_2O_2 formation was found to be produced in the Hams F-12 culture medium (as used for the *in vitro* MN studies) with both Hydroxytyrosol 15% SD (Wöhrle and Török, 2009c) and with pure 3'-hydroxytyrosol (Wöhrle and Török, 2009d) Data from these studies including data for the polyphenol, EGCG, as a positive control, are reviewed and discussed in the publication by Kirkland *et al.,* 2015.

Kirkland *et al.,* 2015, concluded the amounts produced at the concentrations tested may well be sufficient to account for the increased MN frequencies seen with these two substances in the absence of S9. H40 was not evaluated for production of hydrogen peroxide, but given its HT content, it is predicted that it would also have produced significant amounts after short incubations with Hams F-12 culture medium. Thus, it seems highly likely that the MN induced by HT,

Hydroxytyrosol 15% SD and H40 were due either to chemical reaction with the medium leading to hydrogen peroxide production, or to excessive cytotoxicity, or to a combination of the two.

Induction of H_2O_2 *in vitro* can be considered artifactual as it occurs through chemical interaction of the polyphenol with the medium. In the absence of synthetic culture medium, this reaction would be unlikely to occur *in vivo*, but even if H_2O_2 was produced, the normal protective antioxidant mechanisms (*e.g*. catalase) would likely prevent any genotoxic consequences. Therefore, the borderline or positive results found in the absence of S9 in the referred to *in vitro* MN studies discussed earlier are of doubtful toxicological relevance.

6.3.4.4 *In vivo* micronucleus and clastogenicity tests

Table 6-13: Summary of studies reviewed in Kirkland *et al.*, 2015

Reference	Study type	Route	Duration	Animals (sex /group) Doses (mg/kg bw/day)	GLP	Results NOAEL in terms of HT (hydroxytyrosol)
Studies with H35, H40 and H40 Mild Process conditions						
Kirkland *et al.*, 2015 JRF Study No: 443-1-03-4864, 2013	MNT element in rat sub-chronic	Gavage H35, Batch 1107-A05-124	90 days 24 hrs. following last dose	10 /sex/group, plus recovery animals 0, 125, 250 and 500	Yes	MNT phase: 125 mg/kg bw/day Positive MN effect at higher dosages
Kirkland *et al.*, 2015 Dony E, 2014a, Harlan study: 1571901	Classic acute MNT in rat	Gavage H40	Single dose 24 and 48 hrs. post dose	7 /males/group 0, 500, 1000 and 2000	Yes	Non-genotoxic
Kirkland *et al.*, 2015 Dony E, 2014b, Harlan study: 1571902	Classic acute MNT in rat	Gavage H40 MPC	Single dose 24 and 48 hrs. post dose	7 /males/group 0, 500, 1000 and 2000	Yes	Non-genotoxic
Other studies with hydroxytyrosol from different sources						
Kirkland *et al.*, 2015 Edwards *et al.*, 2010a, DSM RDR Report No. 00003941	Rat sub-acute	Gavage HT 15% SD	4 weeks Day 27	10 /sex/group, plus recovery animals 0, 62, 187 and 561	Yes	Non-genotoxic at ≥561 mg/kg bw/day
Christian *et al.*, 2004	acute MNT in rat	Gavage HIDROX	Single dose 24 and 48 hrs. post dose	Up to 2000 mg/kg bw in terms of extract HT content 2.4%	Yes	Non-genotoxic at up to 48 mg/kg bw
Christian *et al.*, 2004	Rat sub-acute	Gavage HIDROX	4 weeks 24 hrs. after last dose	Up to 5000 mg/kg bw/day in terms of extract HT content 2.4%	Yes	Non-genotoxic at up to 120 mg/kg bw/day
Dolan *et al.*, 2014	*OECD 475* rat bone marrow chromosome aberration	Gavage HT	Single dose 24 and 48 hrs.	2000 mg/kg bw of HT	n.i.	Non-clastogenic

n.i. not indicated

Mammalian bone marrow chromosome aberration test

Since the Kirkland *et al.,* 2015 paper went to press in 2014, an *in vivo* chromosome aberration test in rats (Dolan *et al.,* 2014) was published. As the study is not considered in the Kirkland *et a*l publication, the details on the study are presented here:

Table 6-14: Summary of Mammalian bone marrow chromosome aberration test (Dolan *et al.,* 2014)

DSM / External + Ref.	Published study: Dolan *et al.,* 2014
Type	Mammalian bone marrow chromosome aberration test
Guideline + deviations	OECD 475
GLP	Not stated
Test substance / Batch	Pure hydroxytyrosol / not reported
Species / sex	Rat / M, F
Strain	Wistar, Charles River
Route of administration	Oral gavage
Frequency of administration	Single dose
Post-exposure period	Euthanasia 24 and 48 hour time points after treatment (treated and negative control); 24 hour time point after treatment (positive control)
Doses males	five males, at the oral limit dose of 2000 mg/kg bw, pure Hydroxytyrosol
Doses females	As males
Control group	Negative control (distilled water) and positive control (40 mg/kg bw cyclophosphamide by intraperitoneal injection)
Remark	None
Date	Publication in 2014
Result	At 2000 mg/kg bw, in terms of hydroxytyrosol: temporary slight reduction in spontaneous activity observed post dosing; no increase in chromosome aberrations was observed The positive control induced a positive chromosome aberration response.

Materials and Methods

The study was performed in accord with OECD Guideline 475. An oral limit dose of hydroxytyrosol of 2000 mg/kg bw, was used. The test material was dissolved in distilled water one hour before treatment, and administered via gavage to two groups of five males and five females. Two groups of five animals per sex (negative controls) were dosed with vehicle (distilled water) only. Five male and five female rats served as positive controls and received 40 mg/kg bw cyclophosphamide (CPA) in physiological saline by intraperitoneal injection.

Four hours before scheduled euthanization (24 and 48 hour time points for both treated and negative control animals and 24 hours for the positive control group), the rats received 2 mg/kg colchicine (a metaphase arresting agent) by intraperitoneal injection. At termination, femurs were removed and bone marrow was harvested by cutting off the epiphyses and flushing the marrow out with a 0.4% potassium chloride solution. Collected cells were incubated (37°C for 25 min) and fixed with ten drops of ice-cold fixing solution (3:1 methanol: glacial acetic acid) under vigorous mixing. Cell suspensions were then spun in a centrifuge (200 x g for 10 min). The supernatant was discarded and the sediment containing the cells was resuspended in 4 ml of ice-cold fixing solution. The fixing procedure was repeated twice. Microscope slides were prepared by dropping the cell suspension on clean slides, flame-drying, and staining with Giemsa. All slides were independently coded (blinded) before microscopic examination using 100X oil immersion objectives.

At least 100 well-spread metaphases per animal were scored for cytogenetic damage (chromosome breaks, fragments, deletions, exchanges and disintegrations) unless a distinct positive result was observed in fewer than 100 metaphases. Gaps and polyploidy were recorded but were not included in the calculation of the aberration rates. A minimum of 1000 cells per animal were analyzed for mitotic index (percentage of cells in mitosis), to determine the extent of bone marrow cell cytotoxicity.

Results

The oral limit dose of 2000 mg/kg hydroxytyrosol was well tolerated by most rats; however, some rats exhibited clinical signs that abated within 24 hours. Treatment with hydroxytyrosol did not significantly enhance the number of aberrant cells or the mitotic index 24- or 48- hours post-dose. The positive control (cyclophosphamide) induced the expected increase in chromosomal aberrations and a decrease in the mitotic index, confirming the validity of the assay.

Conclusion

An oral limit dose of 2000 mg/kg hydroxytyrosol does not induce chromosome aberrations in bone marrow cells of the rat. Accordingly, hydroxytyrosol is not a clastogen *in vivo*.

Discussion

The results of this study confirm the absence of a clastogenic response in rats *in vivo,* which is consistent with the results of the acute *in vivo* MN studies with H40 and H40 Mild Process Conditions, and consistent with the opinion stated in Kirkland *et al.,* 2015.

6.3.5 Carcinogenicity

6.3.5.1 Summary of carcinogenicity data

We are not aware of any carcinogenicity studies in rodents that have been performed with olive oil, olive polyphenols or hydroxytyrosol.

There are certain rodent efficacy studies that show a potential benefit of olive oil in the diet, including inhibition of colon cancer.

The weight of evidence evaluation for genotoxic potential indicates that the extract from the process used to prepare H40 is most unlikely to be carcinogenic by a genotoxic mechanism. Further no pre-carcinogenic lesions were observed in histopathology of either of the two subchronic studies using an olive material with a high hydroxytyrosol content (*i.e*., H35 or purified HT).

Moreover, we are not aware of any regulatory carcinogenicity studies in rodents that have been performed with olive oil, olive polyphenols or hydroxytyrosol.

6.3.5.2 Chemopreventive efficacy studies with olive oil, olive polyphenols or hydroxytyrosol

There are certain rodent efficacy studies that show potential benefit of olive oil in the diet, including inhibition of colon cancer (Bartoli *et al.,* 2000).

In this study, dietary olive oil prevented the development of aberrant crypt foci and colon carcinomas in rats, suggesting that olive oil may have chemo-preventive activity against colon carcinogenesis. The authors considered these effects may be partly due to modulation of arachidonic acid metabolism and local PGE2 synthesis.

There are also several studies with polyphenols that have shown a protective effect against cancer. Therefore, the polyphenol content in olive extracts could also have a role.

Potentially related to its antioxidant activity, hydroxytyrosol has also been suggested as an anticarcinogenic compound, potentially as a function of its interaction with pathways that relate to the repair of oxidative DNA damage. Hydroxytyrosol may modulate cancer-related pathways by several mechanisms, which may not be consistent within and between model systems, and this is reflected by the suggestion of Bernini (Bernini *et al.,* 2013) that hydroxytyrosol interactions with cancer pathways are likely divided into direct and indirect mechanisms of action, and may overlap with modulation of inflammatory pathways.

It is not the intent of this safety evaluation to review the efficacy studies in rodents, or *in vitro*, as the emphasis is on regulatory safety studies.

6.3.6 Reproduction Toxicity

Table 6-15: Summary table of reproduction toxicity studies

Reference	Study type	Route	Duration	Animal Nos. and sex Doses (mg/kg bw/day)	GLP	Results NOAEL in terms of hydroxytyrosol
Other studies with other olive extracts (HIDROX or Hydroxytyrosol 15% SD)						
Edwards *et al.*, 2010c	Rat developmental toxicity	Gavage	Day 6 through 20 of gestation	0, 333, 1000 and 3000, Hydroxytyrosol 15% SD 0, 56, 168 and 504, HT	yes	168 mg/kg bw/day (intermediate dosage)
Christian *et al.*, 2004	Rat developmental toxicity	Gavage	Day 6 through 20 of gestation	0, 1000, 1500 and 2000, HIDROX 0, 24, 36 and 48, HT	yes	≥48 mg/kg bw/day
Christian *et al.*, 2004	Rat preliminary fertility	Gavage	During mating and lactation	500 to 2000, HIDROX 12 to 48, HT	n.i.	≥48 mg/kg bw/day

n.i. not indicated

6.3.6.1 Developmental Toxicity / Teratogenicity with Hydroxytyrosol 15% SD

Table 6-16: Embryo toxicity study in the rat with Hydroxytyrosol 15% SD

DSM / External + Ref.	Edwards *et al.*, 2010c.
Type	Embryo toxicity study in the rat with Hydroxytyrosol 15% SD
Guideline + deviations	OECD 414
GLP	Yes
Test substance / Batch	Hydroxytyrosol 15% SD / Batch B.2009.S1-04, containing 16.8% hydroxytyrosol
Species / sex	Rat / female
Strain	Wistar, Crl: WI (Han)
Route of administration	orally (gavage)
Period of administration	During organogenesis; days 6 to 19 of gestation inclusive
Frequency of administration	Daily
Doses	0, 333, 1000 and 3000 mg/kg bw/day in terms of formulation (Hydroxytyrosol 15% SD) 0, 56, 168 and 504 mg/kg bw/day in terms of hydroxytyrosol 25 time-mated female rats/group
Control group	Yes
Remark	None
Date	7 May 2010
Result	
NOAEL maternal	168 mg/kg bw/day in terms of hydroxytyrosol
NOAEL developmental	168 mg/kg bw/day in terms of hydroxytyrosol There was no indication of teratogenic hazard at any dosage.

A guideline toxicology study with olive extract from a different olive source

Materials and Methods

Hydroxytyrosol 15% SD was administered orally (gavage) to Wistar rats during the period of embryonic organogenesis, with dosing from days 6 to 19 of gestation inclusive (Edwards *et al.*, 2010c). The dosages 0, 333, 1000 and 3000 mg/kg bw/day, equivalent to doses of 0, 56, 168 and 504 mg/kg bw/day, respectively, in terms of hydroxytyrosol. The study was performed following OECD Guideline 414 and GLP.

The females underwent a caesarean examination on day 20 of gestation and litter parameters were recorded. At necropsy, the females were examined macroscopically and all fetuses were weighed, sexed and examined for external abnormalities. Half of the fetuses were examined internally prior to processing for skeletal examination. The remaining fetuses were preserved for fixed-visceral examination by the modified Wilson-Barrow technique.

Blood samples for proof of exposure were taken from five animals per group on days 6 and 19 of gestation.

Results

Treatment of female Wistar rats with Hydroxytyrosol 15% SD at doses of 333, 1000 and 3000 mg/kg bw/day was associated with immediate post-dose hypersalivation in all groups.

There was a slightly lower mean maternal and fetal bodyweight at the high dose of 3000 mg/kg bw/day, but not at 1000 mg/kg bw/day (168 mg/kg bw/day in terms of hydroxytyrosol). There were no external fetal malformations in any group. Examination of the fetuses for internal visceral or skeletal changes showed no indication of an adverse treatment-related effect. There was no effect on survival of the fetuses and no indication of a teratogenic hazard. The effect on fetal weight at 3000 mg/kg bw/day (504 mg/kg bw/day in terms of hydroxytyrosol) was slight. The effect was only a 5.6% reduction from the control.

Plasma analysis showed animals from all treated groups were exposed to hydroxytyrosol. Free (unconjugated) and total (unconjugated plus conjugated) hydroxytyrosol plasma concentrations increased with dose but in a non-linear fashion.

Conclusion

The NOAEL was defined as the intermediate dosage of 1000 mg/kg bw/day (168 mg/kg bw/day in terms of hydroxytyrosol). Although a 5.6% reduction in adult body weight in isolation would not generally be regarded as adverse, a reduction in fetal weight of the same magnitude needs to be interpreted more cautiously. So, the NOAEL for this developmental toxicity study was conservatively estimated at 168 mg hydroxytyrosol/kg bw/day. There was no effect on survival of the fetuses and no indication of a teratogenic hazard, and possibly the slight reduction in fetal body weight was secondary to the observed maternal effect on body weight.

A dosage of 250 mg HT/kg bw/day (corresponding to the NOAEL in the H35 subchronic study) was not used, so the absence of an effect of fetal body weight at this dosage cannot be categorically confirmed. However, it is most likely the case that no effect would occur, as the effect on fetal body weight at the high dosage of 504 mg HT/kg bw/day was so minor.

6.3.6.2 Published Developmental Toxicity / Teratogenicity with HIDROX

Table 6-17: Embryo toxicity study in the rat with HIDROX

DSM / External + Ref.	External (Christian *et al.,* 2004)
Type	Embryo toxicity study in the rat with HIDROX
Guideline + deviations	OECD 414
GLP	Yes
Test substance / Batch	HIDROX® (hydrolysed aqueous olive pulp extract containing 2.4% hydroxytyrosol) / Mixture of 12 production lots, batch number/s not stated
Species / sex	Rat / female
Strain	Sprague Dawley Crl:CD(SD)IGS BR VAF/Plus
Route of administration	orally (gavage)
Period of administration	During organogenesis; days 6 to 20 of gestation inclusive
Frequency of administration	Daily
Doses	0, 1000, 1500 or 2000 mg/kg bw/day HIDROX, 0, 24, 36 and 48 mg/kg bw/day in terms of hydroxytyrosol
Control group	Yes
Remark	Design included satellite animals for toxicokinetic evaluation
Date	2004, year of publication
Result	
NOAEL maternal	≥ 2000 mg/kg bw/day, ≥ 48 mg/kg bw/day in terms of hydroxytyrosol
NOAEL developmental	≥ 2000 mg/kg bw/day, ≥ 48 mg/kg bw/day in terms of hydroxytyrosol There was no indication of teratogenic hazard

A toxicology study with olive pulp extract

Materials and Methods

HIDROX was administered orally (gavage) to Wistar rats during the period of embryonic organogenesis, with dosing from days 6 to 20 of gestation inclusive (Christian *et al.,* 2004). The dosages 0, 1000, 1500 or 2000 mg/kg bw/day, equivalent to doses of 0, 24, 36 and 48 mg/kg bw/day, respectively, in terms of hydroxytyrosol. The study was performed following OECD guideline 414 and GLP.

The females were submitted to a caesarean examination on day 21 of gestation and litter parameters were recorded. At necropsy, the females were examined macroscopically and all fetuses were weighed, sexed and examined for external abnormalities. Half of the fetuses were examined internally prior to processing for skeletal examination. The remaining fetuses were preserved for fixed-visceral examination by the modified Wilson-Barrow technique.

Blood samples for toxicokinetic evaluation were taken from six satellite animals per group on days 6 and 20 of gestation.

Results

Adverse effects were absent in this rat developmental toxicity study in which pregnant dams were treated with 1000, 1500 or 2000 mg/kg/day olive pulp extract equivalent to doses of 0, 24, 36 and 48 mg/kg bw/day, respectively, in terms of hydroxytyrosol, on days 6 through 20 of gestation. Plasma levels of hydroxytyrosol for pregnant and lactating rats were comparable to non-pregnant rats. Minimal levels of hydroxytyrosol crossed the placenta and were detected in the fetal plasma (detected but were below the stated quantitation limit of 2.50 ng/mL). Also, quantifiable levels were not identified in maternal milk or plasma from nursing pups.

6.3.6.4 Dosage-range reproduction study with HIDROX

Dosages of HIDROX ranging from 500 to 2000 mg/kg bw/day (did not adversely affect any of the mating, fertility, delivery or litter parameters investigated in an oral rat dosage-range reproduction study (Christian *et al.,* 2004). Quantifiable levels of hydroxytyrosol were not identified in maternal milk or plasma from nursing pups.

6.4 Human Safety Data

The purpose of this section is to clarify from human studies if there is any indication of adverse effects arising from intake of olive extracts, olive polyphenols and hydroxytyrosol.

Consumption of olive oil in the southern European countries is on average about 70 g/day and could be as high as 200 g/day for high level consumers. Combining these consumption data with hydroxytyrosol content results in estimates of average intakes of hydroxytyrosol in some Mediterranean countries of 12 mg/day, with the potential for high level intakes to exceed 30 mg/day (Tennant, 2013). Thus, the average combined hydroxytyrosol intake in some Mediterranean countries for a 60 kg adult is 0.2 mg/kg bw/day (12 mg/day) and for a high level consumer 0.5 mg/kg bw/day (30 mg/day).

The European Food Safety Authority has released a health claim concerning the effectiveness of the ingestion of olive oil polyphenols (5 mg/day) on protecting LDL from oxidation (EFSA Panel on Dietetic Products, 2011).

6.4.1 Human data

Hydroxytyrosol is a non-novel dietary component with a known human average dietary intake and range of intake. The estimated intakes can be up to 30 mg hydroxytyrosol/day in high consumers of olives. So, this provides known dosage information for safe human use. It is not expected to be feasible to achieve such high dosages of olive polyphenols over 30 mg/day in terms of hydroxytyrosol from consumption of olive oil and olives. Higher dosages of olive polyphenols have been studied with olive extracts.

A 6-week clinical study in men has been undertaken with olive extract Hydroxytyrosol 15% SD at dosages of 50 and 150 mg/day in terms of hydroxytyrosol with 20 subjects per group. There were no serious adverse events and it was concluded the study showed no safety concern. Therefore, existing human data for olive extracts support an ADI of 150 mg/day, in terms of hydroxytyrosol, as derived from the 90 day rat study with H35.

6.4.2 Olive oil and polyphenol content

Olive oil is about 75% monounsaturated fatty acids (MUFA), mainly oleic acid. Olive oils, particularly virgin olive oil, contain bioactive polyphenols as minor components. There are various clinical studies that have been using olive oil with a high polyphenol concentration.

The US Food and Drug Administration approved a health claim of olive oil consumption (23 g/d) on the basis of the MUFA content of the olive oil (FDA, 2004).

In a randomized, crossover, controlled trial (Castaner *et al.,* 2012) with 18 healthy European volunteers who daily received 25 mL olive oil with a low polyphenol content (LPC) of 2.7 mg/L or a high polyphenol content (HPC) of 366 mg/L in intervention periods of 3 weeks separated by 2-week washout periods. The HPC group was associated with increased tyrosol and hydroxytyrosol in urine and showed beneficial biomarker changes. The polyphenol intake from HPC was 366 mg/L x 25 ml/d = 9.15 mg/d for a 60 kg person. Participants' compliance was reported as good with no mention of side effects. However, the polyphenol intake was still moderate.

It is not feasible to achieve high dosages of olive polyphenols (above high consumer intake of 30 mg/day in terms of hydroxytyrosol) from consumption of olive oil and olives.

6.4.3 Olive extracts

No controlled, GCP clinical study has so far been carried out with the extract from the H40 process. However, there are relevant clinical studies that have been performed with HIDROX and, at higher dosages in terms of hydroxytyrosol, with an olive extract 15% hydroxytyrosol formulation (Hydroxytyrosol 15% SD).

6.4.3.1 H40 extract

To date, no controlled, GCP clinical study has been carried out with the extract from the H40 process.

6.4.3.2 Low hydroxytyrosol extract, HIDROX

A human study was performed with HIDROX (Saunders and Stern, 2009) at 400 mg/day and 800 mg/day, or approximately 8 and 16 mg/day in terms of doses of hydroxytyrosol (total dose split between a.m. and p.m.), over 2 weeks. It showed that supplementation with hydroxytyrosol

resulted in a significant increase in plasma total antioxidant capacity, and there was an up regulation of the glutathione defense system in skeletal muscle following strenuous exercise. No adverse effects or side effects attributable to HIDROX were seen.

A placebo-controlled clinical study with olive water fraction (HIDROX) (Bitler *et al.*, 2007) was performed in patients suffering from rheumatoid arthritis. Patients received 400 mg olive water fraction. The olive water fraction was freeze-dried, yielding a golden brown crystalline product containing at least 6% simple phenols and polyphenols. Dose in terms of hydroxytyrosol was not defined. The supplement significantly reduced levels of C-reactive protein after eight weeks. C-reactive protein is an important biochemical marker of inflammation and it has been previously associated with rheumatoid arthritis and cardiovascular disease and mortality. The same study also demonstrated that the supplement significantly reduced levels of homocysteine after eight weeks. Homocysteine is also an important biochemical marker of inflammation and a number of large clinical studies have established homocysteine as an independent risk factor for venous thromboembolism, stroke, coronary heart disease, and death. All subjects underwent kidney and liver function tests at baseline (before starting trial) and after 8 weeks on placebo or supplement. These tests included serum blood urea nitrogen and creatinine for kidney function, and aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, and total bilirubin for liver function. No adverse changes were reported.

6.4.3.3 Hydroxytyrosol 15% SD

A placebo-controlled, double blind, parallel, cross-over clinical study have been taken with a 15% hydroxytyrosol olive formulation (Hydroxytyrosol 15% SD). The 6-week clinical study (Hospers, 2013) used dosages of 50 and 150 mg/day in terms of hydroxytyrosol given orally to 19 to 22 young men per group.

There were no serious adverse events. There were 4 adverse events (out of 43 across all groups) ascribed by the physician to the treatment:

- Platelet cell decrease in one subject at high dose (already low at baseline)
- Tightness in chest in one subject at both high dose and low dose
- Mood swings in one subject at low dose.
- Two further adverse events were a persistent cough possibly linked to a respiratory infection

It is concluded the study showed no safety concerns for hydroxytyrosol at a dosage of 150 mg/ day orally to young men over 6 weeks. Therefore, this study supports an ADI of 150 mg/day, in terms of hydroxytyrosol, as derived from the 90-day rat safety study with H35.

6.4.4 Pure hydroxytyrosol

Acute supplementation during a short-term intervention study with 200 mg hydroxytyrosol/day (pure extract provided by DSM Delft) prior to exercise in 7 healthy volunteers, on two consecutive days, attenuated the rise in circulating plasma lactate levels during exercise. Slight evidence of a positive influence on sport endurance was observed (Rietjens, 2009). No serious adverse effects were reported.

A pure hydroxytyrosol preparation was GRAS notified to FDA (GRN 600) for use as a as an antioxidant in beverages, fats and oils, fresh and processed fruits and vegetables, fresh and processed fruit and vegetable juices, and gravies and sauces at a level of 5 milligrams (mg) per serving. FDA had no questions at the time of submission.

6.5 Safety Summary and Acceptable Daily Intake (ADI)

It has been concluded based on an overall genotoxicity evaluation that for olive extracts in general, and for the specific olive extract from the process used to make H40, and the main olive polyphenol (hydroxytyrosol) that any genotoxic risks for human consumers are negligible (Kirkland *et al.,* 2015), which is usually regarded as the lowest level of risk.

Application of a 100-fold factor to the NOAEL (250 mg/kg bw/day in terms of hydroxytyrosol content) from the sub-chronic study with olive extract H35 gives an ADI of 150 mg/day in terms of hydroxytyrosol. This study design, although including estrous cycle assessment and sperm analysis, does not include safety for the fetus in the event of consumption during pregnancy.

Among the supporting animal studies achieving high intakes of hydroxytyrosol, an embryo-fetal (developmental) toxicity study in the rat with Hydroxytyrosol 15% SD (Edwards *et al.,* 2010c) was performed and provided a NOAEL of 168 mg/kg bw/day when expressed in terms of hydroxytyrosol. Applying a 100-fold factor to this NOAEL gives an intake up to 100 mg/day in terms of hydroxytyrosol for a 60 kg adult.

At the high dose level of 504 mg HT/kg bw/day in the embryo-fetal toxicity study there was no evidence of obvious fetotoxicity or maternal toxicity. There was, however, a slight reduction in fetal weight (5.6% reduction from the control). A dosage of 250 mg HT/kg bw/day (corresponding to the NOAEL in the H35 subchronic study) was not used, so the absence of an effect of fetal body weight at this dosage cannot be categorically confirmed. However, it is most likely the case that no effect would occur, as the effect on fetal body weight at the high dosage of 504 mg HT/kg bw/day was so minor. Therefore, the results of the available developmental toxicity with high HT dosages do not conflict with the NOAEL defined for the 90-day study with H35. Nevertheless, the company proposes to self-restrict supplementation only up to the intake level of 100 mg/day.

Specific safety information relevant to infants has not been located to enable a specific ADI for infants to be defined. Hydroxytyrosol is a normal dietary component and no particular concern for infants is expected.

Existing human data for olive extracts supports the safety of the ADI of 150 mg/day, in terms of hydroxytyrosol, as derived from the 90-day rat study.

7.0 LIST OF SUPPORTING DATA AND INFORMATION

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APPENDIX 1: Expert Panel Opinion Statement

Expert Panel Consensus Statement on the Generally Recognized as Safe (GRAS) Determination of elaVida™(a Polyphenol Preparation from Olive Fruits) for Use as an Ingredient in Selected Foods

February 4, 2016

At the request of DSM Nutritional Products, (DSM), a panel (the "Expert Panel") of independent scientists, qualified by scientific training and relevant national and international experience to evaluate the safety of food ingredients, was specially convened to conduct a critical and comprehensive evaluation of the available pertinent data and information, and determine whether, under the conditions of intended use as an ingredient (antioxidant[2] and antimicrobial agent[3]-21CFR§ 170.3(o)(3)) in certain selected foods for human consumption, elaVida™(a polyphenol preparation from olive fruits) is safe and "generally recognized as safe" (GRAS) based on scientific procedures. For purposes of this evaluation, "safe" or "safety" as it relates to GRAS within the terms of the Federal Food, Drug, and Cosmetic Act means that there is a reasonable certainty of no harm under the intended conditions of use of the ingredient in foods, as stated in 21 CFR §170.3(i) (U.S. FDA, 2012a). The Expert Panel consisted of the following individuals: Dr. Joseph F. Borzelleca, Ph.D. (Professor Emeritus, Virginia Commonwealth University School of Medicine), Dr. John A. Thomas, Ph.D., F.A.T.S (Professor, Indiana University College of Medicine) and Dr. Stanley M. Tarka Jr. (The Pennsylvania State University College of Medicine, Tarka Group, Inc. and Panel Chair).

The manufacturing process of elaVida™ 40% involves a proprietary solvent-free simple aqueous extraction of the polyphenolic compounds with the primary polyphenol being hydroxytyrosol (HT) from olive fruit pomace. Alternately, the vegetation water co-produced during olive oil production in the absence of organic solvents may be used as source material. The olive fruit extraction process used to produce elaVida™ 40% is precisely defined and is performed under cGMP. There are two variations in the initial steps of the manufacturing process. elaVida™ 40% can be derived either from extraction from the olive pomace or from the vegetation water obtained from the olives, as defined within the manufacturing process documentation. An evaluation of potential by-products in elaVida™ 40% has also been made and no potentially toxic by-products were identified. The preparation of elaVida™ 40% involves

[2] Antioxidants: Substances used to preserve food by retarding deterioration, rancidity, or discoloration due to oxidation.
[3] Antimicrobial agents: Substances used to preserve food by preventing growth of microorganisms and subsequent spoilage, including fungistats, mold and rope inhibitors, and the effects listed by the National Academy of Sciences/National Research Council under "preservatives"

addition of an inert matrix, maltodextrin. Different grades of extract from the process used to produce elaVida™ 40%, based upon HT content, are possible. These vary by the hydroxytyrosol / water ratio. elaVida™ 40% is the extract nominally containing 40% hydroxytyrosol. elaVida™ 35% is an extract from the same process that was used for safety tests described in the dossier. elaVida™ 35% contains approximately 35% hydroxytyrosol, due to a shorter time period for the final water evaporation step.

The Expert Panel, independently and collectively, critically evaluated a dossier provided by DSM **["Summary of Information Supporting the Generally Recognized As Safe (GRAS) Status of elaVida™(a polyphenol preparation from olive fruits)for Use as an Ingredient in Selected Foods" and dated February 3, 2016]**, which included a summary of all available scientific data and information, both favorable and unfavorable, relevant to the safety of the intended food use of DSM's polyphenol extract preparation (elaVida™). This information also included details of the natural occurrence of hydroxytyrosol in olives, information pertaining to the manufacture and characterization of the polyphenol extract preparation, supporting analytical data on compositional analysis and potential products formed from heat in the manufacturing process, stability, intended conditions of use, and estimated exposure under the intended uses. In addition, the Expert Panel evaluated other detailed information from safety studies including Absorption, Distribution, Metabolism and Excretion (ADME) of polyphenols with a focus on hydroxytyrosol, the main polyphenol in DSM's polyphenol extract preparation (elaVida™), plus toxicological studies with olive extracts and hydroxytyrosol including acute, repeat dose, pivotal subchronic toxicity studies, reproductive toxicity, genotoxicity/mutagenicity, specific studies on elaVida™(elaVida™ 35 % and 40%), human safety data and other information deemed appropriate or necessary.

Following its independent critical evaluation, the Expert Panel unanimously concluded that the use of DSM's polyphenol extract preparation, elaVida™40%, meeting appropriate food-grade specifications and manufactured consistent with cGMP, is GRAS based on scientific procedures for use in specified foods. A summary of the basis for the Expert Panel's conclusion is provided below.

Summary and Basis for GRAS Determination

elaVida™ 40% is a polyphenol preparation made from olive fruits using a proprietary, solvent-free process. elaVida™ 40% has a standardized minimum content of 40% of hydroxytyrosol (typical range 41 to 47%), the main olive phenol and antioxidant. Chemical classification and identifying names of hydroxytyrosol include: hydroxytyrosol, CAS number: 10597-60-1; IUPAC name: 4-(2-hydroxyethyl)-1,2-benzenediol; other names include: 3-hydroxytyrosol 3,4-dihydroxyphenylethanol (DOPET). 4-hydroxytyrosol (HT) is the major phenolic component of olives and originates from the hydrolysis of another olive component, oleuropein, during the maturation of olives, during the storage of olive oils, and during the preparation of olives for

consumption (Granados-Principal *et al.,* 2010). The oleuropein component loses glucose to form the aglycone, which then converts to hydroxytyrosol and elenolic acid.

Hydroxytyrosol is commonly consumed in the diet as a component of table olives, olive oil, and red wine and, has a long history of safe use. The European Foods Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies (NDA) has also issued a scientific opinion on health claims in relation to dietary consumption of hydroxytyrosol and related polyphenol compounds from olive fruit and oil and protection of blood lipids from oxidative damage which is known to adversely affect cardiovascular health (EFSA Journal, 2011). EFSA in their assessment considered the polyphenol preparation from olives that is the subject of this health claim a "food constituent" and therefore did not do a safety assessment. EFSA noted that the food constituent that is the subject of the health claims is polyphenols (e.g. Hydroxytyrosol and oleuropein complex) in olive (olive fruit, olive mill waste waters or olive oil, *Olea europaea* L. extract and leaf). The conditions of use specifiy 200 mg/day of polyphenols, 2-15 mg per day of hydroxytyrosol or oleuropein complex, and 250—500 mg of an *Olea europaea* L. extract standardized to 4-23% oleuropein. Based on a review of a well designed and conducted clinical study, EFSA determined that a minimum 5 mg of hydroxytyrosol and its derivatives in olives should be consumed daily to use a cardiovascular health claim.

Hydroxytyrosol from olives is a non-novel dietary component with an estimated average intake in some Mediterranean countries of 12 mg/day and a high intake of up to 30 mg/day. In this assessment, the estimated daily intakes of hydroxytyrosol from existing dietary sources (i.e. olives and olive oil) in mg/day and mg/kg-bw/day were determined for the U.S. population ages 2 years and older and for four subpopulations (children-2-5 y, children-6-10 y, teens-13-18 y, and adults- 19+y). The highest 90th percentile *per user* reported intake of hydroxytyrosol from existing dietary sources was 1.2 mg/day (0.01 mg/kg-bw/day) among adults ages 19 years and older. The existing EDI at 90th percentile *per user* for U.S. population 2 years and older was 1.0 mg/day (0.01 mg/kg-bw/day). Approximately 50% of the U.S. population ages 2+ years reported eating a food containing hydroxytyrosol.

DSM's olive oil extract product, elaVida™ 40%, is proposed for use in bakery products; beverages (non-alcoholic); dairy products and substitutes; desserts; fats and oils; fruit juices and nectars; dry seasoning mixes for meat, poultry and fish; chewing gum; sauces, dips, gravies and condiments; snacks; and vegetable juices to deliver 5 to 10 mg of hydroxytyrosol per serving of food. It is not intended for use in infant formula. The estimated daily intake of hydroxytyrosol from the proposed uses in 11 broad categories of food was determined for the U.S. population ages 2 years and older and in four sub populations (children-2-5 y, children-6-10 y, teens-13-18 y, and adults- 19+y). The highest 90th percentile *per user* EDI of hydroxytyrosol was 54.7 mg/day among teenagers ages 13 to 18 years (0.9 mg/kg-bw/day). The 90th percentile *per user* EDI for U.S. population 2 years and older was 51.9 mg/day (0.9 mg/kg-bw/day).

The cumulative estimated daily intake (CEDI) of hydroxytyrosol from existing dietary sources and DSM's proposed uses of elaVida™ 40% (to deliver 5 to 10 mg/serving of hydroxytyrosol in 11 food categories) was determined for the U.S. population ages 2 years and older and in four subpopulations (children-2-5 y, children-6-10 y, teens-13-18 y, and adults-19+y). The highest 90th percentile *per user* cumulative estimated dietary intake (CEDI) of hydroxytyrosol was 55.1 mg/day among teenagers ages 13 to 18 years (0.9 mg/kg-bw/day). The 90th percentile *per user* CEDI for the U.S. population 2 years and older was 52.4 mg/day (0.9 mg/kg-bw/day). The CEDI is well below the Acceptable Daily Intake (ADI) of mg HT/kg bw.

The safety evaluation of elaVida™ 40% involved the assessment of the pivotal safety studies with extract from the process used to make elaVida™ 40% and data from safety studies with other olive extracts. To fulfil the "common knowledge" element of a Generally Recognized As Safe (GRAS) determination, the studies regarded as pivotal included published genotoxicity studies and a 90-day rat study (Kirkland *et al.,* 2015; Heilman *et al.,* 2015, respectively). Safety data for other olive extracts, including a less concentrated elaVida™ 15%, and studies with pure hydroxytyrosol, are presented in this dossier as supporting information.

Supporting safety information that was critically evaluated for this assessment includes published studies from another olive extract, HIDROX, containing 10% HT, published studies with pure chemically synthesized hydroxytyrosol, and proprietary safety studies conducted by DSM with an olive formulation from a different manufacturing process containing 15% HT.

A weight of evidence analysis of in vitro and in vivo genotoxicity data for olive extracts in general, for the specific olive extract from the process used to make elaVida™ 40%, and the main olive polyphenol (hydroxytyrosol), demonstrates that any genotoxic risks for human consumers are negligible (Kirkland *et al.,* 2015).

Application of a 100-fold safety factor to the NOAEL (250 mg HT/kg bw/day) from the pivotal sub-chronic study with olive extract elaVida™ 35% results in an ADI of 150 mg HT/day (for a 60 kg person).

Among the supporting animal studies achieving high intakes of hydroxytyrosol, an embryo-fetal (developmental) toxicity study in the rat with Hydroxytyrosol 15% SD (Edwards *et al.,* 2010c) was performed and provided a NOAEL of 168 mg/kg bw/day when expressed in terms of hydroxytyrosol. Applying a 100-fold factor to this NOAEL gives an intake up to 100 mg/day in terms of hydroxytyrosol for a 60 kg adult.

DSM proposes to self-restrict upper limit of use up to 100 mg/day. The proposed uses and upper limit of DSM's elaVida™ 40% are similar to other commercial forms of hydroxytyrosol currently marketed.

Hydroxytyrosol is a normal dietary component and may be consumed by infants although specific intake information is not available. There is no reason to suspect safety concerns for infants consuming elaVida™ 40%.

Existing human data for olive extracts supports the safety of 150 mg HT/day. This is the ADI based on the pivotal published rat sub-chronic study.

The proposed uses of DSM's elaVida™ 40% in the specified foods identified in this dossier as an antioxidant or antimicrobial agent at use levels up to 10 mg/serving are considered safe and suitable. The proposed uses are compatible with current regulations, i.e., used as an ingredient (antioxidant[4] and antimicrobial agent[5]-21CFR § 170.3(o)(3)) in bakery products; beverages (non-alcoholic); dairy products and substitutes; desserts; fats and oils; fruit juices and nectars; dry seasoning mixes for meat, poultry and fish; chewing gum; sauces, dips, gravies and condiments; snacks; and vegetable juices to deliver 5 to 10 mg of hydroxytyrosol per serving of food (reference amounts customarily consumed, 21 CFR § 101.12 when not otherwise precluded by a Standard of Identity as described in this monograph and resulting in the 90th percentile all-user cumulative estimated intake from combined dietary sources of 52.4 mg/day (0.9 mg/kg-bw/day).

The proposed uses of DSM's elaVida™ 40% in the specified foods identified in this dossier as an antioxidant or antimicrobial agent at use levels up to 10 mg/serving [and up to 100 mg/day] are Generally Recognized As Safe based on scientific procedures since the pivotal data and information are generally available, satisfying the "common knowledge" element of a GRAS determination.

[4] Antioxidants: Substances used to preserve food by retarding deterioration, rancidity, or discoloration due to oxidation.
[5] Antimicrobial agents: Substances used to preserve food by preventing growth of microorganisms and subsequent spoilage, including fungistats, mold and rope inhibitors, and the effects listed by the National Academy of Sciences/National Research Council under "preservatives"

Conclusion

We, the members of the Expert Panel, have independently and collectively critically evaluated the data and information summarized above, and conclude that that the intended uses as an ingredient in foods and beverages at a level up to 10 mg HT/serving of DSM's elaVida™ 40%, a polyphenol preparation from olive fruits and having a standardized minimum content of 40% HT, produced consistent with current Good Manufacturing Practice (cGMP) and meeting appropriate food-grade specifications as presented in the supporting dossier **("Summary of Information Supporting the Generally Recognized As Safe (GRAS) Status of elaVida™ (a polyphenol preparation from olive fruits) for Use as an Ingredient in Selected Foods)** are safe and suitable.

We, the members of the Expert Panel, further conclude that the intended uses of DSM's elaVida™ 40%, produced consistent with current Good Manufacturing Practice (cGMP) and meeting appropriate food-grade specifications as presented in the supporting dossier are Generally Recognized as Safe (GRAS) based on scientific procedures.

It is our opinion that other qualified experts would concur with these conclusions.

(b) (6)

12 February 2016

Stanley M. Tarka, Jr., Ph.D.
The Pennsylvania State University College of Medicine, Tarka Group, Inc. (Panel Chair)

Date

(b) (6)

11 February 2016

Joseph F. Borzelleca, Ph.D.
Professor Emeritus
Pharmacology & Toxicology
Virginia Commonwealth University School of Medicine
(Panel Member)

Date

(b) (6)

10 Feb 2016

John A. Thomas, Ph.D., F.A.T.S.
Indiana University School of Medicine (Panel Member)

Date

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APPENDIX 2: Certificates of Analysis

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Certificate of Analysis

Ref. / Rev.: 11 / A | Page: 1 of 1

Document code: CoA_QC_VA 11/EV40

Product: elaVida™ 40%
Product code: *6015334*
Lot Number: EV17032201
Manufacturing Date: 22 MAR 2017
Shelf life: 22 MAR 2019

Item	Specification	Results
Appearance	Viscous liquid	Complies
Colour	Yellow to dark brown	Brownish
Identity	Corresponds	Complies
Hydroxytyrosol	Min. 41.6% w/w	48.3 %
Minor phenols	Max. 8 %	4.2 %
Tyrosol	Max. 1:58 w/w of hydroxytyrosol content	1:71.4
Oleuropein	Max. 1:230 w/w of hydroxytyrosol content	N.D. (oleuropein not detected)
Total ash	≤ 3.0 %	1.6 %
pH of an aqueous solution	pH 2.5 to 4.0	3.7
Heavy metals		
- Lead	max. 1.0 ppm	< 0.1 ppm
- Mercury	max. 0.1 ppm	< 0.1 ppm
- Cadmium	max. 0.5 ppm	< 0.1 ppm
- Arsenic	max. 1.0 ppm	< 0.1 ppm
- Heavy metals	max. 10 ppm	< 1.0 ppm
Microbiological purity		
- Total aerobic plate count	below 10^3 CFU / g	Complies
- Total yeasts and moulds count	below 10^2 CFU / g	Complies
- Enterobacteria	below 10 CFU / g	Complies
- *Pseudomonas aeruginosa*	negative in 10 g	Complies
- *Staphylococcus aureus*	negative in 10 g	Complies
- *Escherichia coli*	negative in 10 g	Complies
- Salmonella species	negative in 25 g	Complies
- Clostridia	negative in 1 g	Complies

Date of analysis: 25 APR 2017

(b) (6)

Quality control Department

Date of release: 25 APR 2017

(b) (6)

Quality Assurance Department

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probeltebio	Certificate of Analysis	Ref. / Rev.: 11 / A	Page: 1 of 1
		Document code: CoA_QC_VA 11/EV40	

Product: elaVida® 40%
Product code: *6016334*
Lot Number: EV17032202
Manufacturing Date: 22 MAR 2017
Shelf life: 22 MAR 2019

Item	Specification	Results
Appearance	Viscous liquid	Complies
Colour	Yellow to dark brown	Brownish
Identity	Corresponds	Complies
Hydroxytyrosol	Min. 41.5% w/w	42.5 %
Minor phenols	Max. 6 %	3.8 %
Tyrosol	Max. 1:58 w/w of hydroxytyrosol content	1:91.1
Oleuropein	Max. 1:230 w/w of hydroxytyrosol content	N.D. (oleuropein not detected)
Total ash	≤ 3.0 %	2.7 %
pH of an aqueous solution	pH 2,5 to 4,0	3,6
Heavy metals		
- Lead	max. 1.0 ppm	< 0.1 ppm
- Mercury	max. 0.1 ppm	< 0.1 ppm
- Cadmium	max. 0.5 ppm	< 0.1 ppm
- Arsenic	max. 1.0 ppm	< 0.1 ppm
- Heavy metals	max. 10 ppm	< 1.0 ppm
Microbiological purity		
- Total aerobic plate count	below 10^3 CFU / g	Complies
- Total yeasts and moulds count	below 10^2 CFU / g	Complies
- Enterobacteria	below 10 CFU / g	Complies
- *Pseudomonas aeruginosa*	negative in 10 g	Complies
- *Staphylococcus aureus*	negative in 10 g	Complies
- *Escherichia coli*	negative in 10 g	Complies
- Salmonella species	negative in 25 g	Complies
- Clostridia	negative in 1 g	Complies

Date of analysis: 25 APR 2017

(b) (6)

Quality control Department

Date of release: 26 APR 2017

(b) (6)

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DSM

probeltebio

Certificate of Analysis

Ref. / Rev.:	Page
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Document code:	
CoA_QC_VA 11/EV40	

Product: oleVida™ 40%
Product code: *5016334*
Lot Number: EV17032203
Manufacturing Date: 22 MAR 2017
Shelf life: 22 MAR 2019

Item	Specification	Results
Appearance	Viscous liquid	Complies
Colour	Yellow to dark brown	Brownish
Identity	Corresponds	Complies
Hydroxytyrosol	Min. 41.5% w/w	45.2 %
Minor phenols	Max. 6 %	4.9 %
Tyrosol	Max. 1:56 w/w of hydroxytyrosol content	1:107.5
Oleuropein	Max. 1:230 w/w of hydroxytyrosol content	N.D. (oleuropein not detected)
Total ash	≤ 3.0 %	2.2 %
pH of an aqueous solution	pH 2,6 to 4,0	3,8
Heavy metals		
- Lead	max. 1.0 ppm	< 0.1 ppm
- Mercury	max. 0.1 ppm	< 0.1 ppm
- Cadmium	max. 0.5 ppm	< 0.1 ppm
- Arsenic	max. 1.0 ppm	< 0.1 ppm
- Heavy metals	max. 10 ppm	< 1.0 ppm
Microbiological purity		
- Total aerobic plate count	below 10^3 CFU / g	Complies
- Total yeasts and moulds count	below 10^2 CFU / g	Complies
- Enterobacteria	below 10 CFU / g	Complies
- *Pseudomonas aeruginosa*	negative in 10 g	Complies
- *Staphylococcus aureus*	negative in 10 g	Complies
- *Escherichia coli*	negative in 10 g	Complies
- Salmonella species	negative in 25 g	Complies
- Clostridia	negative in 1 g	Complies

Date of analysis: 25 APR 2017

(b) (6)

Quality control Department

Date of release: 25 APR 2017

(b) (6)

Quality Assurance Department

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APPENDIX 3: Minor phenolic compounds in elaVida™

Memo

Date
July 25, 2017

From
Richard Gössl

To
Cedric Martin

cc
Katja Studer
Todd Katz
Georges Bergen
James Edwards

Minor phenolic compounds in Elavida

Summary

For the purpose of specification setting three batches of Elavida 40% were analyzed for phenolic constituents by means of UHPLC-DAD-QTOF-MS analysis. The batches were manufactured in 2017 by company Probelte. The content of Hydroxytyrosol as measured by the QC release of the manufacturer was 42.5 %, 45,2% and 48.3% in. The content of minor phenolic compounds as quantified by UHPLC-DAD-QTOF-MS was found to be 3.9 %, 4.9 % and 4.2 % in these three batches.

Results

Table 1 below is summarizing the analytical results. The individual chromatogram reports, the recorded UV spectra and QTOF-MS data are attached in Appendix 1-3. Figure 1 is depicting the chromatograms of the analyzed Elavida 40% batches.

Table 1 Results from UHPLC-DAD-QTOF-MS analysis of three Elavida batches

RRT*	m/z**	λ_{max} [nm]	Formula	Assignment	Concentration [%] EV17032201	EV17032202	EV17032203
0.86	305.103	283	$C_{16}H_{18}O_6$	Dimeric phenylethanoid	0.54	0.30	0.30
1.00	153.056	280	$C_8H_{10}O_3$	3,4-DHPEA (Hydroxytyrosol, HT)	48.3	42.5	45.2
1.26	137.061	276	$C_8H_{10}O_2$	4-HPEA (Tyrosol)	0.31	0.22	0.20
1.82	337.129	282	$C_{17}H_{22}O_7$	Hydrated form of 3,4-DHPEA-EDA	0.37	0.39	0.46
2.16	337.129	280	$C_{17}H_{22}O_7$	Hydrated form of 3,4-DHPEA-EDA	0.32	0.31	0.36
2.45	349.129	281	$C_{18}H_{22}O_7$	Other Phenol	0.60	0.47	0.45
2.24	321.134	282	$C_{17}H_{22}O_6$	Other phenol	0.28	0.12	0.10
2.28	279.124	281	$C_{15}H_{20}O_5$	Other phenol	0.30	0.54	0.76
2.55	319.118	281	$C_{17}H_{20}O_6$	3,4-DHPEA-EDA	1.20	1.30	1.92

3.15	473.181	281	$C_{25}H_{30}O_9$	Other phenol	0.26	0.26	0.40
				Sum of phenols [%]	52.5	46.4	50.1
				Non-HT phenols (minor phenolic compounds) [%]	4.2	3.9	4.9

* Relative retention time (retention time of phenolic compound divided by retention time of HT)

** Mass-to-charge ratio of detected pseudomolecular ions $[M-H]^-$

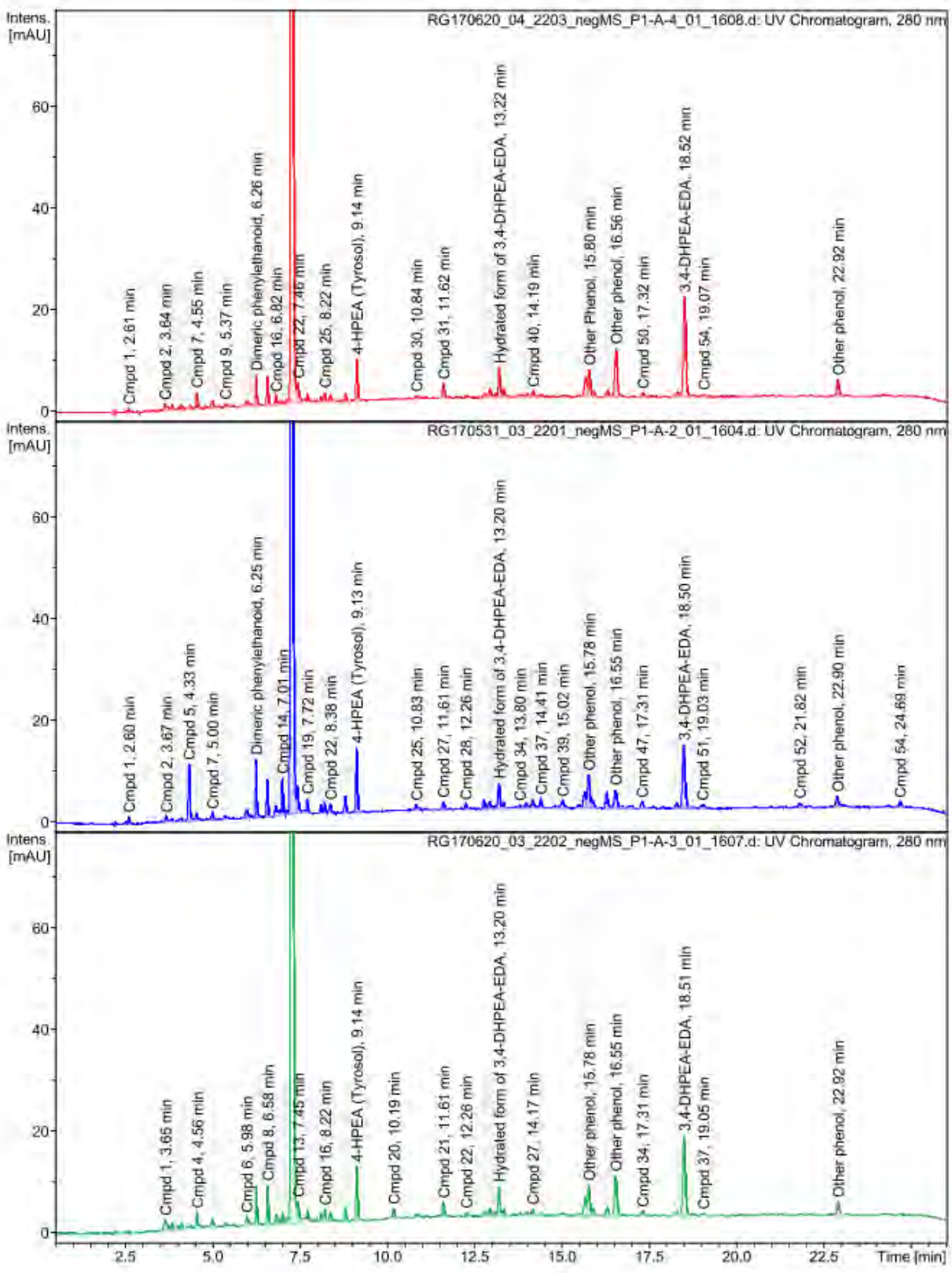

Figure 1 UHPLC-UV chromatograms of the analyzed Elavida 40% batches. Top: Batch EV17032203, middle: batch EV17032201, bottom: batch EV17032202

Discussion

Nine phenolic by-products compounds have been identified in the three Elavida 40 % batches. Their proportion in total and the hydroxytyrosol content was found to be 3.9 % (46.4 % HT), 4.2 % (52.5 % HT) and 4.9% (50.1% HT). By far the most prominent phenolic by-product, with proportions of 1.3 %, 1.2 % and 1.92 % was 3,4-DHPEA-EDA (also known as oleacin or decarboxymethyl oleuropein aglycon) which is a known antioxidant of olives (Olea europaea) and extra virgin olive oils [2,3]. In an earlier analysis of two Elavida batches from 2013 the proportion of the sum of by-products and the hydroxytyrosol content were found to be slightly lower with values ranging 2.6 % (40.5 % HT) to 3.6% (41.6% HT). All by-products from the 2017 batches have been identified and characterized already in earlier batches of Elavida with the exception of a dimeric phenylethanoid eluting at a relative retention time of 0.86. The occurrence of different by-products as well as the variation in concentrations is likely due to seasonal, climatical and local variations in the olives used for processing of the staring material.

Materials and methods

Samples. The samples analyzed are listed in table 2 below. They were produced in 2017 by the company Probelte, Spain. The samples arrived in the lab in sealed aluminum bottles with a net weight of 50g. All samples were stored at room temperature to await analysis.

Table 2 Elavida batches used in this study

Product	Lot number	Manufacturing date	Expiry date
Elavida 40%	EV17032201	22 Mar 2017	22 Mar 2019
Elavida 40%	EV17032202	22 Mar 2017	22 Mar 2019
Elavida 40%	EV17032203	22 Mar 2017	22 Mar 201

Sample preparation. Liquid Elavida 40% samples were accurately weighed by means of a Mettler AX205 analytical balance, dissolved in 0.25% aqueous acetic acid and filled to mark in a 20 ml volumetric flask. The concentrations of the sample solutions were 2031, 2340 and 3090 μg/ml.

UHPLC-ESI-QTOF-MS analysis. The method applied was described in detail in a DSM internal report [1]. The method is based on a research article published by Lozano in 2008 [2]. The column was a Zorbax Eclipse Plus C18 HD (3.0x150 mm, 1.8 um).The injection volume was 2 μl.

Quantitation. Phenolic constituents were quantified by UHPLC-UV using an Agilent 1290 diode array detector. The detection wavelength was 280 nm. The hydroxytyrosol peak was used as standard for internal quantification. The molar absorptivity of phenolic compounds was assumed to be equal with that of hydroxytyrosol. The hydroxytyrosol concentration was measured by a HPLC method via external calibration by company Probelte (QC release method). Concentrations were then computed according the formula:

$$Conc_{(PC)} = \frac{Area_{(PC)}\ x\ Conc_{(HT)}}{Area_{(HT)}}\ x\frac{MW_{(PC)}}{MW_{(HT)}}$$

$Conc_{(PC)}$: Concentration of phenolic compound in % (w/w)
$Area_{(PC)}$: Peak area of phenolic compound measured at 280 nm
$Conc_{(HT)}$: Concentration of hydroxytyrosol as determined by QC release method
$Area_{(HT)}$: Peak area of hydroxytyrosol measured at 280 nm
$MW_{(PC)}$: Molecular weight of phenolic compound
$MW_{(HT)}$: Molecular weight of hydroxytyrosol

References

[1] Gössl R., Baur M. (2015) Characterization and profiling of Elavida formats by UHPLC-UV-QTOF-MS, DSM internal report 00051116

[2] Lozano-Sánchez, J., Segura-Carretero, A., Menendez, J. A., Oliveras-Ferraros, C., Cerretani, L., & Fernández-Gutiérrez, A. (2010). Prediction of extra virgin olive oil varieties through their phenolic profile. Potential cytotoxic activity against human breast cancer cells. Journal of Agricultural and Food Chemistry, 58(18), 9942-9955.

[3] Dictionary of Natural Products 26.1 ©2017 CRC Press, Taylor and Francis

Data retrieval

The analytical raw data are stored on Computer CHKAU66DCZC1134 under the analysis names mentioned on the chromatogram reports. A electronic backup of the raw data is available in the folder LC/MS_13 on the server of the Kaiseraugst technical network. This report, pdf documents of the analytical data and the calculations done for quantitation is stored on lectronic lab notebook NBK019052-001.

APPENDIX 4: Intake Assessment Report

Center for Chemical Regulation and Food Safety

Estimated Daily Intake of Hydroxytyrosol from Existing and Proposed Uses In the U.S. Population Diet

Exponent

Estimated Daily Intake of Hydroxytyrosol from Existing and Proposed Uses in the U.S. Population Diet

Prepared for

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Acronyms and Abbreviations

bw	Body weight
CEDI	Cumulative Estimated Daily Intake
DHHS	U.S. Department of Health and Human Services
DSBI	Dietary Supplement Blend Information
DSD	Dietary Supplement Database
DSII	Dietary Supplement Ingredient Information
DSPI	Dietary Supplement Product Information
EDI	Estimated Daily Intake
EFSA	European Food Safety Authority
FDA	U.S. Food and Drug Administration
FNDDS	Food and Nutrient Database for Dietary Studies
g	Grams
GRAS	Generally Recognized as Safe
GRN	Generally Recognized as Safe Notice
kg	Kilograms
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Survey
U.S.	United States
USDA	U.S. Department of Agriculture
WWEIA	What We Eat In America
y	Years

Executive Summary

Hydroxytyrosol is naturally occurring polyphenol found in olives and processed olive products such as olive oil. DSM Nutritional Products Ltd. (DSM)'s olive oil extract product, elaVida, contains between 15% to 40% hydroxytyrosol, delivers 5 to 10 mg of hydroxytyrosol per serving of food and is proposed for use in 11 broad food categories including the following: bakery products; beverages; dairy products and substitutes; desserts; fats and oils; fruit juices and nectars; dry seasoning mixes for meat, poultry and fish; chewing gum; sauces, dips, gravies and condiments; snacks; and vegetable juices.

At the request of DSM, Exponent conducted an intake assessment to estimate the total daily intake of hydroxytyrosol from both naturally occurring sources in the diet and proposed uses in eleven broad food categories. The Estimated Daily Intake (EDI) of hydroxytyrosol was based upon the levels reported in publicly available literature for naturally occurring sources, levels provided by DSM for the proposed uses and the U.S. Department of Agriculture (USDA)'s food consumption data from the 2007-2010 What We Eat In America (WWEIA) component of the National Health and Examination Survey (NHANES). Estimates were provided for the U.S. population ages 2 years (y) and older and 4 subpopulations including: 1.) children ages 2 to 5 y, 2.) children ages 6 to 12 y, 3.) teenagers ages 13 to 18 y and 4.) adults ages 19 y and older. The data and methods used to conduct the intake assessment and results are summarized in this report.

Proposed Uses

Hydroxytyrosol is naturally occurring polyphenol found in olives and processed olive products such as olive oil. DSM's olive oil extract product, elaVida, containing between 15% to 40% hydroxytyrosol is proposed for use in 11 broad food categories: bakery products; beverages; dairy products and substitutes; desserts; fats and oils; fruit juices and nectars; dry seasoning mixes for meat, poultry and fish; chewing gum; sauces, dips, gravies and condiments; snacks; and vegetable juices to deliver 5 to10 mg of hydroxytyrosol per serving of food. Based on the FDA reference amounts customarily consumed per eating occasion (RACC) outlined in 21 Code of Federal Regulations (CFR) 101.12[1], the elaVida use rates that correspond to the delivery of 5 to 10 mg hydroxytyrosol per serving for each of the 11 food categories, when assuming the maximum concentration of hydroxytyrosol (40%) for DSM's elaVida, are summarized in Table 1.

[1] Exception: for the food category "meat, poultry, and fish coating mixes, dry; seasoning mixes, dry" the RACC for dry seasoning mixes was estimated to be 4.5 g dry spice rub (i.e., 2 teaspoons per serving) based upon publicly available food recipes for mixed dishes containing dry seasonings and rubs from McCormick Spices (http://www.mccormick.com/Grill-Mates/Recipes). This is the lowest value, which would provide a worst case scenario for estimating exposure to a food additive in dry seasonings and rubs.

Table 1. Proposed food uses and use rates of elaVida containing 40% hydroxytyrosol

Food Category	Use Level (mg/serving)		RACC[c] (g/serving)	Use Level elaVida[b] (ppm)
	HT[a]	elaVida[b]		
Bakery Products				
Crackers that are usually used as snacks	5	12.5	30	417
Croutons	5	12.5	7	1786
Grain-based bars with or without filling or coating (e.g., breakfast bars, granola bars, rice cereal bars)	10	25	40	625
Protein based, meal replacement and energy bars	10	25	40	625
Beverages				
Sport drinks, energy drinks, milk-based meal replacements, flavored waters and fruit-flavored drinks	5	12.5	240	52
Dairy Products and Substitutes				
Yogurt	10	25	225	111
Desserts				
Frozen yogurt	10	25	120	208
Fats and Oils				
Butter, margarine, oil and shortening	5	12.5	15	833
Dressing for salads	5	12.5	30	417
Mayonnaise, sandwich spreads, mayonnaise-type dressings	5	12.5	15	833
Fruit and Fruit Juices				
Fruit juices and fruit nectars	5	12.5	240	52
Miscellaneous				
Meat, poultry, and fish coating mixes, dry; seasoning mixes, dry (e.g., chilli seasoning mixes, pasta salad seasoning mixes)[d]	5	12.5	4.5	2778
Chewing gum	10	25	3	8333
Sauces, Dips, Gravies, Condiments				
Major main entree sauces (e.g., spaghetti sauce)	5	12.5	125	100
Minor main entree sauces (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g. gravy, white sauce, cheese sauce), cocktail sauce	5	12.5	60	208
Major condiments: catsup only	5	12.5	15	833
Barbecue sauce, hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa)	5	12.5	30	417
Snacks				
All varieties, chips, pretzels, popcorns, extruded snacks, fruit-based snacks (e.g., fruit chips), grain-based snack mixes	5	12.5	30	417
Vegetable Juices				
Vegetable juice	5	12.5	240	53

[a] Hydroxytyrosol
[b] DSM's elaVida contains 40% hydroxytyrosol
[c]. U.S. FDA reference amounts customarily consumed per eating occasion (RACC) 21CFR101.12.
[d] The estimated RACC for dry seasoning mixes was estimated to be 4.5 g dry spice rub (i.e., 2 teaspoons per serving) based upon publicly available food recipes for mixed dishes containing dry seasonings and rubs from McCormick Spices (http://www.mccormick.com/Grill-Mates/Recipes). This is the lowest value, which would provide a worst case scenario for estimating exposure to a food additive in dry seasonings and rubs.

Available Data and Methods

Consumption Data

The U.S. population's consumption of hydroxytyrosol from existing and proposed uses was based on food consumption records collected in the What We Eat in America (WWEIA) component of the National Health and Nutrition Examination Surveys (NHANES) conducted in 2007-2008 and 2009-2010 (2007-2010). This continuous survey is a complex multistage probability sample designed to be representative of the civilian U.S. population (NCHS 2013a-b). The NHANES datasets provide nationally representative nutrition and health data and prevalence estimates for nutrition and health status measures in the U.S.. To produce reliable statistics, NHANES over-samples adults 60 years of age and older, African Americans and Hispanics. Statistical weights are provided by the National Center for Health Statistics (NCHS) for the surveys to adjust for the differential probabilities of selection. As part of the examination, trained dietary interviewers collect detailed information on all foods and beverages consumed by respondents in the previous 24-hour time period (midnight to midnight). A second dietary recall is administered by telephone 3 to 10 days after the first dietary interview, but not on the same day of the week as the first interview. The dietary component of the survey is conducted as a partnership between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). The DHHS is responsible for the sample design and data collection, and the USDA is responsible for the survey's dietary data collection methodology, maintenance of the databases used to code and process the data, and data review and processing. A total of 16,244 individuals in the survey period 2007-2010 provided 2 complete days of dietary recalls.

Consumption data in the NHANES are reported on an "as consumed basis". That is, if a survey participant consumed an apple pie, the consumption amount reported in the survey for that subject would be for the amount of pie consumed, and not for the ingredients (flour, butter, apples, sugar, etc.) used to make that pie.

In cases where the food of interest is a component of mixed dish, (e.g., oil component in a casserole, mayonnaise component of a sandwich, spaghetti sauce in pasta noodles with sauce, catsup on a hamburger, etc.) Exponent utilized USDA's Food and Nutrient Database for Dietary Studies (FNDDS), version 5.0 (USDA, 2012), that translates the food as consumed into its corresponding ingredients (and gram amounts) or recipes. The list of NHANES food codes (and their description) that was captured in determining the foods with hydroxytyrosol from the proposed uses is provided in Appendix A.

The NHANES and USDA FNDDS recipes database do not include food codes for either the whole food or the portion of foods containing meat, poultry, and fish dry coating mixes, or dry seasoning mix (i.e., dry seasoning mixes). Exponent calculated the portion of mixed dish recipes (mainly meat, poultry and fish) containing dry seasonings and rubs based upon publicly available food recipes from McCormick Spices (http://www.mccormick.com/Grill-Mates/Recipes). These recipes indicated that 1 to 3% of the mixed dish was dry seasoning mix. Based upon this range, Exponent made a conservative assumption that 5% of mixed dishes contain dry seasonings or rubs. The portion of meat based mixed dishes that noted seasoning in the nomenclature (e.g., taco seasoning) including frozen meals were included in the analysis. Most meat and poultry dishes were assumed to contain dry seasoning mixes with the exception of the following categories: baby food, organ meats, hot dogs/sausages, cold cuts, meat spreads, bacon, canned meats (not usually prepared with rub/spices), meat or fish used in soups, and any meats/fish that indicated "no coating" in the food description.

Existing Dietary Sources

Hydroxytyrosol is naturally occurring in olives and processed olive products such as olive oil.

Exponent conducted a literature search to determine the levels of hydroxytyrosol in olives and olive oil. The search included a review of multiple sources including: 1) the U.S. Food and Drug Association (FDA) inventory of Generally Recognized as Safe (GRAS) notices using any of the following key words [hydroxy, tyrosol, 3,4-DHEPA, olive, hydrox, hytolive, polyphenol], 2) pubmed scientific literature search [hydroxy, tyrosol, 3,4-DHEPA, olive, hydrox, hytolive, polyphenol], 3) European Food Safety Authority (EFSA) opinions using the key words [olive, hydroxy, tyrosol, hydroxytyrosol].

The FDA GRAS notice inventory included one GRAS notice related to olive pulp extract (GRN 459); however, at the notifiers request, the FDA ceased to evaluate the notice (FDA, 2013). A review of the cited references in GRN 459 resulted in one article which provided measured hydroxytyrosol levels in olives (Blekas et al., 2002).

The Pubmed search resulted in two articles which provided measured hydroxytyrosol levels in various types of olives and olive oils (Mazzottia et al., 2012; Romero and Brenes, 2012).

The EFSA published scientific opinions on the substantiation of health claims related to polyphenols in olives and various measures of health (EFSA, 2011; EFSA, 2012). One particular claim (Claim ID 1638) related to the antioxidant properties of the food constituents, polyphenols from olive (olive fruit, olive mild waste waters or olive oil), was approved under the following conditions of use: 20 g of an olive oil with a polyphenol content of 200 mg/kg or a minimum of 2 mg/day of hydroxytyrosol. This implies that approximately 100 mg

hydroxytyrosol /kg olive oil would be a reasonable quantity to occur naturally in olives or olive oil. The EFSA data were not used in Exponent's analysis.

Exponent summarized the reported hydroxytyrosol concentration in olives and olive oil from three literature sources and calculated the averages hydroxytyrosol concentration per broad food category (Table 2) (Blekas et al., 2002; Mazzottia et al., 2012; Romero and Brenes, 2012). A listing of the data derived from the three individual sources is summarized in Appendix B.

Table 2. Average hydroxytyrosol concentration of olives and olive oil[a]

Food	Average hydroxytyrosol concentration (mg/kg)
All Olives	**315.1[b]**
Black Olives	312.5
Green Olives	320.6
All Olive Oil	**66.0[b]**
Extra Virgin Olive Oil	74.2
Other Olive Oil	8.5

[a] Blekas et al., 2002; Mazzottia et al., 2012; Romero and Brenes, 2012
[b] Bolded values are the average of the sub-categories

Based on NHANES 2007-2010 in combination with the USDA FNDDS recipes database, the following olive and olive oil ingredients are available and included in the intake assessment:

4053 Oil, olive, salad or cooking
9193 Olives, ripe, canned (small-extra large)
9194 Olives, ripe, canned (jumbo-super colossal)
9195 Olives, pickled, canned or bottled, green

The average concentration of hydroxytyrosol (315.1 ppm for olives, and 66 ppm for olive oil, see Table 2) were used.

Dietary Supplement

The NHANES also contains a Dietary Supplement Database (NHANES-DSD) which includes detailed information on the dietary supplements reported by survey participants since NHANES 1999. The NHANES-DSD consists of three datasets which contain information on products

(i.e., product label database); Dietary Supplement Product Information (DSPI), Dietary Supplement Ingredient Information (DSII), and Dietary Supplement Blend Information (DSBI). These files incorporate all products that have been reported by respondents since 1999. NCHS attempts to obtain a product label for all dietary supplements or antacids reported by NHANES participants from sources such as the manufacturer or retailer, the Internet, company catalogs, and the Physician's Desk Reference. Selected label information is then entered into the product label database including, but not limited to: supplement name; manufacturer and/or distributor; serving size; form of serving size; and ingredients and amounts. The ingredient information entered into the database is taken directly from the supplement facts box on the dietary supplement label or carton.

Starting in 1999, NHANES collected information on respondent's 30-day supplement use during the household interview component. Participants who indicated they reported taking one or more supplements in the past month were asked to show the interviewer the supplement container for all reported products, which was recorded. In cases where a container was not provided, the interviewer asked the participant to record the name of each supplement consumed. For each supplement reported consumed, participants were asked to report how long they had been taking the supplement, how many times they took it in the past 30 days, and how much they typically consumed daily on the days they had taken it.

Exponent searched the database for any dietary supplements containing ingredient "hydroxytyrosol" (10007639 hydroxytyrosol). One dietary supplement in the database was reported to contain hydroxytyrosol as an ingredient; however, there were no reported consumers of this dietary supplement (Natures Plus Herbal Actives Oliceutic-20 standardized olive leaf 250 MG 20-25% oleuropein).

The database was also searched for any dietary supplement containing the ingredient "olive" which resulted in 11 ingredients.

10000275	OLIVE OIL
10000406	OLIVE LEAF EXTRACT
10002604	OLIVOL OLIVE EXTRACT
10005098	HIDROX (OLIVE EXTRACT 6%) (FRUIT)
10005121	NEW CHAPTER BROCCOLIVE PLUS PROPRIETARY BLEND
10005478	POLYPHEN-OIL OLIVE FRUIT EXTRACT
10006167	OLIVE LEAF POWDER (LEAF)
10006478	OLIVE JUICE EXTRACT (FRUIT)
10006581	OLIVE EXTRACT (FRUIT)
10006749	OLIVOL (OLIVE EXTRACT FRUIT)
10007622	BENOLEA OLIVE EXTRACT (LEAF)

A total of 25 dietary supplements contained these 11 ingredients. The total combined estimated usual intake of these ingredients based on 30-day recall data resulted in a total of 25 reported consumers of a total 15,994 respondents, representing 0.2% of the U.S. population, in the NHANES 2007-10.

Due to the limited reported users of olive and hydroxytyrosol containing dietary supplements, this potential exposure from dietary supplements was not included in the analysis.

Analysis

Using the WWEIA consumption data, Exponent estimated the daily intake of foods with existing and proposed uses of hydroxytyrosol on a *per capita* and *per user* basis. In this analysis, a user is anyone who reported consuming any of the existing or proposed foods on either of the survey days (USDA's user definition), as appropriate. We identified each participant who reported consuming the foods of interest on either of the survey days, and we used that individual's responses for both survey days. Zero consumption days are included in calculating that individual's average daily intake. For example, if someone reported consuming 15 grams of olives on day 1 and 0 grams of olives on day 2, the consumer's 2-day average olive consumption would be 7.5 grams ([15+0]/2). The current analysis was limited to individuals who provided two complete and reliable dietary recalls as determined by NCHS. The 2-day average intakes by each individual were estimated using Exponent's Foods and Residues Evaluation Program (FARE® version 10.06) software. Exponent uses the statistically weighted values from the survey in its analyses. The statistical weights compensate for variable probabilities of selection, adjust for non-response, and provide intake estimates that are representative of the U.S. population.

For the existing dietary exposure to hydroxytyrosol from olives and olive oil, the 2-day average intake of hydroxytyrosol was estimated by multiplying the reported intake of foods from the 24-hr recall with the hydroxytyrosol concentration derived from the literature and the cumulative sum over the two 24-hr recalls was divided by two. Estimates were also derived on a bodyweight basis based on each participant's reported bodyweight.

For the proposed uses of DSM's elaVida in foods, the reported intake of foods from the 24-hr recall was multiplied by the proposed use level of DSM's elaVida (containing 40% HT). The EDI of elaVida is then multiplied by 40% to estimate the EDI for HT.

The cumulative estimated daily intake (CEDI) for hydroxytyrosol was calculated by summing at the individual level the EDI from existing dietary sources with the EDI from proposed uses of DSM's elaVida.

Results

Existing Dietary Exposure

The estimated daily intake of hydroxytyrosol from existing dietary sources (i.e. olives and olive oil) in units of mg/day and mg/kg-bw/day are provided in Table 3 for the U.S. population ages 2 years and older and four subpopulations. The highest 90th percentile *per user* reported intake of hydroxytyrosol from existing dietary sources was 1.2 mg/day (0.01 mg/kg-bw/day) among adults ages 19 years and older. The existing EDI at 90th percentile *per user* for U.S. population 2 years and older was 1.0 mg/day (0.01 mg/kg-bw/day). Approximately 50% of the U.S. population ages 2+ years reported eating a food containing hydroxytyrosol.

Table 3. U.S. Population ages 2+ years average daily hydroxytyrosol intake from olives and olive oil (NHANES 2007-2010)

			2 Day Average (mg/day)				2 Day Average (mg/kg-bw/day)			
			Per Capita		Per User		Per Capita		Per User	
Subpopulation	N[a]	%User	Mean	90th	Mean	90th	Mean	90th	Mean	90th
Children 2-5 y	649	47.2%	0.1	0.05	0.2	0.1	0.005	0.003	0.01	0.006
Children 6-12 y	1010	44.0%	0.1	0.1	0.2	0.4	0.003	0.002	0.008	0.009
Teens 13-18 y	685	40.6%	0.1	0.1	0.3	0.5	0.002	0.002	0.005	0.009
Adults 19+ y	5540	54.1%	0.3	0.4	0.6	1.2	0.004	0.005	0.007	0.01
U.S. population 2+ y	7884	51.5%	0.3	0.3	0.5	1.0	0.004	0.004	0.007	0.01

[a] Unweighted number of users; % user, per capita and per user estimates derived using the statistical weights provided by the National Center for Health Statistics (NCHS).

Proposed Uses

The estimated daily intake of elaVida from proposed uses in 11 broad categories of food in units of mg/day and mg/kg-bw/day are provided in Table 4 for the U.S. population ages 2 years and older and four sub populations. The highest 90th percentile *per user* EDI of elaVida was 136.8 mg/day among teenagers ages 13 to 18 years (2.1 mg/kg-bw/day). The 90th percentile *per user* EDI of elaVida for U.S. population 2 years and older was 129.8 mg/day (2.2 mg/kg-bw/day). Nearly everyone 2 years and older in the U.S. population reported eating a food with proposed uses of elaVida.

Table 4. Estimated daily intake of elaVida [containing 40% hydroxytyrosol] from proposed uses in foods[a] (NHANES 2007-2010)

			2 Day Average (mg/day)				2 Day Average (mg/kg-bw/day)			
			Per Capita		Per User		Per Capita		Per User	
Population	N[b]	%User	Mean	90th	Mean	90th	Mean	90th	Mean	90th
Children 2-5 y	1374	99.8%	48.9	82.2	49.0	82.2	2.9	5.0	2.9	5.0
Children 6-12 y	2127	99.9%	60.6	97.8	60.7	97.8	1.8	3.2	1.8	3.2
Teens 13-18 y	1563	100%	76.2	136.8	76.2	136.8	1.2	2.1	1.2	2.1
Adults 19+ y	9950	99.8%	76.1	133.9	76.3	133.9	1.0	1.7	1.0	1.7
U.S. Population 2+ Years	15014	99.9%	73.1	129.7	73.2	129.8	1.2	2.2	1.2	2.2

[a] DSM's elaVida proposed for use in 11 broad food categories including bakery products; beverages; dairy products and substitutes; desserts; fats and oils; fruit juices and nectars; dry seasoning mixes for meat, poultry and fish; chewing gum; sauces, dips, gravies and condiments; snacks; and vegetable juices.
[b] Unweighted number of users; % user, per capita and per user estimates derived using the statistical weights provided by the National Center for Health Statistics (NCHS).

The estimated daily intake of hydroxytyrosol from proposed uses in 11 broad categories of food in units of mg/day and mg/kg-bw/day are provided in Table 5 for the U.S. population ages 2 years and older and four sub populations. The highest 90th percentile *per user* EDI of hydroxytyrosol was 54.7 mg/day among teenagers ages 13 to 18 years (0.9 mg/kg-bw/day). The 90th percentile *per user* EDI for U.S. population 2 years and older was 51.9 mg/day (0.9 mg/kg-bw/day).

Table 5. Estimated daily intake of hydroxytyrosol from proposed uses of elaVida[a, b] (NHANES 2007-2010)

Population	N [c]	%User	2 Day Average (mg/day)[a, b] Per Capita Mean	2 Day Average (mg/day)[a, b] Per Capita 90th	2 Day Average (mg/day)[a, b] Per User Mean	2 Day Average (mg/day)[a, b] Per User 90th	2 Day Average (mg/kg-bw/day)[a, b] Per Capita Mean	2 Day Average (mg/kg-bw/day)[a, b] Per Capita 90th	2 Day Average (mg/kg-bw/day)[a, b] Per User Mean	2 Day Average (mg/kg-bw/day)[a, b] Per User 90th
Children 2-5 y	1374	99.8%	19.6	32.9	19.6	32.9	1.2	2.0	1.2	2.0
Children 6-12 y	2127	99.9%	24.3	39.1	24.3	39.1	0.7	1.3	0.7	1.3
Teens 13-18 y	1563	100%	30.5	54.7	30.5	54.7	0.5	0.9	0.5	0.9
Adults 19+ y	9950	99.8%	30.5	53.6	30.5	53.6	0.4	0.7	0.4	0.7
U.S. Population 2+ Years	15014	99.9%	29.3	51.9	29.3	51.9	0.5	0.9	0.5	0.9

[a] Based upon use rates of elaVida containing 40% hydroxytyrosol equating to 5-10 mg hydroxytyrosol per serving of food.
[b] DSM's elaVida proposed for use in 11 broad food categories including bakery products; beverages; dairy products and substitutes; desserts; fats and oils; fruit juices and nectars; dry seasoning mixes for meat, poultry and fish; chewing gum; sauces, dips, gravies and condiments; snacks; and vegetable juices
[c] Unweighted number of users; % user, per capita and per user estimates derived using the statistical weights provided by the National Center for Health Statistics (NCHS).

Cumulative Estimated Daily Intake for Hydroxytyrosol

The cumulative EDI of hydroxytyrosol from existing dietary sources and DSM's proposed uses of elaVida (to deliver 5 to 10 mg/serving of hdyroxytorosol in 11 food categories) in units of mg/day and mg/kg-bw/day are provided in Table 6 for the U.S. population ages 2 years and older and four sub populations. The highest 90th percentile *per user* CEDI of hydroxytyrosol was 55.1 mg/day among teenagers ages 13 to 18 years (0.9 mg/kg-bw/day). The 90th percentile *per user* CEDI for U.S. population 2 years and older was 52.4 mg/day (0.9 mg/kg-bw/day).

Table 6. Cumulative estimated daily intake of hydroxytyrosol (existing dietary exposure plus proposed uses), (NHANES 2007-2010)

			2 Day Average (mg/day)[b,c]				2 Day Average (mg/kg-bw/day)[b,c]			
			Per Capita		Per User		Per Capita		Per User	
Population	N[a]	%User	Mean	90th	Mean	90th	Mean	90th	Mean	90th
Children 2-5 y	1374	99.8%	19.6	33.0	19.7	33.0	1.2	2.0	1.2	2.0
Children 6-12 y	2127	99.9%	24.4	39.9	24.4	39.9	0.7	1.3	0.7	1.3
Teens 13-18 y	1563	100%	30.6	55.1	30.6	55.1	0.5	0.9	0.5	0.9
Adults 19+ y	9950	99.8%	30.8	53.9	30.8	53.9	0.4	0.7	0.4	0.7
U.S. Population 2+ Years	15014	99.9%	29.5	52.4	29.5	52.4	0.5	0.9	0.5	0.9

[a] Unweighted number of users; % user, per capita and per user estimates derived using the statistical weights provided by the National Center for Health Statistics (NCHS).

[b] Cumulative EDI of hydroxytyrosol based upon existing uses of hydroxytyrosol in olive and olive oil and proposed uses of DSM's elaVida containing 40% hydroxytyrosol in 11 broad food categories including bakery products; beverages; dairy products and substitutes; desserts; fats and oils; fruit juices and nectars; dry seasoning mixes for meat, poultry and fish; chewing gum; sauces, dips, gravies and condiments; snacks; and vegetable juices at a use rate of 5-10 mg of hydroxytyrosol per serving of food.

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Appendix A Foods Included in the Analysis

Foods included for proposed EDI analysis

Crackers

Food Code	Description
51187000	Melba toast
51188100	Pannetone (Italian-style sweetbread)
53210900	Cookie, graham cracker sandwich with chocolate and marshmallow filling*
54001000	Crackers, NS as to sweet or nonsweet
54101010	Cracker, animal
54102010	Crackers, graham
54102020	Crackers, graham, chocolate covered
54102060	Crackers, Cuban
54102100	Crackers, graham, lowfat
54102110	Crackers, graham, fat free
54102200	Crackers, graham, sandwich-type, with filling
54202010	Crackers, saltine, low sodium
54202050	Crackers, saltine, fat free, low sodium
54203010	Crackers, toast thins (rye, wheat, white flour), low sodium
54204010	Cracker, 100% whole wheat, low sodium
54205010	Cracker, snack, low sodium
54205030	Cracker, cheese, low sodium
54205100	Cracker, snack, lowfat, low sodium
54207010	Crispbread, wheat, low sodium
54210010	Cracker, multigrain, salt free
54222000	Crispbread, rye, low sodium
54301000	Cracker, snack
54301100	Cracker, snack, reduced fat
54301200	Cracker, snack, fat free
54304000	Cracker, cheese
54304100	Cracker, cheese, reduced fat
54304500	Cracker, high fiber, no added fat
54305000	Crispbread, wheat, no added fat
54305500	Crispbread, wheat or rye, extra crispy
54307000	Crackers, matzo
54308000	Crackers, milk
54313000	Crackers, oyster
54318500	Rice cake, cracker-type

54319000	Crackers, rice
54319010	Puffed rice cake
54319020	Popcorn cake
54322000	Crispbread, rye, no added fat
54325000	Crackers, saltine
54325050	Crackers, saltine, whole wheat
54327950	Crackers, cylindrical, peanut-butter filled
54328000	Crackers, sandwich-type, NFS
54328100	Cracker, sandwich-type, peanut butter filled
54328110	Cracker, sandwich-type, peanut butter filled, reduced fat
54328200	Cracker, sandwich-type, cheese-filled
54334000	Crackers, toast thins (rye, pumpernickel, white flour)
54336000	Crackers, water biscuits
54337000	Cracker, 100% whole wheat
54337050	Cracker, 100% whole wheat, reduced fat
54337100	Crackers, whole wheat and bran
54338000	Crackers, wheat
54338100	Crackers, wheat, reduced fat
54339000	Crackers, corn

* Only component of proposed food category of food was applied in analysis

Croutons

Food Code	Description
27446360	Chicken or turkey caesar garden salad (chicken and/or turkey, lettuce, tomato, cheese), no dressing*
28145110	Turkey with vegetable, stuffing (diet frozen meal)*
51185000	Croutons
75147000	Spinach salad, no dressing*

* Only component of proposed food category of food was applied in analysis

Grain-based bars

Food Code	Description
53211000	Cookie bar, with chocolate, nuts, and graham crackers
53220000	Cookie, fruit-filled bar
53220010	Cookie, fruit-filled bar, fat free
53220020	Cookie, date bar
53220030	Cookie, fig bar
53220040	Cookie, fig bar, fat free
53224250	Cookie, lemon bar
53242500	Cookie, toffee bar

53540000	Breakfast bar, NFS
53540200	Breakfast bar, cereal crust with fruit filling, lowfat
53540300	Fiber One Chewy Bar
53540400	Kellogg's Nutri-Grain Cereal Bar
53540402	Kellogg's Nutri-Grain Yogurt Bar
53540404	Kellogg's Nutri-Grain Fruit and Nut Bar
53540500	Breakfast bar, date, with yogurt coating
53540600	Milk 'n Cereal bar
53540700	Kellogg's Special K bar
53540800	Kashi GOLEAN Chewy Bars
53540802	Kashi TLC Chewy Granola Bar
53540804	Kashi GOLEAN Crunchy Bars
53540806	Kashi TLC Crunchy Granola Bar
53540900	Nature Valley Chewy Trail Mix Granola Bar
53540902	Nature Valley Chewy Granola Bar with Yogurt Coating
53540904	Nature Valley Sweet and Salty Nut Granola Bar
53540906	Nature Valley Crunchy Granola Bar
53541000	Quaker Chewy Granola Bar
53541002	Quaker Chewy 90 Calorie Granola Bar
53541004	Quaker Chewy 25% Less Sugar Granola Bar
53541006	Quaker Chewy Dipps Granola Bar
53542000	Snack bar, oatmeal
53542100	Granola bar, oats, sugar, raisins, coconut
53542200	Granola bar, oats, fruit and nuts, lowfat
53542210	Granola bar, nonfat
53543000	Granola bar, oats, reduced sugar
53543100	Granola bar, peanuts, oats, sugar, wheat germ
53544200	Granola bar, chocolate-coated
53544210	Granola bar, with coconut, chocolate-coated
53544220	Granola bar with nuts, chocolate-coated
53544230	Granola bar, oats, nuts, coated with non-chocolate coating
53544250	Granola bar, coated with non-chocolate coating
53544300	Granola bar, high fiber, coated with non-chocolate yogurt coating
53544400	Granola bar, with rice cereal

* Only component of proposed food category of food was applied in analysis

Protein-based meal replacement and energy bars

Food Code	Description
41435110	High protein bar, candy-like, soy and milk base
41435120	Zone Perfect Classic Crunch nutrition bar

41435300	Balance Original Bar
41435500	Clif Bar
41435700	South Beach Living High Protein Cereal Bar
41435710	South Beach Living Meal Replacement Bar
53541200	Meal replacement bar
53541300	Slim Fast Original Meal Bar
53544450	PowerBar (fortified high energy bar)
91780010	Snickers Marathon Energy bar
91781010	Snickers Marathon Protein bar

* Only component of proposed food category of food was applied in analysis

Beverages

Food Code	Description
11612000	Instant breakfast, powder, milk added
11623000	Meal supplement or replacement, commercially prepared, ready-to-drink
11631000	High calorie beverage, canned or powdered, reconstituted
11641000	Meal supplement or replacement, milk-based, high protein, liquid
11641020	Meal replacement or supplement, milk based, ready-to-drink
11830800	Instant breakfast, powder, not reconstituted
11830810	Instant breakfast, powder, sweetened with low calorie sweetener, not reconstituted
11830900	Protein supplement, milk-based, powdered, not reconstituted
11830940	Meal replacement, high protein, milk based, fruit juice mixable formula, powdered, not reconstituted
11830970	Meal replacement, protein type, milk-based, powdered, not reconstituted
11830990	Nutrient supplement, milk-based, powdered, not reconstituted
11831500	Nutrient supplement, milk-based, high protein, powdered, not reconstituted
11832000	Meal replacement, protein type, milk- and soy-based, powdered, not reconstituted
11836000	Protein supplement, milk-based, Muscle Milk, powdered, not reconstituted
11836100	Protein supplement, milk-based, Muscle Milk Light, powdered, not reconstituted
92510610	Fruit drink
92510650	Tamarind drink, Puerto Rican (Refresco de tamarindo)
92510720	Fruit punch, made with fruit juice and soda
92510730	Fruit punch, made with soda, fruit juice, and sherbet or ice cream
92511010	Lemonade
92511250	Citrus fruit juice drink
92530410	Citrus drink with vitamin C added
92530510	Cranberry juice drink with vitamin C added
92530610	Fruit punch, fruit drink, or fruitade, with vitamin C added
92530950	Vegetable and fruit juice drink, with vitamin C added
92531030	Fruit juice drink, with thiamin (vitamin B1) and vitamin C
92541010	Fruit-flavored drink, made from sweetened powdered mix (fortified with vitamin C)

92542000	Fruit-flavored drink, made from powdered mix, mainly sugar, with high vitamin C added
92550030	Fruit juice drink, low calorie, with high vitamin C
92550040	Fruit juice drink, low calorie
92550110	Cranberry juice drink, low calorie, with vitamin C added
92550350	Light orange juice beverage, 40-50% juice, lower sugar and calories, with artificial sweetener
92550400	Vegetable and fruit juice drink, low calorie, with high vitamin C
92550610	Fruit-flavored drinks, punches, ades, low calorie, with vitamin C added
92550620	Fruit flavored drink, low calorie
92552000	Fruit-flavored drink, made from powdered mix with high vitamin C added, low calorie
92552010	Fruit flavored drink, made from powdered mix, low calorie
92552020	Fruit juice drink, reduced sugar, with thiamin (vitamin B1) and vitamin C
92552030	Fruit juice drink, reduced sugar, with vitamin E
92553000	Fruit-flavored thirst quencher beverage, low calorie
92560000	Fruit-flavored thirst quencher beverage
92560100	Gatorade Thirst Quencher sports drink
92560200	Powerade sports drink
92565000	Fruit-flavored sports drink or thirst quencher beverage, low calorie
92565100	Gatorade G2 thirst quencher sports drink, low calorie
92565200	Powerade Zero sports drink, low calorie
92582100	Citrus juice drink, calcium fortified
92582110	Fruit juice drink, with thiamin (vitamin B1) and vitamin C plus calcium
92582120	Fruit flavored drink, reduced sugar, with high vitamin C, plus added calcium
92650000	Red Bull Energy Drink
92650005	Red Bull Energy Drink, sugar-free
92650100	Full Throttle Energy Drink
92650200	Monster Energy Drink
92650205	Mountain Dew AMP Energy Drink
92650210	Mountain Dew AMP Energy Drink, sugar-free
92650700	Rockstar Energy Drink
92650705	Rockstar Energy Drink, sugar-free
92650800	Vault Energy Drink
92650805	Vault Zero Energy drink
92651000	Energy drink
92900110	Fruit-flavored concentrate, dry powder, with sugar and vitamin C added
92900200	Fruit-flavored beverage, dry concentrate, low calorie, not reconstituted
93301270	Fruit punch, alcoholic*
93301330	Gin Rickey*
93301360	Long Island iced tea*
94100200	Water, bottled, sweetened, with low or no calorie sweetener
94100300	Water, fruit flavored, sweetened, with high fructose corn syrup and low calorie sweetener
94210100	Propel Fitness Water

94210200	Vitamin Water

* Only component of proposed food category of food was applied in analysis

Yogurt

Food Code	Description
11410000	Yogurt, NS as to type of milk or flavor
11411010	Yogurt, plain, NS as to type of milk
11411100	Yogurt, plain, whole milk
11411200	Yogurt, plain, lowfat milk
11411300	Yogurt, plain, nonfat milk
11420000	Yogurt, vanilla, lemon, or coffee flavor, NS as to type of milk
11421000	Yogurt, vanilla, lemon, or coffee flavor, whole milk
11422000	Yogurt, vanilla, lemon, maple, or coffee flavor, lowfat milk
11422100	Yogurt, vanilla, lemon, maple, or coffee flavor, lowfat milk, sweetened with low calorie sweetener
11423000	Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk
11424000	Yogurt, vanilla, lemon, maple, or coffee flavor, nonfat milk, sweetened with low calorie sweetener
11425000	Yogurt, chocolate, NS as to type of milk
11426000	Yogurt, chocolate, whole milk
11430000	Yogurt, fruit variety, NS as to type of milk
11431000	Yogurt, fruit variety, whole milk
11432000	Yogurt, fruit variety, lowfat milk
11432500	Yogurt, fruit variety, lowfat milk, sweetened with low-calorie sweetener
11433000	Yogurt, fruit variety, nonfat milk
11433500	Yogurt, fruit variety, nonfat milk, sweetened with low-calorie sweetener
11446000	Fruit and lowfat yogurt parfait
41420380	Soy yogurt
63401015	Apple and grape salad with yogurt and walnuts*

* Only component of proposed food category of food was applied in analysis

Frozen yogurt

Food Code	Description
11459990	Yogurt, frozen, NS as to flavor, NS as to type of milk
11460000	Yogurt, frozen, flavors other than chocolate, NS as to type of milk
11460100	Yogurt, frozen, chocolate, NS as to type of milk
11460150	Yogurt, frozen, NS as to flavor, lowfat milk
11460160	Yogurt, frozen, chocolate, lowfat milk
11460170	Yogurt, frozen, flavors other than chocolate, lowfat milk
11460200	Yogurt, frozen, chocolate, nonfat milk

11460250	Yogurt, frozen, flavors other than chocolate, with sorbet or sorbet-coated
11460300	Yogurt, frozen, flavors other than chocolate, nonfat milk
11460400	Yogurt, frozen, chocolate, nonfat milk, with low-calorie sweetener
11460410	Yogurt, frozen, flavors other than chocolate, nonfat milk, with low-calorie sweetener
11460430	Yogurt, frozen, chocolate, whole milk
11460440	Yogurt, frozen, flavors other than chocolate, whole milk
11461250	Yogurt, frozen, cone, chocolate
11461260	Yogurt, frozen, cone, flavors other than chocolate
11461270	Yogurt, frozen, cone, flavors other than chocolate, lowfat milk
11461280	Yogurt, frozen, cone, chocolate, lowfat milk
53104580	Cheesecake -type dessert, made with yogurt, with fruit*
53366000	Pie, yogurt, frozen*

* Only component of proposed food category of food was applied in analysis

Butter, margarine, oil and shortening

Food Code	Description
11121210	Milk, dry, reconstituted, lowfat*
11211400	Milk, evaporated, 2% fat, NS as to dilution*
11512510	Hot chocolate, Puerto Rican style, made with low fat milk*
11812000	Milk, dry, lowfat, not reconstituted*
13120760	Ice cream cone, chocolate covered or dipped, chocolate ice cream*
13120770	Ice cream cone, no topping, chocolate ice cream*
13120780	Ice cream cone, chocolate covered, with nuts, chocolate ice cream*
13130100	Light ice cream, NS as to flavor (formerly ice milk)*
13130610	Light ice cream, soft serve, chocolate (formerly ice milk)*
13135010	Ice cream sandwich, made with light chocolate ice cream*
13140100	Light ice cream, bar or stick, chocolate-coated (formerly ice milk)*
13140550	Light ice cream, cone, chocolate (formerly ice milk)*
13140680	Light ice cream, sundae, soft serve, not fruit or chocolate topping (without whipped cream) (formerly ice milk)*
13160150	Fat free ice cream, no sugar added, chocolate*
13161500	Milk dessert sandwich bar, frozen, made from lowfat milk*
13210110	Pudding, bread*
13210180	Pudding, Mexican bread (Capirotada)*
13210750	Pudding, pumpkin*
13210810	Puerto Rican pumpkin pudding (Flan de calabaza)*
13250200	Mousse, chocolate, lowfat, reduced calorie, prepared from dry mix, water added*
14201200	Cottage cheese, farmer's*
14620300	Topping from cheese pizza*
14620310	Topping from vegetable pizza*
14620320	Topping from meat pizza*

14630200	Cheese souffle*
14630300	Welsh rarebit*
14640100	Cheese sandwich, grilled*
21103110	Beef steak, breaded or floured, baked or fried, NS as to fat eaten*
21103120	Beef steak, breaded or floured, baked or fried, lean and fat eaten*
21103130	Beef steak, breaded or floured, baked or fried, lean only eaten*
21104110	Beef steak, battered, fried, NS as to fat eaten*
21104120	Beef steak, battered, fried, lean and fat eaten*
21104130	Beef steak, battered, fried, lean only eaten*
21500200	Ground beef or patty, breaded, cooked*
22000300	Pork, NS as to cut, breaded or floured, fried, NS as to fat eaten*
22000310	Pork, NS as to cut, breaded or floured, fried, lean and fat eaten*
22000320	Pork, NS as to cut, breaded or floured, fried, lean only eaten*
22002100	Pork, ground or patty, breaded, cooked*
22101300	Pork chop, breaded or floured, fried, NS as to fat eaten*
22101310	Pork chop, breaded or floured, fried, lean and fat eaten*
22101320	Pork chop, breaded or floured, fried, lean only eaten*
22101400	Pork chop, battered, fried, NS as to fat eaten*
22101410	Pork chop, battered, fried, lean and fat eaten*
22101420	Pork chop, battered, fried, lean only eaten*
22201050	Pork steak or cutlet, battered, fried, NS as to fat eaten*
22201060	Pork steak or cutlet, battered, fried, lean and fat eaten*
22201400	Pork steak or cutlet, breaded or floured, fried, NS as to fat eaten*
22201410	Pork steak or cutlet, breaded or floured, fried, lean and fat eaten*
22201420	Pork steak or cutlet, breaded or floured, fried, lean only eaten*
22210310	Pork, tenderloin, breaded, fried*
22210450	Pork, tenderloin, battered, fried*
22300120	Ham, fried, NS as to fat eaten*
22300130	Ham, fried, lean and fat eaten*
22300140	Ham, fried, lean only eaten*
22300160	Ham, breaded or floured, fried, lean and fat eaten*
23150200	Goat, fried*
23203030	Veal chop, fried, lean only eaten*
23311120	Rabbit, NS as to domestic or wild, breaded, fried*
24104000	Chicken, NS as to part, fried, no coating, NS as to skin eaten*
24104010	Chicken, NS as to part, fried, no coating, skin eaten*
24104020	Chicken, NS as to part, fried, no coating, skin not eaten*
24107000	Chicken, NS as to part, coated, baked or fried, prepared with skin, NS as to skin/coating eaten*
24107010	Chicken, NS as to part, coated, baked or fried, prepared with skin, skin/coating eaten*
24107020	Chicken, NS as to part, coated, baked or fried, prepared with skin, skin/coating not eaten*
24107040	Chicken, NS as to part, coated, baked or fried, prepared skinless, NS as to coating eaten*

24107050	Chicken, NS as to part, coated, baked or fried, prepared skinless, coating eaten*
24107060	Chicken, NS as to part, coated, baked or fried, prepared skinless, coating not eaten*
24124100	Chicken, breast, fried, no coating, NS as to skin eaten*
24124110	Chicken, breast, fried, no coating, skin eaten*
24124120	Chicken, breast, fried, no coating, skin not eaten*
24127100	Chicken, breast, coated, baked or fried, prepared with skin, NS as to skin/coating eaten*
24127110	Chicken, breast, coated, baked or fried, prepared with skin, skin/coating eaten*
24127120	Chicken, breast, coated, baked or fried, prepared with skin, skin/coating not eaten*
24127140	Chicken, breast, coated, baked or fried, prepared skinless, NS as to coating eaten*
24127150	Chicken, breast, coated, baked or fried, prepared skinless, coating eaten*
24127160	Chicken, breast, coated, baked or fried, prepared skinless, coating not eaten*
24134200	Chicken, leg (drumstick and thigh), fried, no coating, NS as to skin eaten*
24134210	Chicken, leg (drumstick and thigh), fried, no coating, skin eaten*
24134220	Chicken, leg (drumstick and thigh), fried, no coating, skin not eaten*
24137200	Chicken, leg (drumstick and thigh), coated, baked or fried, prepared with skin, NS as to skin/coating eaten*
24137210	Chicken, leg (drumstick and thigh), coated, baked or fried, prepared with skin, skin/coating eaten*
24137220	Chicken, leg (drumstick and thigh), coated, baked or fried, prepared with skin, skin/coating not eaten*
24137250	Chicken, leg (drumstick and thigh), coated, baked or fried, prepared skinless, coating eaten*
24137260	Chicken, leg (drumstick and thigh), coated, baked or fried, prepared skinless, coating not eaten*
24144200	Chicken, drumstick, fried, no coating, NS as to skin eaten*
24144210	Chicken, drumstick, fried, no coating, skin eaten*
24144220	Chicken, drumstick, fried, no coating, skin not eaten*
24147200	Chicken, drumstick, coated, baked or fried, prepared with skin, NS as to skin/coating eaten*
24147210	Chicken, drumstick, coated, baked or fried, prepared with skin, skin/coating eaten*
24147220	Chicken, drumstick, coated, baked or fried, prepared with skin, skin/coating not eaten*
24147240	Chicken, drumstick, coated, baked or fried, prepared skinless, NS as to coating eaten*
24147250	Chicken, drumstick, coated, baked or fried, prepared skinless, coating eaten*
24147260	Chicken, drumstick, coated, baked or fried, prepared skinless, coating not eaten*
24154210	Chicken, thigh, fried, no coating, skin eaten*
24154220	Chicken, thigh, fried, no coating, skin not eaten*
24157200	Chicken, thigh, coated, baked or fried, prepared with skin, NS as to skin/coating eaten*
24157210	Chicken, thigh, coated, baked or fried, prepared with skin, skin/coating eaten*
24157220	Chicken, thigh, coated, baked or fried, prepared with skin, skin/coating not eaten*
24157240	Chicken, thigh, coated, baked or fried, prepared skinless, NS as to coating eaten*
24157250	Chicken, thigh, coated, baked or fried, prepared skinless, coating eaten*
24157260	Chicken, thigh, coated, baked or fried, prepared skinless, coating not eaten*
24164100	Chicken, wing, fried, no coating, NS as to skin eaten*
24164110	Chicken, wing, fried, no coating, skin eaten*
24164120	Chicken, wing, fried, no coating, skin not eaten*

24167100	Chicken, wing, coated, baked or fried, prepared with skin, NS as to skin/coating eaten*
24167110	Chicken, wing, coated, baked or fried, prepared with skin, skin/coating eaten*
24167120	Chicken, wing, coated, baked or fried, prepared with skin, skin/coating not eaten*
24198840	Chicken crackling, Puerto Rican style (Chicharron de pollo)*
24201050	Turkey, light meat, breaded, baked or fried, NS as to skin eaten*
24201060	Turkey, light meat, breaded, baked or fried, skin not eaten*
24201070	Turkey, light meat, breaded, baked or fried, skin eaten*
24208000	Turkey, nuggets*
24302010	Duck, pressed, Chinese*
25110450	Chicken liver, fried*
26100120	Fish, NS as to type, baked or broiled*
26100130	Fish, NS as to type, breaded or battered, baked*
26100150	Fish, NS as to type, battered, fried*
26105120	Carp, baked or broiled*
26107120	Catfish, baked or broiled*
26107130	Catfish, breaded or battered, baked*
26107150	Catfish, battered, fried*
26109120	Cod, baked or broiled*
26109130	Cod, breaded or battered, baked*
26109150	Cod, battered, fried*
26111120	Croaker, baked or broiled*
26111130	Croaker, breaded or battered, baked*
26115110	Flounder, cooked, NS as to cooking method*
26115120	Flounder, baked or broiled*
26115130	Flounder, breaded or battered, baked*
26115150	Flounder, battered, fried*
26117120	Haddock, baked or broiled*
26117130	Haddock, breaded or battered, baked*
26117150	Haddock, battered, fried*
26119120	Herring, baked or broiled*
26121110	Mackerel, cooked, NS as to cooking method*
26121120	Mackerel, baked or broiled*
26125120	Ocean perch, baked or broiled*
26125150	Ocean perch, battered, fried*
26127120	Perch, baked or broiled*
26127130	Perch, breaded or battered, baked*
26127150	Perch, battered, fried*
26129120	Pike, baked or broiled*
26131110	Pompano, cooked, NS as to cooking method*
26131120	Pompano, baked or broiled*
26133120	Porgy, baked or broiled*

26133150	Porgy, battered, fried*
26137120	Salmon, baked or broiled*
26137150	Salmon, battered, fried*
26141110	Sea bass, cooked, NS as to cooking method*
26141120	Sea bass, baked or broiled*
26141130	Sea bass, breaded or battered, baked*
26143120	Shark, baked or broiled*
26149120	Swordfish, baked or broiled*
26151120	Trout, baked or broiled*
26151150	Trout, battered, fried*
26153110	Tuna, fresh, cooked, NS as to cooking method*
26153120	Tuna, fresh, baked or broiled*
26157120	Whiting, baked or broiled*
26157130	Whiting, breaded or battered, baked*
26157150	Whiting, battered, fried*
26158000	Tilapia, cooked, NS as to cooking method*
26158010	Tilapia, baked or broiled*
26158020	Tilapia, breaded or battered, baked*
26158040	Tilapia, battered, fried*
26207110	Roe, shad, cooked*
26213120	Squid, baked, broiled*
26303120	Clams, baked or broiled*
26305120	Crab, baked or broiled*
26311120	Lobster, baked or broiled*
26313110	Mussels, cooked, NS as to cooking method*
26315110	Oysters, cooked, NS as to cooking method*
26315120	Oysters, baked or broiled*
26317120	Scallops, baked or broiled*
26319120	Shrimp, baked or broiled*
26321110	Snails, cooked, NS as to cooking method*
27111000	Beef with tomato-based sauce (mixture)*
27111100	Beef goulash*
27111200	Beef burgundy (beef bourguignonne)*
27111300	Mexican style beef stew, no potatoes, tomato-based sauce (mixture) (Carne guisada sin papas)*
27111310	Mexican style beef stew, no potatoes, with chili peppers, tomato-based sauce (mixture) (Carne guisada con chile)*
27113000	Beef with cream or white sauce (mixture)*
27113100	Beef stroganoff*
27113200	Creamed chipped or dried beef*
27115000	Beef with soy-based sauce (mixture)*
27116100	Beef curry*

27116300	Beef with sweet and sour sauce (mixture)*
27118110	Meatballs, Puerto Rican style (Albondigas guisadas)*
27118120	Stewed seasoned ground beef, Puerto Rican style (Picadillo guisado, picadillo de carne)*
27118180	Puerto Rican style beef stew, meat with gravy (potatoes reported separately)*
27120060	Sweet and sour pork*
27120080	Ham stroganoff*
27120100	Ham or pork with tomato-based sauce (mixture)*
27120130	Mexican style pork stew, no potatoes, tomato-based sauce (mixture) (cerdo guisado sin papas)*
27121010	Stewed pork, Puerto Rican style*
27130100	Lamb curry*
27133010	Stewed goat, Puerto Rican style (Cabrito en fricase, chilindron de chivo)*
27135050	Veal Marsala*
27135110	Veal parmigiana*
27141000	Chicken or turkey cacciatore*
27141050	Stewed chicken with tomato-based sauce, Mexican style (mixture) (Pollo guisado con tomate)*
27143000	Chicken or turkey with cream sauce (mixture)*
27146050	Chicken wing with hot pepper sauce*
27146100	Sweet and sour chicken or turkey*
27146150	Chicken curry*
27146160	Chicken with mole sauce*
27146250	Chicken or turkey cordon bleu*
27146300	Chicken or turkey parmigiana*
27146400	Chicken kiev*
27150030	Crab imperial*
27150060	Lobster newburg*
27150070	Lobster with butter sauce (mixture)*
27150100	Shrimp, curried*
27150130	Seafood newburg*
27150160	Shrimp with lobster sauce (mixture)*
27150170	Sweet and sour shrimp*
27150190	Lobster sauce (broth-based)*
27150230	Shrimp scampi*
27150310	Fish with tomato-based sauce (mixture)*
27150320	Fish curry*
27151040	Crabs in tomato-based sauce, Puerto Rican style (mixture) (Salmorejo de jueyes)*
27151050	Shrimp in garlic sauce, Puerto Rican style (mixture) (Camarones al ajillo)*
27151070	Stewed codfish, Puerto Rican style, no potatoes (potatoes reported separately)*
27211100	Beef stew with potatoes, tomato-based sauce (mixture)*
27211110	Mexican style beef stew with potatoes, tomato-based sauce (mixture) (Carne guisada con papas)*
27211150	Beef goulash with potatoes*

27211200	Beef stew with potatoes, gravy*
27211300	Beef (roast) hash*
27211500	Beef and potatoes with cheese sauce (mixture)*
27212000	Beef and noodles, no sauce (mixture)*
27212150	Beef goulash with noodles*
27212300	Beef and noodles with cream or white sauce (mixture)*
27212350	Beef stroganoff with noodles*
27213000	Beef and rice, no sauce (mixture)*
27213100	Beef and rice with tomato-based sauce (mixture)*
27218210	Puerto Rican style beef stew with potatoes (Carne guisada con papas)*
27218310	Stewed corned beef, Puerto Rican style ("Corned beef" guisado)*
27220020	Ham and noodles with cream or white sauce (mixture)*
27220030	Ham and rice with (mushroom) soup (mixture)*
27220080	Ham croquette*
27220190	Sausage and noodles with cream or white sauce (mixture)*
27220210	Ham and noodles, no sauce (mixture)*
27220310	Ham or pork and rice, no sauce (mixture)*
27220520	Ham or pork and potatoes with cheese sauce (mixture)*
27221100	Stewed pig's feet, Puerto Rican style (Patitas de cerdo guisadas)*
27221150	Mexican style pork stew, with potatoes, tomato-based sauce (mixture) (cerdo guisado con papas)*
27242000	Chicken or turkey and noodles, no sauce (mixture)*
27242300	Chicken or turkey and noodles with cream or white sauce (mixture)*
27242310	Chicken or turkey and noodles with cheese sauce (mixture)*
27242350	Chicken or turkey tetrazzini*
27242400	Chicken or turkey and noodles, tomato-based sauce (mixture)*
27242500	Chicken or turkey and noodles with soy-based sauce (mixture)*
27243000	Chicken or turkey and rice, no sauce (mixture)*
27243300	Chicken or turkey and rice with cream sauce (mixture)*
27243400	Chicken or turkey and rice with (mushroom) soup (mixture)*
27243500	Chicken or turkey and rice with tomato-based sauce (mixture)*
27243600	Chicken or turkey and rice with soy-based sauce (mixture)*
27246100	Chicken or turkey with dumplings (mixture)*
27246300	Chicken or turkey cake, patty, or croquette*
27246400	Chicken or turkey souffle*
27250020	Clams, stuffed*
27250040	Crab cake*
27250110	Scallops and noodles with cheese sauce (mixture)*
27250120	Shrimp and noodles, no sauce (mixture)*
27250122	Shrimp and noodles with gravy (mixture)*
27250124	Shrimp and noodles with (mushroom) soup (mixture)*
27250126	Shrimp and noodles with cream or white sauce (mixture)*

27250128	Shrimp and noodles with soy-based sauce (mixture)*
27250130	Shrimp and noodles with cheese sauce (mixture)*
27250132	Shrimp and noodles with tomato sauce (mixture)*
27250210	Clam cake or patty*
27250220	Oyster fritter*
27250250	Flounder with crab stuffing*
27250410	Shrimp with crab stuffing*
27250610	Tuna noodle casserole with cream or white sauce*
27250630	Tuna noodle casserole with (mushroom) soup*
27250810	Fish and rice with tomato-based sauce*
27250820	Fish and rice with cream sauce*
27250900	Fish and noodles with (mushroom) soup*
27260500	Vienna sausages stewed with potatoes, Puerto Rican style (Salchichas guisadas)*
27311110	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27311120	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27311210	Corned beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27311220	Corned beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27311310	Beef stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce*
27311320	Beef stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce*
27311410	Beef stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy*
27311420	Beef stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy*
27311510	Shepherd's pie with beef*
27311600	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27311605	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27311610	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), (mushroom) soup (mixture)*
27311620	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), (mushroom) soup (mixture)*
27311625	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27311630	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27311635	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), cheese sauce (mixture)*
27311640	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27311645	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)*
27311650	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)*

27313010	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27313020	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27313110	Beef chow mein or chop suey with noodles*
27313160	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)*
27313210	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27313220	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27313320	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), (mushroom) soup (mixture)*
27313410	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27313420	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27315010	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27315020	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27315210	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27315220	Beef, rice, and vegetables (excluding carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27315270	Stuffed grape leaves with beef and rice*
27315310	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), (mushroom) soup (mixture)*
27315320	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), (mushroom) soup (mixture)*
27315340	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27315410	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27315420	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27315510	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)*
27315520	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)*
27317010	Beef pot pie*
27320030	Ham or pork, noodles and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27320040	Pork, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27320070	Ham or pork, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27320080	Sausage, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce*
27320090	Sausage, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce*
27320120	Sausage, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*

27320130	Sausage, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27320140	Pork, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27320150	Pork, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27320210	Pork, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27320310	Pork chow mein or chop suey with noodles*
27320320	Pork, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)*
27320330	Pork, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)*
27320340	Pork, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27320410	Ham, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27320450	Ham, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27330010	Shepherd's pie with lamb*
27330050	Lamb or mutton, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27330060	Lamb or mutton, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27336200	Venison/deer, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27336310	Venison/deer, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27341010	Chicken or turkey, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27341020	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27341025	Chicken or turkey, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27341030	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27341035	Chicken or turkey, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27341040	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27341050	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27341055	Chicken or turkey, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27341060	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27341310	Chicken or turkey stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy*
27341320	Chicken or turkey stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy*
27341510	Chicken or turkey stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce*
27341520	Chicken or turkey stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato- based sauce*

27343010	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27343020	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27343470	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27343480	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27343520	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27343910	Chicken or turkey chow mein or chop suey with noodles*
27343950	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), cheese sauce (mixture)*
27343960	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27345010	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27345020	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27345210	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27345220	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27345310	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)*
27345320	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)*
27345410	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27345420	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27345440	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), cheese sauce (mixture)*
27345450	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27345510	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27345520	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27347200	Chicken or turkey, stuffing, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27347210	Chicken or turkey,stuffing, and vegetables (excluding carrots, broccoli, and dark green leafy), no sauce (mixture)*
27347220	Chicken or turkey, stuffing, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27347240	Chicken or turkey, dumplings, and vegetables (including carrots, broccoli, and/or dark green leafy), gravy (mixture)*
27347250	Chicken or turkey, dumplings, and vegetables (excluding carrots, broccoli, and dark green leafy), gravy (mixture)*
27348100	Chicken fricassee, Puerto Rican style (Fricase de pollo)*
27350020	Paella with seafood*
27350030	Seafood stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-base sauce*

27350050	Shrimp chow mein or chop suey with noodles*
27350060	Shrimp creole, with rice*
27350080	Tuna noodle casserole with vegetables, cream or white sauce*
27350110	Bouillabaisse*
27350410	Tuna noodle casserole with vegetables and (mushroom) soup*
27360010	Goulash, NFS*
27360080	Chow mein or chop suey, NS as to type of meat, with noodles*
27360090	Paella, NFS*
27360100	Brunswick stew*
27360120	Chow mein or chop suey, various types of meat, with noodles*
27362000	Stewed tripe, Puerto Rican style, with potatoes (Mondongo)*
27363000	Gumbo with rice (New Orleans type with shellfish, pork, and/or poultry, tomatoes, okra, rice)*
27410210	Beef and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), no sauce (mixture)*
27410220	Beef and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), no sauce (mixture)*
27411100	Beef with vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27411120	Swiss steak*
27411200	Beef with vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27414100	Beef with vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), (mushroom) soup (mixture)*
27414200	Beef with vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), (mushroom) soup (mixture)*
27415100	Beef and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27415120	Beef, tofu, and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27415150	Beef chow mein or chop suey, no noodles*
27415170	Kung Pao beef*
27415200	Beef and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27415220	Beef, tofu, and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27416150	Pepper steak*
27416450	Beef and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), gravy (mixture)*
27416500	Beef and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), gravy (mixture)*
27418210	Puerto Rican style beef stew with vegetables, excluding potatoes (Carne a la Judia)*
27418310	Corned beef with tomato sauce and onion, Puerto Rican style (mixture)*
27418410	Beef steak with onions, Puerto Rican style (mixture) (Biftec encebollado)*
27420060	Pork and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), no sauce (mixture)*
27420160	Moo Shu (Mu Shi) Pork, without Chinese pancake*
27420170	Pork and onions with soy-based sauce (mixture)*

27420200	Pork hash, Hawaiian style-ground pork, vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce*
27420250	Ham and vegetables (including carrots, broccoli, and/or dark- green leafy (no potatoes)), no sauce (mixture)*
27420270	Ham and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), no sauce (mixture)*
27420370	Pork, tofu, and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27420390	Pork chow mein or chop suey, no noodles*
27420400	Pork and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27420410	Pork and vegetables (excluding carrots, broccoli, and dark- green leafy (no potatoes)), tomato-based sauce (mixture)*
27420460	Sausage and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27420500	Pork and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)*
27420510	Pork and vegetables (excluding carrots, broccoli, and dark- green leafy), soy-based sauce (mixture)*
27422010	Pork chop stewed with vegetables, Puerto Rican style (mixture) (Chuletas a la jardinera)*
27440110	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), no sauce (mixture)*
27440120	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), no sauce (mixture)*
27442110	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), gravy (mixture)*
27442120	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), gravy (mixture)*
27443110	Chicken or turkey a la king with vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), cream, white, or soup-based sauce*
27443120	Chicken or turkey a la king with vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), cream, white, or soup-based sauce*
27443150	Chicken or turkey divan*
27445110	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27445120	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27445125	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27445130	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27445180	Moo Goo Gai Pan*
27445220	Kung pao chicken*
27445250	Almond chicken*
27446100	Chicken or turkey chow mein or chop suey, no noodles*
27446400	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), cheese sauce (mixture)*
27446410	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), cheese sauce (mixture)*
27450040	Shrimp chow mein or chop suey, no noodles*
27450400	Shrimp and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), no sauce (mixture)*

27450405	Shrimp and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), no sauce (mixture)*
27450410	Shrimp and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27450420	Shrimp and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27450430	Shrimp shish kabob with vegetables, excluding potatoes*
27450450	Shrimp creole, no rice*
27450470	Kung Pao shrimp*
27450510	Tuna casserole with vegetables and (mushroom) soup, no noodles*
27450610	Shellfish mixture and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce*
27450660	Shellfish mixture and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), (mushroom) soup (mixture)*
27450700	Fish and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27450710	Fish and vegetables (excluding carrots, broccoli, and dark- green leafy (no potatoes)), tomato-based sauce (mixture)*
27450740	Fish and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27450750	Fish and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27451030	Lobster creole, Puerto Rican style (Langosta a la criolla)*
27460010	Chow mein or chop suey, NS as to type of meat, no noodles*
27460750	Liver, beef or calves, and onions*
27464000	Gumbo, no rice (New Orleans type with shellfish, pork, and/or poultry, tomatoes, okra)*
27510260	Cheeseburger, 1/4 lb meat, with mushrooms in sauce, on bun*
27510480	Cheeseburger (hamburger with cheese sauce), 1/4 lb meat, with grilled onions, on rye bun*
27515050	Fajita-style beef sandwich with cheese, on pita bread, with lettuce and tomato*
27515070	Steak and cheese submarine sandwich, with fried peppers and onions, on roll*
27515080	Steak sandwich, plain, on biscuit*
27516010	Gyro sandwich (pita bread, beef, lamb, onion, condiments), with tomato and spread*
27520410	Cuban sandwich, (Sandwich cubano), with spread*
27540180	Chicken patty sandwich or biscuit*
27540200	Fajita-style chicken sandwich with cheese, on pita bread, with lettuce and tomato*
27540250	Chicken fillet, broiled, sandwich with cheese, on whole wheat roll, with lettuce, tomato and non-mayonaise type spread*
27540270	Chicken fillet, broiled, sandwich, with lettuce, tomato, and non-mayonnaise type spread*
27560350	Pig in a blanket (frankfurter or hot dog wrapped in dough)*
28101000	Frozen dinner, NFS*
28110000	Beef dinner, NFS (frozen meal)*
28110220	Sirloin, chopped, with gravy, mashed potatoes, vegetable (frozen meal)*
28110270	Sirloin beef with gravy, potatoes, vegetable (frozen meal)*
28110300	Salisbury steak dinner, NFS (frozen meal)*
28110310	Salisbury steak with gravy, potatoes, vegetable (frozen meal)*
28110330	Salisbury steak with gravy, whipped potatoes, vegetable, dessert (frozen meal)*

28110370	Salisbury steak with gravy, macaroni and cheese, vegetable (frozen meal)*
28110380	Salisbury steak with gravy, macaroni and cheese (frozen meal)*
28110390	Salisbury steak, potatoes, vegetable, dessert (diet frozen meal)*
28110510	Beef, sliced, with gravy, potatoes, vegetable (frozen meal)*
28110620	Beef short ribs, boneless, with barbecue sauce, potatoes, vegetable (frozen meal)*
28110640	Meatballs, Swedish, in sauce, with noodles (frozen meal)*
28110660	Meatballs, Swedish, in gravy, with noodles (diet frozen meal)*
28113110	Salisbury steak, baked, with tomato sauce, vegetable (diet frozen meal)*
28113140	Beef with spaetzle or rice, vegetable (frozen meal)*
28133110	Veal, breaded, with spaghetti, in tomato sauce (frozen meal)*
28140100	Chicken dinner, NFS (frozen meal)*
28140710	Chicken, fried, with potatoes, vegetable (frozen meal)*
28140720	Chicken patty, or nuggets, boneless, breaded, potatoes, vegetable (frozen meal)*
28140730	Chicken patty, breaded, with tomato sauce and cheese, fettuccine alfredo, vegetable (frozen meal)*
28140740	Chicken patty, or nuggets, boneless, breaded, with pasta and tomato sauce, fruit, dessert (frozen meal)*
28140810	Chicken, fried, with potatoes, vegetable, dessert (frozen meal)*
28141010	Chicken, fried, with potatoes, vegetable, dessert (frozen meal, large meat portion)*
28141050	Chicken patty parmigiana, breaded, with vegetable (diet frozen meal)*
28141250	Chicken with rice-vegetable mixture (diet frozen meal)*
28141300	Chicken with rice and vegetable, reduced fat and sodium (diet frozen meal)*
28141600	Chicken a la king with rice (frozen meal)*
28141610	Chicken and vegetables in cream or white sauce (diet frozen meal)*
28143010	Chicken and vegetable entree with rice, Oriental (frozen meal)*
28143020	Chicken and vegetable entree with rice, Oriental (diet frozen meal)*
28143080	Chicken with noodles and cheese sauce (diet frozen meal)*
28143110	Chicken cacciatore with noodles (diet frozen meal)*
28143130	Chicken and vegetable entree with noodles (frozen meal)*
28143150	Chicken and vegetable entree with noodles (diet frozen meal)*
28143170	Chicken in cream sauce with noodles and vegetable (frozen meal)*
28143180	Chicken in butter sauce with potatoes and vegetable (diet frozen meal)*
28143190	Chicken in mushroom sauce, white and wild rice, vegetable (frozen meal)*
28143200	Chicken in soy-based sauce, rice and vegetables (frozen meal)*
28143210	Chicken in orange sauce with almond rice (diet frozen meal)*
28144100	Chicken and vegetable entree with noodles and cream sauce (frozen meal)*
28145100	Turkey with dressing, gravy, vegetable and fruit (diet frozen meal)*
28145610	Turkey with gravy, dressing, potatoes, vegetable, dessert (frozen meal, large meat portion)*
28150000	Fish dinner, NFS (frozen meal)*
28150210	Haddock with chopped spinach (diet frozen meal)*
28150220	Flounder with chopped broccoli (diet frozen meal)*
28150510	Fish in lemon-butter sauce with starch item, vegetable (frozen meal)*

28152030	Seafood newburg with rice, vegetable (frozen meal)*
28152050	Shrimp with rice, vegetable (frozen meal)*
28154010	Shrimp and vegetables in sauce with noodles (diet frozen meal)*
28160310	Meat loaf with potatoes, vegetable (frozen meal)*
28160650	Stuffed green pepper (frozen meal)*
28160710	Stuffed cabbage, with meat and tomato sauce (diet frozen meal)*
28310230	Meatball soup, Mexican style (Sopa de Albondigas)*
28321130	Bacon soup, cream of, prepared with water*
28340590	Chicken corn soup with noodles, home recipe*
28340640	Chicken vegetable soup with noodles, stew type, chunky style*
28340660	Chicken or turkey vegetable soup, home recipe*
28350110	Crab soup, NS as to tomato-base or cream style*
28350120	Crab soup, tomato-base*
28351110	Fish and vegetable soup, no potatoes (Sopa de pescado)*
28351120	Fish soup, with potatoes (Sopa de Pescado)*
28355210	Crab soup, cream of, prepared with milk*
28355250	Lobster bisque*
28355310	Oyster stew*
28355420	Shrimp soup, cream of, prepared with milk*
28355440	Shrimp gumbo*
28355450	Seafood soup with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy)*
28355460	Seafood soup with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy)*
28355470	Seafood soup with vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes))*
28355480	Seafood soup with vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes))*
31105000	Egg, whole, fried*
31106000	Egg, whole, baked, NS as to fat added in cooking*
31106020	Egg, whole, baked, fat added in cooking*
31109000	Egg, white only, cooked, NS as to fat added in cooking*
31109020	Egg, white only, cooked, fat added in cooking*
31111000	Egg, yolk only, cooked, NS as to fat added in cooking*
31111020	Egg, yolk only, cooked, fat added in cooking*
32101500	Egg, Benedict*
32104900	Egg omelet or scrambled egg, NS as to fat added in cooking*
32105000	Egg omelet or scrambled egg, fat added in cooking*
32105010	Egg omelet or scrambled egg, with cheese*
32105013	Egg omelet or scrambled egg, with seafood*
32105020	Egg omelet or scrambled egg, with fish*
32105030	Egg omelet or scrambled egg, with ham or bacon*
32105040	Egg omelet or scrambled egg, with dark-green vegetables*

32105045	Egg omelet or scrambled egg, with cheese and dark-green vegetables*
32105048	Egg omelet or scrambled egg, with mushrooms*
32105050	Egg omelet or scrambled egg, with vegetables other than dark-green vegetables*
32105055	Egg omelet or scrambled egg, with cheese and vegetables other than dark-green*
32105060	Egg omelet or scrambled egg, with peppers, onion, and ham*
32105080	Egg omelet or scrambled egg, with cheese and ham or bacon*
32105081	Egg omelet or scrambled egg, with ham or bacon, cheese, and dark-green vegetables*
32105082	Egg omelet or scrambled egg, with ham or bacon, cheese, and vegetables other than dark-green*
32105085	Egg omelet or scrambled egg, with cheese, ham or bacon, and tomatoes*
32105100	Egg omelet or scrambled egg, with potatoes and/or onions (Tortilla Espanola, traditional style Spanish omelet)*
32105110	Egg omelet or scrambled egg, with beef*
32105118	Egg omelet or scrambled egg, with sausage and vegetables other than dark-green*
32105119	Egg omelet or scrambled egg, with sausage, cheese, and vegetables other than dark-green*
32105121	Egg omelet or scrambled egg, with sausage and cheese*
32105122	Egg omelet or scrambled egg, with sausage*
32105125	Egg omelet or scrambled egg, with hot dogs*
32105126	Egg omelet or scrambled egg, with hot dog and cheese*
32105130	Egg omelet or scrambled egg, with onions, peppers, tomatoes, and mushrooms*
32105150	Egg omelet or scrambled egg, with cheese, beans, tomatoes, and chili sauce*
32105160	Egg omelet or scrambled egg, with chorizo*
32105161	Egg omelet or scrambled egg, with chorizo and cheese*
32105170	Egg omelet or scrambled egg with chicken*
32105180	Huevos rancheros*
32105200	Egg foo yung (young), NFS*
32105220	Pork egg foo yung (young)*
32105230	Shrimp egg foo yung (young)*
32105240	Beef egg foo yung (young)*
32105330	Scrambled eggs with jerked beef, Puerto Rican style (Revoltillo de tasajo)*
32202200	Egg and cheese on biscuit*
32400010	Egg white omelet or scrambled egg, NS as to fat added in cooking*
32400012	Egg white omelet or scrambled egg, fat added in cooking*
32400050	Egg white omelet or scrambled egg, with cheese*
33000100	Egg substitute, NS as to powdered, frozen, or liquid*
33102010	Scrambled egg, made from powdered mixture*
33201010	Scrambled egg, made from cholesterol-free frozen mixture*
33201110	Scrambled egg, made from cholesterol-free frozen mixture with cheese*
33201500	Scrambled egg, made from cholesterol-free frozen mixture with vegetables*
33202010	Scrambled egg, made from frozen mixture*
33301010	Scrambled egg, made from packaged liquid mixture*
35001000	Scrambled eggs, sausage, hash brown potatoes (frozen meal)*

41101000	Beans, dry, cooked, NS as to type and as to fat added in cooking*
41101010	Beans, dry, cooked, NS as to type, fat added in cooking*
41101100	White beans, dry, cooked, NS as to fat added in cooking*
41101110	White beans, dry, cooked, fat added in cooking*
41102000	Black, brown, or Bayo beans, dry, cooked, NS as to fat added in cooking*
41102010	Black, brown, or Bayo beans, dry, cooked, fat added in cooking*
41102210	Fava beans, cooked, fat added in cooking*
41103000	Lima beans, dry, cooked, NS as to fat added in cooking*
41103010	Lima beans, dry, cooked, fat added in cooking*
41103070	Pink beans, dry, cooked, fat added in cooking*
41104000	Pinto, calico, or red Mexican beans, dry, cooked, NS as to fat added in cooking*
41104010	Pinto, calico, or red Mexican beans, dry, cooked, fat added in cooking*
41106000	Red kidney beans, dry, cooked, NS as to fat added in cooking*
41106010	Red kidney beans, dry, cooked, fat added in cooking*
41108010	Mung beans, fat added in cooking*
41202500	Beans and tomatoes, NS as to fat added in cooking*
41202510	Beans and tomatoes, fat added in cooking*
41205010	Refried beans*
41209000	Falafil*
41210000	Bean cake*
41210100	Stewed dry red beans, Puerto Rican style (Habichuelas coloradas guisadas)*
41210150	Stewed pink beans with white potatoes and ham, Puerto Rican style*
41210190	Stewed red beans with pig's feet and potatoes, Puerto Rican style*
41210200	Black beans, Cuban style (Habichuelas negras guisadas a la Cubana)*
41301000	Cowpeas, dry, cooked, NS as to fat added in cooking*
41301010	Cowpeas, dry, cooked, fat added in cooking*
41302000	Chickpeas, dry, cooked, NS as to fat added in cooking*
41302010	Chickpeas, dry, cooked, fat added in cooking*
41303010	Green or yellow split peas, dry, cooked, fat added in cooking*
41303020	Green or yellow split peas, dry, cooked, NS as to fat added in cooking*
41304980	Lentils, dry, cooked, NS as to fat added in cooking*
41304990	Lentils, dry, cooked, fat added in cooking*
41306000	Loaf, lentil*
41310100	Stewed pigeon peas, Puerto Rican style (Gandules guisados, Gandur, Gandules)*
41310220	Fried chickpeas with bacon, Puerto Rican style (Garbanzos fritos con tocineta)*
41480000	Tofu, frozen dessert, flavors other than chocolate*
41480010	Tofu, frozen dessert, chocolate*
41601070	Soybean soup, miso broth*
41601090	Bean soup, with macaroni*
41601110	Bean and ham soup, chunky style*
41601170	Bean and rice soup*

41603010	Lentil soup*
41811950	Swiss steak, with gravy, meatless*
41812400	Vegetarian pot pie*
41812450	Vegetarian chili (made with meat substitute)*
41812500	Tofu and vegetables (including carrots, broccoli, and/or dark-green leafy vegetables (no potatoes)), with soy-based sauce (mixture)*
41812510	Tofu and vegetables (excluding carrots, broccoli, and dark-green leafy vegetables (no potatoes)), with soy-based sauce (mixture)*
42116100	Walnuts, honey-roasted*
51000180	Bread, made from home recipe or purchased at a bakery, NS as to major flour*
51000190	Bread, made from home recipe or purchased at a bakery, toasted, NS as to major flour*
51000250	Roll, made from home recipe or purchased at a bakery, NS as to major flour*
51000400	Roll, bran, NS as to type of bran*
51101050	Bread, white, made from home recipe or purchased at a bakery*
51101060	Bread, white, made from home recipe or purchased at a bakery, toasted*
51108100	Naan, Indian flatbread*
51115010	Bread, cornmeal and molasses*
51115020	Bread, cornmeal and molasses, toasted*
51140100	Bread, dough, fried*
51158100	Roll, Mexican, bolillo*
51161030	Roll, sweet, with fruit, frosted, diet*
51161050	Roll, sweet, with nuts, frosted*
51161250	Roll, sweet, no topping, Mexican (Pan Dulce)*
51161280	Roll, sweet, with raisins and icing, Mexican (Pan Dulce)*
51165060	Coffee cake, yeast type, made from home recipe or purchased at a bakery*
51168000	Bread, Spanish coffee*
51182010	Bread stuffing*
51184030	Bread stick, soft, prepared with garlic and parmesan cheese*
51201060	Bread, whole wheat, 100%, made from home recipe or purchased at bakery*
51300140	Bread, whole wheat, NS as to 100%, made from home recipe or purchased at bakery*
51300150	Bread, whole wheat, NS as to 100%, made from home recipe or purchased at bakery, toasted*
51300180	Bread, puri or poori (Indian puffed bread), whole wheat, NS as to 100%, fried*
51301040	Bread, wheat or cracked wheat, made from home recipe or purchased at bakery*
51301050	Bread, wheat or cracked wheat, made from home recipe or purchased at bakery, toasted*
51301540	Bread, French or Vienna, whole wheat, NS as to 100%, made from home recipe or purchased at bakery*
51301550	Bread, French or Vienna, whole wheat, NS as to 100%, made from home recipe or purchased at bakery, toasted*
51302500	Muffin, English, wheat bran*
51303050	Muffin, English, wheat or cracked wheat, with raisins*
51303070	Muffin, English, whole wheat, NS as to 100%, with raisins*
51320040	Roll, wheat or cracked wheat, made from home recipe or purchased at bakery*
51503000	Muffin, English, oat bran*

51601210	Bread, multigrain, with raisins*
51601220	Bread, multigrain, with raisins, toasted*
51801010	Bread, barley*
51804010	Bread, soy*
52101000	Biscuit, baking powder or buttermilk type, NS as to made from mix, refrigerated dough, or home recipe*
52104010	Biscuit, baking powder or buttermilk type, made from home recipe*
52104040	Biscuit, whole wheat*
52104100	Biscuit, cheese*
52104200	Biscuit, cinnamon-raisin*
52105100	Scone*
52105200	Scone, with fruit*
52202060	Cornbread, made from home recipe*
52206060	Cornbread muffin, stick, round, made from home recipe*
52207010	Corn flour patty or tart, fried*
52208010	Corn pone, baked*
52215260	Tortilla, whole wheat*
52220110	Cornmeal bread, Dominican style (Arepa Dominicana)*
52302500	Muffin, chocolate chip*
52302600	Muffin, chocolate*
52302610	Muffin, chocolate, lowfat*
52303010	Muffin, whole wheat*
52303500	Muffin, wheat*
52304040	Muffin, bran with fruit, lowfat*
52304100	Muffin, oatmeal*
52306010	Muffin, plain*
52306300	Muffin, cheese*
52306500	Muffin, pumpkin*
52306550	Muffin, zucchini*
52306700	Muffin, carrot*
52307120	Muffin, multigrain, with fruit*
52311010	Popover*
52403000	Bread, nut*
52404060	Bread, pumpkin*
52405010	Bread, fruit, without nuts*
52405100	Bread, fruit and nut*
52406010	Bread, whole wheat, with nuts*
52407000	Bread, zucchini*
52408000	Bread, Irish soda*
53100100	Cake, NS as to type, with or without icing*
53102000	Cake, applesauce, NS as to icing*
53102100	Cake, applesauce, without icing*

53102200	Cake, applesauce, with icing*
53102600	Cake, banana, without icing*
53102700	Cake, banana, with icing*
53103550	Cake, butter, without icing*
53103600	Cake, butter, with icing*
53104000	Cake, carrot, NS as to icing*
53104100	Cake, carrot, without icing*
53104260	Cake, carrot, with icing*
53104300	Cake, carrot, diet*
53104520	Cheesecake, diet*
53104550	Cheesecake with fruit*
53104580	Cheesecake -type dessert, made with yogurt, with fruit*
53104600	Cheesecake, chocolate*
53105050	Cake, chocolate, devil's food, or fudge, made from home recipe or purchased ready-to-eat, NS as to icing*
53105160	Cake, chocolate, devil's food, or fudge, without icing or filling, made from home recipe or purchased ready-to-eat*
53105200	Cake, chocolate, devil's food, or fudge, standard-type mix (eggs and water added to dry mix), with icing, coating, or filling*
53105300	Cake, German chocolate, with icing and filling*
53105500	Cake, chocolate, with icing, diet*
53106000	Cake, chocolate, devil's food, or fudge, pudding-type mix (oil, eggs, and water added to dry mix), without icing or filling*
53106050	Cake, chocolate, devil's food, or fudge, pudding-type mix (oil, eggs, and water added to dry mix), with icing, coating, or filling*
53107000	Cake, cupcake, NS as to type or icing*
53107200	Cake, cupcake, NS as to type, with icing*
53108000	Cake, cupcake, chocolate, NS as to icing*
53109270	Cake, cupcake, chocolate, with or without icing, fruit filling or cream filling, lowfat, cholesterol free*
53109300	Cake, Dobos Torte (non-chocolate layer cake with chocolate filling and icing)*
53111500	Cake, graham cracker, without icing*
53112000	Cake, ice cream and cake roll, chocolate*
53112100	Cake, ice cream and cake roll, not chocolate*
53114000	Cake, lemon, without icing*
53114100	Cake, lemon, with icing*
53115310	Cake, nut, without icing*
53115320	Cake, nut, with icing*
53115410	Cake, oatmeal, with icing*
53115450	Cake, peanut butter, with icing*
53115600	Cake, poppyseed, without icing*
53116000	Cake, pound, without icing*
53116020	Cake, pound, with icing*
53116270	Cake, pound, chocolate*

53116350	Cake, pound, Puerto Rican style (Ponque)*
53116390	Cake, pound, reduced fat, cholesterol free*
53116490	Cake, pumpkin, NS as to icing*
53116500	Cake, pumpkin, without icing*
53116510	Cake, pumpkin, with icing*
53116560	Cake, raisin-nut, with icing*
53117200	Cake, spice, with icing*
53118310	Cake, sponge, chocolate, with icing*
53118350	Cake, sweetpotato, with icing*
53118500	Cake, torte*
53119000	Cake, upside down (all fruits)*
53120060	Cake, white, made from home recipe or purchased ready-to-eat, NS as to icing*
53120160	Cake, white, without icing, made from home recipe or purchased ready-to-eat*
53120200	Cake, white, standard-type mix (egg whites and water added to mix), with icing*
53120260	Cake, white, with icing, made from home recipe or purchased ready-to-eat*
53120330	Cake, white, pudding-type mix (oil, egg whites, and water added to dry mix), without icing*
53120350	Cake, white, pudding-type mix (oil, egg whites, and water added to dry mix), with icing*
53120400	Cake, white, eggless, lowfat*
53120500	Cake, whole wheat, with fruit and nuts, without icing*
53121060	Cake, yellow, made from home recipe or purchased ready-to- eat, NS as to icing*
53121160	Cake, yellow, without icing, made from home recipe or purchased ready-to-eat*
53121200	Cake, yellow, standard-type mix (eggs and water added to dry mix), with icing*
53121260	Cake, yellow, with icing, made from home recipe or purchased ready-to-eat*
53121300	Cake, yellow, pudding-type mix (oil, eggs, and water added to dry mix), without icing*
53121330	Cake, yellow, pudding-type mix (oil, eggs, and water added to dry mix), with icing*
53122070	Cake, shortcake, biscuit type, with whipped cream and fruit*
53122080	Cake, shortcake, biscuit type, with fruit*
53124110	Cake, zucchini, without icing*
53124120	Cake, zucchini, with icing*
53200100	Cookie, batter or dough, raw, not chocolate*
53201000	Cookie, NFS*
53202000	Cookie, almond*
53203500	Cookie, biscotti (Italian sugar cookie)*
53204000	Cookie, brownie, NS as to icing*
53204010	Cookie, brownie, without icing*
53204500	Cookie, brownie, with cream cheese filling, without icing*
53204830	Cookie, brownie, lowfat, with icing*
53204840	Cookie, brownie, lowfat, without icing*
53205250	Cookie, butterscotch, brownie*
53205500	Cookie, butterscotch chip*
53205600	Cookie, caramel coated, with nuts*

53206020	Cookie, chocolate chip, made from home recipe or purchased at a bakery*
53206030	Cookie, chocolate chip, reduced fat*
53206550	Cookie, chocolate, made with oatmeal and coconut (no-bake)*
53209020	Cookie, chocolate sandwich, reduced fat*
53215500	Cookie, coconut*
53216000	Cookie, coconut and nut*
53226500	Cookie, marshmallow, with rice cereal (no-bake)*
53226550	Cookie, marshmallow, with rice cereal and chocolate chips*
53231400	Cookie, multigrain, high fiber*
53233000	Cookie, oatmeal*
53233040	Cookie, oatmeal, reduced fat, with raisins*
53233050	Cookie, oatmeal sandwich, with creme filling*
53233060	Cookie, oatmeal, with chocolate chips*
53233100	Cookie, oatmeal, with chocolate and peanut butter (no-bake)*
53233500	Cookie, oat bran*
53234250	Cookie, peanut butter with rice cereal (no-bake)*
53235500	Cookie, with peanut butter filling, chocolate-coated*
53236000	Cookie, pizzelle (Italian style wafer)*
53236100	Cookie, pumpkin*
53237010	Cookie, raisin sandwich, cream-filled*
53241500	Cookie, butter or sugar cookie*
53243050	Cookie, vanilla sandwich, reduced fat*
53244010	Cookie, butter or sugar, with chocolate icing or filling*
53244020	Cookie, butter or sugar, with icing or filling other than chocolate*
53247050	Cookie, vanilla wafer, reduced fat*
53247500	Cookie, vanilla with caramel, coconut, and chocolate coating*
53248000	Cookie, whole wheat, dried fruit, nut*
53300170	Pie, individual size or tart, NFS*
53301500	Pie, apple, one crust*
53301750	Pie, apple, diet*
53303000	Pie, blackberry, two crust*
53303500	Pie, berry, not blackberry, blueberry, boysenberry, huckleberry, raspberry, or strawberry; two crust*
53303510	Pie, berry, not blackberry, blueberry, boysenberry, huckleberry, raspberry, or strawberry; one crust*
53304050	Pie, blueberry, one crust*
53304070	Pie, blueberry, individual size or tart*
53305010	Pie, cherry, one crust*
53305700	Pie, lemon (not cream or meringue)*
53305720	Pie, lemon (not cream or meringue), individual size or tart*
53306070	Pie, mince, individual size or tart*
53307050	Pie, peach, one crust*

53307070	Pie, peach, individual size or tart*
53307500	Pie, pear, two crust*
53308000	Pie, pineapple, two crust*
53308500	Pie, prune, one crust*
53309070	Pie, raisin, individual size or tart*
53310050	Pie, raspberry, two crust*
53311000	Pie, rhubarb, two crust*
53311050	Pie, rhubarb, one crust*
53312000	Pie, strawberry, one crust*
53313000	Pie, strawberry-rhubarb, two crust*
53340500	Pie, cherry, made with cream cheese and sour cream*
53341750	Pie, chess*
53342000	Pie, chocolate cream*
53342070	Pie, chocolate cream, individual size or tart*
53343070	Pie, coconut cream, individual size or tart*
53345000	Pie, lemon cream*
53345070	Pie, lemon cream, individual size or tart*
53346000	Pie, peanut butter cream*
53346500	Pie, pineapple cream*
53347100	Pie, raspberry cream*
53348000	Pie, strawberry cream*
53360000	Pie, sweetpotato*
53366000	Pie, yogurt, frozen*
53385500	Pie, oatmeal*
53386000	Pie, pudding, flavors other than chocolate*
53387000	Pie, Toll house chocolate chip*
53390000	Pie, shoo-fly*
53400200	Blintz, cheese-filled*
53400300	Blintz, fruit-filled*
53410100	Cobbler, apple*
53410300	Cobbler, berry*
53410500	Cobbler, cherry*
53410800	Cobbler, peach*
53410850	Cobbler, pear*
53410860	Cobbler, pineapple*
53415100	Crisp, apple, apple dessert*
53415120	Fritter, apple*
53415200	Fritter, banana*
53415300	Crisp, blueberry*
53415400	Crisp, cherry*
53415500	Crisp, peach*

53420210	Cream puff, eclair, custard or cream filled, iced, reduced fat*
53420300	Air filled fritter or fried puff, without syrup, Puerto Rican style (Bunuelos de viento)*
53420400	Sopaipilla, without syrup or honey*
53430000	Crepe, dessert type, NS as to filling*
53430100	Crepe, dessert type, chocolate-filled*
53430200	Crepe, dessert type, fruit-filled*
53430750	Tamale, sweet, with fruit*
53440300	Strudel, berry*
53440500	Strudel, cherry*
53440600	Strudel, cheese*
53440800	Strudel, cheese and fruit*
53441110	Baklava*
53441210	Basbousa (semolina dessert dish)*
53450000	Turnover or dumpling, apple*
53450500	Turnover or dumpling, cherry*
53452100	Pastry, fruit-filled*
53452120	Pastry, Oriental, made with bean or lotus seed paste filling (baked)*
53452130	Pastry, Oriental, made with bean paste and salted egg yolk filling (baked)*
53452170	Pastry, cookie type, fried*
53452200	Pastry, Italian, with cheese*
53452450	Cheese pastry puffs*
53452500	Pastry, mainly flour and water, fried*
53453150	Empanada, Mexican turnover, fruit-filled*
53453170	Empanada, Mexican turnover, pumpkin*
53520150	Doughnut, cake type, chocolate covered, dipped in peanuts*
53520160	Doughnut, chocolate, cake type, with chocolate icing*
53520200	Churros*
53521100	Doughnut, chocolate, raised or yeast, with chocolate icing*
53521130	Doughnut, raised or yeast, chocolate covered*
54403040	Popcorn, air-popped, buttered*
55101010	Pancakes, reduced calorie, high fiber*
55103000	Pancakes, with fruit*
55103100	Pancakes, with chocolate chips*
55105000	Pancakes, buckwheat*
55105100	Pancakes, cornmeal*
55105200	Pancakes, whole wheat*
55202000	Waffle, wheat, bran, or multigrain*
55203500	Waffle, nut and honey*
55204000	Waffle, cornmeal*
55205000	Waffle, 100% whole wheat or 100% whole grain*
55206000	Waffle, oat bran*

55207000	Waffle, multi-bran*
55211050	Waffle, plain, lowfat*
55301000	French toast, plain*
55401000	Crepe, plain*
55610200	Dumpling, fried, Puerto Rican style*
55610300	Dumpling, plain*
56101030	Macaroni, cooked, fat added in cooking*
56102020	Macaroni, whole wheat, cooked, fat added in cooking*
56104020	Macaroni, cooked, vegetable, fat added in cooking*
56112030	Noodles, cooked, fat added in cooking*
56114020	Noodles, cooked, spinach, fat added in cooking*
56117010	Long rice noodles (made from mung beans), cooked, fat added in cooking*
56117110	Chow fun rice noodles, cooked, fat added in cooking*
56131000	Spaghetti, cooked, fat added in cooking*
56133010	Spaghetti, cooked, whole wheat, fat added in cooking*
56200510	Buckwheat groats, cooked, fat added in cooking*
56201020	Grits, cooked, corn or hominy, regular, fat added in cooking*
56201040	Grits, cooked, corn or hominy, NS as to regular, quick, or instant, fat added in cooking*
56201072	Grits, cooked, corn or hominy, with cheese, regular, fat added in cooking*
56201082	Grits, cooked, corn or hominy, with cheese, quick, fat added in cooking*
56201092	Grits, cooked, corn or hominy, with cheese, instant, fat added in cooking*
56201120	Grits, cooked, corn or hominy, quick, fat added in cooking*
56201220	Grits, cooked, corn or hominy, instant, fat added in cooking*
56201550	Cornmeal dumpling*
56202100	Millet, cooked, fat added in cooking*
56203040	Oatmeal, cooked, NS as to regular, quick, or instant, fat added in cooking*
56203050	Oatmeal, cooked, regular, fat added in cooking*
56203060	Oatmeal, cooked, quick (1 or 3 minutes), fat added in cooking*
56203070	Oatmeal, cooked, instant, fat added in cooking*
56203221	Oatmeal, cooked, regular, made with milk, fat added in cooking*
56203222	Oatmeal, cooked, quick (1 or 3 minutes), made with milk, fat added in cooking*
56203223	Oatmeal, cooked, instant, made with milk, fat added in cooking*
56205000	Rice, cooked, NFS*
56205170	Yellow rice, cooked, regular, fat added in cooking*
56205230	Rice dessert bar, frozen, flavors other than chocolate, nondairy, carob covered*
56205320	Rice, white and wild, cooked, fat added in cooking*
56205330	Rice, white and wild, cooked, NS as to fat added in cooking*
56205340	Rice, brown and wild, cooked, fat added in cooking*
56205400	Rice, cooked, NS as to type, fat added in cooking*
56205410	Rice, white, cooked with (fat) oil, Puerto Rican style (Arroz blanco)*
56205420	Rice, white, cooked, regular, fat added in cooking*

56205430	Rice, white, cooked, instant, fat added in cooking*
56205440	Rice, white, cooked, converted, fat added in cooking*
56205510	Rice, brown, cooked, regular, fat added in cooking*
56205550	Rice, brown, cooked, instant, fat added in cooking*
56207060	Wheat, cream of, cooked, instant, fat added in cooking*
56207080	Wheat, cream of, cooked, NS as to regular, quick, or instant, fat added in cooking*
56207180	Couscous, plain, cooked, fat added in cooking*
56207220	Wheat, cream of, cooked, regular, fat added in cooking*
56207230	Wheat, cream of, cooked, quick, fat added in cooking*
56207330	Whole wheat cereal, wheat and barley, cooked, fat added in cooking*
56208510	Oat bran cereal, cooked, fat added in cooking*
58100150	Burrito with beef and potato, no beans*
58100180	Burrito with pork and beans*
58100210	Burrito with chicken and beans*
58100220	Burrito with chicken, beans, and cheese*
58100245	Burrito with chicken, beans, cheese, and sour cream*
58100300	Burrito with beans and rice, meatless*
58100310	Burrito with beans, meatless*
58100330	Burrito with rice, beans, cheese, sour cream, lettuce, tomato and guacamole, meatless*
58100340	Burrito with eggs, sausage, cheese and vegetables*
58100360	Chilaquiles, tortilla casserole with salsa, cheese, and egg*
58100370	Chilaquiles, tortilla casserole with salsa and cheese, no egg*
58100400	Enchilada with beef, no beans*
58100510	Enchilada with beef and beans*
58100520	Enchilada with beef, beans, and cheese*
58100530	Enchilada with beef and cheese, no beans*
58100600	Enchilada with chicken, tomato-based sauce*
58100620	Enchilada with chicken, beans, and cheese, tomato- based sauce*
58100630	Enchilada with chicken and cheese, no beans, tomato- based sauce*
58100710	Enchilada with beans, meatless*
58100720	Enchilada with beans and cheese, meatless*
58100800	Enchilada with cheese, meatless, no beans*
58100900	Enchilada with seafood, tomato-based sauce*
58101230	Flauta with beef*
58101240	Flauta with chicken*
58101600	Soft taco with bean, cheese, and lettuce*
58101610	Soft taco with bean, cheese, lettuce, and tomato and/or salsa*
58101615	Soft taco with bean, cheese, lettuce, tomato and/or salsa, and sour cream*
58101710	Taco or tostada with beans, meatless, with lettuce, tomato and salsa*
58101720	Taco or tostada with beans and cheese, meatless, with lettuce, tomato and salsa*
58101730	Taco or tostada with beans, cheese, meat, lettuce, tomato and salsa*

58101740	Soft taco with egg and potato*
58104260	Chalupa with beans, cheese, lettuce and tomato*
58104520	Chimichanga with beans and cheese, meatless, with lettuce and tomato*
58104530	Chimichanga with chicken and cheese*
58104550	Chimichanga with chicken, sour cream, lettuce and tomato, no cheese*
58104710	Quesadilla with cheese, meatless*
58104730	Quesadilla with meat and cheese*
58104820	Taquitos with meat*
58104830	Taquitos with chicken*
58105100	Pupusa, cheese-filled*
58105105	Pupusa, bean-filled*
58105110	Pupusa, meat-filled*
58106820	Pizza with beans and vegetables, thin crust*
58106830	Pizza with beans and vegetables, thick crust*
58107030	Pizza, no cheese, NS as to type of crust*
58107050	Pizza, no cheese, thin crust*
58107060	Pizza, no cheese, regular crust*
58107100	Pizza, no cheese, thick crust*
58108000	Calzone, with cheese, meatless*
58108010	Calzone, with meat and cheese*
58108050	Pizza rolls*
58112510	Dumpling, steamed, filled with meat, poultry, or seafood*
58116110	Meat turnover, Puerto Rican style (Pastelillo de carne; Empanadilla)*
58116115	Empanada, Mexican turnover, filled with cheese and vegetables*
58116120	Empanada, Mexican turnover, filled with meat and vegetables*
58116130	Empanada, Mexican turnover, filled with chicken and vegetables*
58116310	Cheese turnover, Puerto Rican style (Pastelillo de queso; Empanadilla)*
58117110	Cornmeal fritter, Puerto Rican style (Arepa; P.R. arepita)*
58117410	Codfish fritter, Puerto Rican style (Bacalaito)*
58120110	Crepes, filled with meat, fish, or poultry, with sauce*
58120120	Crepe, filled with beef, pork, fish and/or poultry, no sauce on top*
58121510	Dumpling, meat-filled*
58121610	Dumpling, potato- or cheese-filled*
58122210	Gnocchi, cheese*
58122220	Gnocchi, potato*
58122310	Knish, potato (pastry filled with potato)*
58122320	Knish, cheese (pastry filled with cheese)*
58122330	Knish, meat (pastry filled with meat)*
58123110	Sweet bread dough, filled with meat, steamed*
58123120	Sweet bread dough, filled with bean paste, meatless, steamed*
58124210	Pastry, cheese-filled*

58124250	Spanakopitta*
58124500	Pastry, filled with potatoes and peas, fried*
58125110	Quiche with meat, poultry or fish*
58125120	Spinach quiche, meatless*
58125180	Cheese quiche, meatless*
58126000	Bierock (turnover filled with ground beef and cabbage mixture)*
58126110	Turnover, meat-filled, no gravy*
58126280	Turnover, chicken- or turkey-, and vegetable-filled, lower in fat*
58126290	Turnover, meat- and cheese-filled, lower in fat*
58126300	Turnover, meat- and cheese-filled, tomato-based sauce, lower in fat*
58126310	Turnover, chicken, with gravy*
58126400	Turnover, filled with egg, meat and cheese*
58127110	Vegetables in pastry*
58127150	Vegetables and cheese in pastry*
58127210	Croissant sandwich, filled with ham and cheese*
58128000	Biscuit with gravy*
58128110	Chicken cornbread*
58128120	Cornmeal dressing with chicken or turkey and vegetables*
58128210	Dressing with oysters*
58128220	Dressing with chicken or turkey and vegetables*
58128250	Dressing with meat and vegetables*
58131110	Ravioli, NS as to filling, with tomato sauce*
58131120	Ravioli, NS as to filling, with cream sauce*
58131320	Ravioli, meat-filled, with tomato sauce or meat sauce*
58131330	Ravioli, meat-filled, with cream sauce*
58131530	Ravioli, cheese-filled, with meat sauce*
58131535	Ravioli, cheese-filled, with cream sauce*
58131600	Ravioli, cheese and spinach-filled, with cream sauce*
58132110	Spaghetti with tomato sauce, meatless*
58132310	Spaghetti with tomato sauce and meatballs or spaghetti with meat sauce or spaghetti with meat sauce and meatballs*
58132340	Spaghetti with tomato sauce and vegetables*
58132350	Spaghetti with tomato sauce, meatless, whole wheat noodles*
58132360	Spaghetti with tomato sauce and meatballs, whole wheat noodles or spaghetti with meat sauce, whole wheat noodles or spaghetti with meat sauce and meatballs, whole wheat noodles*
58132450	Spaghetti with tomato sauce, meatless, made with spinach noodles*
58132460	Spaghetti with tomato sauce and meatballs made with spinach noodles, or spaghetti with meat sauce made with spinach noodles, or spaghetti with meat sauce and meatballs made with spinach noodles*
58132710	Spaghetti with tomato sauce and frankfurters or hot dogs*
58132800	Spaghetti with clam sauce, NS as to red or white*
58132820	Spaghetti with white clam sauce*

58132910	Spaghetti with tomato sauce and chicken or turkey*
58134623	Tortellini, cheese-filled, meatless, with tomato sauce, canned*
58134650	Tortellini, meat-filled, no sauce*
58134710	Tortellini, spinach-filled, with tomato sauce*
58134720	Tortellini, spinach-filled, no sauce*
58134810	Cannelloni, cheese- and spinach-filled, no sauce*
58135110	Chow fun noodles with meat and vegetables*
58135120	Chow fun noodles with vegetables, meatless*
58136110	Lo mein, NFS*
58136120	Lo mein, meatless*
58136130	Lo mein, with shrimp*
58136140	Lo mein, with pork*
58136150	Lo mein, with beef*
58136160	Lo mein, with chicken*
58137210	Pad Thai, NFS*
58137220	Pad Thai, meatless*
58137230	Pad Thai with chicken*
58137240	Pad Thai with seafood*
58137250	Pad Thai with meat*
58145110	Macaroni or noodles with cheese*
58145114	Macaroni or noodles with cheese, made from dry mix*
58145120	Macaroni or noodles with cheese and tuna*
58145130	Macaroni or noodles with cheese and beef*
58145140	Macaroni or noodles with cheese and tomato*
58145150	Macaroni or noodles with cheese and pork or ham*
58145160	Macaroni or noodles with cheese and frankfurters or hot dogs*
58145170	Macaroni and cheese with egg*
58145190	Macaroni or noodles with cheese and chicken or turkey*
58146100	Pasta with tomato sauce, meatless*
58146110	Pasta with meat sauce*
58146120	Pasta with cheese and meat sauce*
58146130	Pasta with carbonara sauce*
58146150	Pasta with cheese and tomato sauce, meatless*
58146160	Pasta with vegetables, no sauce or dressing*
58146200	Pasta, meat-filled, with gravy, canned*
58146300	Pasta, whole wheat, with meat sauce*
58147100	Pasta with pesto sauce*
58147110	Macaroni or noodles with beans or lentils and tomato sauce*
58147510	Flavored pasta*
58149110	Noodle pudding*
58149160	Noodle pudding, with milk*

58155110	Rice with chicken, Puerto Rican style (Arroz con Pollo)*
58155320	Seafood paella, Puerto Rican style*
58155610	Rice meal fritter, Puerto Rican style (Almojabana)*
58155810	Stewed rice, Puerto Rican style (arroz quisado)*
58156210	Rice with vienna sausage, Puerto Rican style (arroz con salchichas)*
58156310	Rice with Spanish sausage, Puerto Rican style*
58156610	Pigeon pea asopao (Asopao de gandules)*
58156710	Rice with stewed beans, Puerto Rican style*
58160110	Rice with beans*
58160120	Rice with beans and tomatoes*
58160130	Rice with beans and chicken*
58160135	Rice with beans and beef*
58160140	Rice with beans and pork*
58160150	Red beans and rice*
58160200	Rice with vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce, NS as to fat added in cooking*
58160204	Rice with vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce, fat added in cooking*
58160205	Rice with vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce, NS as to fat added in cooking*
58160209	Rice with vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce, fat added in cooking*
58160220	Rice with vegetables, tomato-based sauce (mixture)*
58160290	Rice with corn, NS as to fat added in cooking*
58160294	Rice with corn, fat added in cooking*
58160300	Rice with peas*
58160304	Rice with peas, fat added in cooking*
58160310	Rice with peas and carrots, NS as to fat added in cooking*
58160314	Rice with peas and carrots, fat added in cooking*
58160320	Rice with tomatoes, NS as to fat added in cooking*
58160324	Rice with tomatoes, fat added in cooking*
58161200	Rice, cooked with coconut milk (Arroz con coco)*
58161300	White rice with tomato sauce*
58161310	Rice, brown, with tomato sauce*
58161320	Rice, brown, with beans*
58161325	Rice, brown, with beans and tomatoes*
58161400	Rice, brown, with vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce, NS as to fat added in cooking*
58161404	Rice, brown, with vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce, fat added in cooking*
58161405	Rice, brown, with vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce, NS as to fat added in cooking*
58161409	Rice, brown, with vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce, fat added in cooking*
58161430	Rice, brown, with peas, NS as to fat added in cooking*

58161454	Rice, brown, with tomatoes, fat added in cooking*
58161510	Grape leaves stuffed with rice*
58161710	Rice croquette*
58162090	Stuffed pepper, with meat*
58162110	Stuffed pepper, with rice and meat*
58162120	Stuffed pepper, with rice, meatless*
58162140	Stuffed tomato, with rice, meatless*
58162310	Rice pilaf*
58163130	Dirty rice*
58163310	Flavored rice mixture*
58163330	Flavored rice mixture with cheese*
58163380	Flavored rice and pasta mixture*
58163400	Flavored rice and pasta mixture, reduced sodium*
58163410	Spanish rice*
58163450	Spanish rice with ground beef*
58163510	Rice dressing*
58163610	Rice-vegetable medley*
58164110	Rice with raisins*
58175110	Tabbouleh (bulgar with tomatoes and parsley)*
58301020	Lasagna with cheese and sauce (diet frozen meal)*
58301050	Lasagna with cheese and meat sauce (diet frozen meal)*
58301080	Lasagna with cheese and meat sauce, reduced fat and sodium (diet frozen meal)*
58301110	Vegetable lasagna (frozen meal)*
58302080	Noodles with vegetables in tomato-based sauce (diet frozen meal)*
58303100	Rice, with broccoli, cheese sauce (frozen side dish)*
58304010	Spaghetti and meatballs dinner, NFS (frozen meal)*
58304050	Spaghetti with meat and mushroom sauce (diet frozen meal)*
58304200	Ravioli, cheese-filled, with tomato sauce (diet frozen meal)*
58304220	Rigatoni with meat sauce and cheese (diet frozen meal)*
58305250	Pasta with vegetable and cheese sauce (diet frozen meal)*
58306020	Beef enchilada, chili gravy, rice, refried beans (frozen meal)*
58306070	Cheese enchilada (frozen meal)*
58310210	Sausage and french toast (frozen meal)*
58310310	Pancakes and sausage (frozen meal)*
58402020	Beef dumpling soup*
58402100	Beef noodle soup, home recipe*
58403040	Chicken noodle soup, home recipe*
58404030	Chicken or turkey rice soup, home recipe*
58404100	Rice and potato soup, Puerto Rican style*
58404500	Matzo ball soup*
58406020	Turkey noodle soup, home recipe*

58408500	Noodle soup with vegetables, Oriental style*
58409000	Noodle soup, with fish ball, shrimp, and dark green leafy vegetable*
58421010	Sopa Seca de Fideo, Mexican style, made with dry noodles*
58421020	Sopa de Fideo Aguada, Mexican style noodle soup*
58421060	Sopa seca de arroz (dry rice soup), Mexican style*
58421080	Sopa de tortilla, Mexican style tortilla soup*
58450300	Noodle soup, made with milk*
59003000	Meat substitute, cereal- and vegetable protein-based, fried*
61113500	Lemon pie filling*
63101410	Apple rings, fried*
63101500	Apple, fried*
63107210	Banana, ripe, fried*
63113030	Cherry pie filling*
63401070	Fruit, chocolate covered*
71000100	White potato, NFS*
71101100	White potato, baked, peel eaten, NS as to fat added in cooking*
71101120	White potato, baked, peel eaten, fat added in cooking*
71103000	White potato, boiled, without peel, NS as to fat added in cooking*
71103020	White potato, boiled, without peel, fat added in cooking*
71103100	White potato, boiled, with peel, NS as to fat added in cooking*
71103120	White potato, boiled, with peel, fat added in cooking*
71104000	White potato, roasted, NS as to fat added in cooking*
71104020	White potato, roasted, fat added in cooking*
71106000	Stewed potatoes, Puerto Rican style (Papas guisadas)*
71301000	White potato, cooked, with sauce, NS as to sauce*
71301020	White potato, cooked, with cheese*
71301120	White potato, cooked, with ham and cheese*
71305010	White potato, scalloped*
71305110	White potato, scalloped, with ham*
71402040	White potato, french fries, breaded or battered*
71403000	White potato, home fries*
71403500	White potato, home fries, with green or red peppers and onions*
71501020	White potato, from fresh, mashed, made with milk and fat*
71501025	White potato, from fresh, mashed, made with milk, sour cream and/or cream cheese and fat*
71501030	White potato, from fresh, mashed, made with fat*
71501040	White potato, from dry, mashed, made with milk and fat*
71501050	White potato, from fresh, mashed, made with milk, fat and cheese*
71501055	White potato, from fresh, mashed, made with sour cream and/or cream cheese and fat*
71501060	White potato, from dry, mashed, made with milk, fat and egg*
71501070	White potato, from dry, mashed, made with milk, fat, egg and cheese*
71501200	White potato, from complete dry mix, mashed, made with water*

71501300	White potato, from dry, mashed, NS as to milk or fat*
71501310	White potato, from fresh, mashed, NS as to milk or fat*
71503010	White potato, patty*
71507000	White potato, stuffed, baked, peel not eaten, NS as to topping*
71507005	White potato, stuffed, baked, peel not eaten, stuffed with butter or margarine*
71507010	White potato, stuffed, baked, peel not eaten, stuffed with sour cream*
71507020	White potato, stuffed, baked, peel not eaten, stuffed with cheese*
71507040	White potato, stuffed, baked, peel not eaten, stuffed with broccoli and cheese sauce*
71507050	White potato, stuffed, baked, peel not eaten, stuffed with meat in cream sauce*
71508005	White potato, stuffed, baked, peel eaten, stuffed with butter or margarine*
71508010	White potato, stuffed, baked, peel eaten, stuffed with sour cream*
71508020	White potato, stuffed, baked, peel eaten, stuffed with cheese*
71508040	White potato, stuffed, baked, peel eaten, stuffed with broccoli and cheese sauce*
71508060	White potato, stuffed, baked, peel eaten, stuffed with bacon and cheese*
71508070	White potato, stuffed, baked, peel not eaten, stuffed with bacon and cheese*
71701000	Potato pancake*
71703000	Stewed potatoes, Mexican style (Papas guisadas)*
71703040	Stewed potatoes with tomatoes, Mexican style (Papas guisadas con tomate)*
71704000	Stewed potatoes with tomatoes*
71801100	Potato and cheese soup*
71802010	Macaroni and potato soup*
71803010	Potato chowder*
71900200	Plantain, fried, NS as to green or ripe*
71901110	Fried green plantain, Puerto Rican style (Tostones)*
71905120	Plantain, ripe, rolled in flour, fried*
71910210	Green banana, fried*
71910310	Pickled green bananas, Puerto Rican style (Guineos verdes en escabeche)*
71930090	Cassava (yuca blanca), cooked, NS as to fat added in cooking*
71930120	Cassava (yuca blanca), cooked, fat added in cooking*
72104220	Chard, cooked, fat added in cooking*
72107200	Collards, cooked, NS as to form, NS as to fat added in cooking*
72107201	Collards, cooked, from fresh, NS as to fat added in cooking*
72107202	Collards, cooked, from frozen, NS as to fat added in cooking*
72107203	Collards, cooked, from canned, NS as to fat added in cooking*
72107220	Collards, cooked, NS as to form, fat added in cooking*
72107221	Collards, cooked, from fresh, fat added in cooking*
72107222	Collards, cooked, from frozen, fat added in cooking*
72107223	Collards, cooked, from canned, fat added in cooking*
72110221	Cress, cooked, from fresh, fat added in cooking*
72116140	Caesar salad (with romaine)*
72116220	Escarole, cooked, fat added in cooking*

72118200	Greens, cooked, NS as to form, NS as to fat added in cooking*
72118201	Greens, cooked, from fresh, NS as to fat added in cooking*
72118202	Greens, cooked, from frozen, NS as to fat added in cooking*
72118220	Greens, cooked, NS as to form, fat added in cooking*
72118221	Greens, cooked, from fresh, fat added in cooking*
72118223	Greens, cooked, from canned, fat added in cooking*
72119200	Kale, cooked, NS as to form, NS as to fat added in cooking*
72119221	Kale, cooked, from fresh, fat added in cooking*
72122200	Mustard greens, cooked, NS as to form, NS as to fat added in cooking*
72122203	Mustard greens, cooked, from canned, NS as to fat added in cooking*
72122220	Mustard greens, cooked, NS as to form, fat added in cooking*
72122221	Mustard greens, cooked, from fresh, fat added in cooking*
72122222	Mustard greens, cooked, from frozen, fat added in cooking*
72122223	Mustard greens, cooked, from canned, fat added in cooking*
72123020	Poke greens, cooked, fat added in cooking*
72125200	Spinach, cooked, NS as to form, NS as to fat added in cooking*
72125201	Spinach, cooked, from fresh, NS as to fat added in cooking*
72125202	Spinach, cooked, from frozen, NS as to fat added in cooking*
72125220	Spinach, cooked, NS as to form, fat added in cooking*
72125221	Spinach, cooked, from fresh, fat added in cooking*
72125222	Spinach, cooked, from frozen, fat added in cooking*
72125223	Spinach, cooked, from canned, fat added in cooking*
72125240	Spinach souffle*
72125500	Spinach and chickpeas, fat added*
72128200	Turnip greens, cooked, NS as to form, NS as to fat added in cooking*
72128201	Turnip greens, cooked, from fresh, NS as to fat added in cooking*
72128203	Turnip greens, cooked, from canned, NS as to fat added in cooking*
72128220	Turnip greens, cooked, NS as to form, fat added in cooking*
72128221	Turnip greens, cooked, from fresh, fat added in cooking*
72128222	Turnip greens, cooked, from frozen, fat added in cooking*
72128223	Turnip greens, cooked, from canned, fat added in cooking*
72128520	Turnip greens, canned, low sodium, cooked, fat added in cooking*
72201200	Broccoli, cooked, NS as to form, NS as to fat added in cooking*
72201201	Broccoli, cooked, from fresh, NS as to fat added in cooking*
72201202	Broccoli, cooked, from frozen, NS as to fat added in cooking*
72201220	Broccoli, cooked, NS as to form, fat added in cooking*
72201221	Broccoli, cooked, from fresh, fat added in cooking*
72201222	Broccoli, cooked, from frozen, fat added in cooking*
72202010	Broccoli casserole (broccoli, noodles, and cream sauce)*
72202020	Broccoli casserole (broccoli, rice, cheese, and mushroom sauce)*
72202030	Broccoli, batter-dipped and fried*

72308500	Dark-green leafy vegetable soup, meatless, Oriental style*
73102200	Carrots, cooked, NS as to form, NS as to fat added in cooking*
73102201	Carrots, cooked, from fresh, NS as to fat added in cooking*
73102202	Carrots, cooked, from frozen, NS as to fat added in cooking*
73102203	Carrots, cooked, from canned, NS as to fat added in cooking*
73102220	Carrots, cooked, NS as to form, fat added in cooking*
73102221	Carrots, cooked, from fresh, fat added in cooking*
73102222	Carrots, cooked, from frozen, fat added in cooking*
73102223	Carrots, cooked, from canned, fat added in cooking*
73102241	Carrots, cooked, from fresh, glazed*
73102242	Carrots, cooked, from frozen, glazed*
73102243	Carrots, cooked, from canned, glazed*
73111200	Peas and carrots, cooked, NS as to form, NS as to fat added in cooking*
73111202	Peas and carrots, cooked, from frozen, NS as to fat added in cooking*
73111203	Peas and carrots, cooked, from canned, NS as to fat added in cooking*
73111220	Peas and carrots, cooked, NS as to form, fat added in cooking*
73111221	Peas and carrots, cooked, from fresh, fat added in cooking*
73111222	Peas and carrots, cooked, from frozen, fat added in cooking*
73111260	Peas and carrots, canned, low sodium, fat added in cooking*
73111400	Carrots in tomato sauce*
73201000	Pumpkin, cooked, NS as to form, NS as to fat added in cooking*
73201001	Pumpkin, cooked, from fresh, NS as to fat added in cooking*
73201021	Pumpkin, cooked, from fresh, fat added in cooking*
73211110	Sweetpotato and pumpkin casserole, Puerto Rican style*
73301000	Squash, winter type, mashed, NS as to fat or sugar added in cooking*
73301020	Squash, winter type, mashed, fat added in cooking, no sugar added in cooking*
73303000	Squash, winter type, baked, NS as to fat or sugar added in cooking*
73303020	Squash, winter type, baked, fat added in cooking, no sugar added in cooking*
73305010	Squash, winter, baked with cheese*
73401000	Sweetpotato, NFS*
73402000	Sweetpotato, baked, peel eaten, NS as to fat added in cooking*
73402020	Sweetpotato, baked, peel eaten, fat added in cooking*
73403000	Sweetpotato, baked, peel not eaten, NS as to fat added in cooking*
73403020	Sweetpotato, baked, peel not eaten, fat added in cooking*
73405000	Sweetpotato, boiled, without peel, NS as to fat added in cooking*
73405020	Sweetpotato, boiled, without peel, fat added in cooking*
73406000	Sweetpotato, candied*
73409000	Sweetpotato, casserole or mashed*
74202050	Tomatoes, red, NS as to form, fried*
74202051	Tomatoes, red, from fresh, fried*
74204011	Tomatoes, from fresh, stewed*

74205010	Tomatoes, green, cooked, NS as to form*
74205011	Tomatoes, green, cooked, from fresh*
74402200	Salsa, red, cooked, homemade*
74402250	Enchilada sauce, red*
74410110	Puerto Rican seasoning with ham*
74415110	Puerto Rican seasoning with ham and tomato sauce*
74504020	Tomato and okra, cooked, fat added in cooking*
74504100	Tomato and onion, cooked, NS as to fat added in cooking*
74504120	Tomato and onion, cooked, fat added in cooking*
74505020	Tomato with corn and okra, cooked, fat added in cooking*
74506000	Tomato and cucumber salad made with tomato, cucumber, oil, and vinegar*
75142550	Cucumber salad made with cucumber, oil, and vinegar*
75200100	Vegetables, NS as to type, cooked, NS as to fat added in cooking*
75200120	Vegetables, NS as to type, cooked, fat added in cooking*
75201000	Artichoke, globe (French), cooked, NS as to form, NS as to fat added in cooking*
75201021	Artichoke, globe (French), cooked, from fresh, fat added in cooking*
75201030	Artichoke salad in oil*
75202000	Asparagus, cooked, NS as to form, NS as to fat added in cooking*
75202001	Asparagus, cooked, from fresh, NS as to fat added in cooking*
75202020	Asparagus, cooked, NS as to form, fat added in cooking*
75202021	Asparagus, cooked, from fresh, fat added in cooking*
75202023	Asparagus, cooked, from canned, fat added in cooking*
75204000	Beans, lima, immature, cooked, NS as to form, NS as to fat added in cooking*
75204001	Beans, lima, immature, cooked, from fresh, NS as to fat added in cooking*
75204002	Beans, lima, immature, cooked, from frozen, NS as to fat added in cooking*
75204021	Beans, lima, immature, cooked, from fresh, fat added in cooking*
75204022	Beans, lima, immature, cooked, from frozen, fat added in cooking*
75204023	Beans, lima, immature, cooked, from canned, fat added in cooking*
75204120	Beans, lima, immature, canned, low sodium, fat added in cooking*
75204980	Beans, string, cooked, NS as to form, NS as to color, fat added in cooking*
75204981	Beans, string, cooked, from fresh, NS as to color, fat added in cooking*
75204982	Beans, string, cooked, from frozen, NS as to color, fat added in cooking*
75204983	Beans, string, cooked, from canned, NS as to color, fat added in cooking*
75205000	Beans, string, cooked, NS as to form, NS as to color, NS as to fat added in cooking*
75205001	Beans, string, cooked, from fresh, NS as to color, NS as to fat added in cooking*
75205003	Beans, string, cooked, from canned, NS as to color, NS as to fat added in cooking*
75205010	Beans, string, green, cooked, NS as to form, NS as to fat added in cooking*
75205011	Beans, string, green, cooked, from fresh, NS as to fat added in cooking*
75205012	Beans, string, green, cooked, from frozen, NS as to fat added in cooking*
75205013	Beans, string, green, cooked, from canned, NS as to fat added in cooking*
75205030	Beans, string, green, cooked, NS as to form, fat added in cooking*

75205031	Beans, string, green, cooked, from fresh, fat added in cooking*
75205032	Beans, string, green, cooked, from frozen, fat added in cooking*
75205033	Beans, string, green, cooked, from canned, fat added in cooking*
75205110	Beans, string, green, canned, low sodium, NS as to fat added in cooking*
75205130	Beans, string, green, canned, low sodium, fat added in cooking*
75206000	Beans, string, yellow, cooked, NS as to form, NS as to fat added in cooking*
75206003	Beans, string, yellow, cooked, from canned, NS as to fat added in cooking*
75206021	Beans, string, yellow, cooked, from fresh, fat added in cooking*
75206022	Beans, string, yellow, cooked, from frozen, fat added in cooking*
75206023	Beans, string, yellow, cooked, from canned, fat added in cooking*
75207020	Bean sprouts, cooked, NS as to form, fat added in cooking*
75207021	Bean sprouts, cooked, from fresh, fat added in cooking*
75208000	Beets, cooked, NS as to form, NS as to fat added in cooking*
75208021	Beets, cooked, from fresh, fat added in cooking*
75208310	Bitter melon, cooked, fat added in cooking*
75208520	Breadfruit, fried*
75208720	Broccoflower, cooked, fat added in cooking*
75209000	Brussels sprouts, cooked, NS as to form, NS as to fat added in cooking*
75209001	Brussels sprouts, cooked, from fresh, NS as to fat added in cooking*
75209002	Brussels sprouts, cooked, from frozen, NS as to fat added in cooking*
75209021	Brussels sprouts, cooked, from fresh, fat added in cooking*
75209022	Brussels sprouts, cooked, from frozen, fat added in cooking*
75210000	Cabbage, Chinese, cooked, NS as to fat added in cooking*
75210020	Cabbage, Chinese, cooked, fat added in cooking*
75211010	Cabbage, green, cooked, NS as to fat added in cooking*
75211030	Cabbage, green, cooked, fat added in cooking*
75212000	Cabbage, red, cooked, NS as to fat added in cooking*
75213100	Cactus, cooked, NS as to fat added in cooking*
75213120	Cactus, cooked, fat added in cooking*
75214000	Cauliflower, cooked, NS as to form, NS as to fat added in cooking*
75214001	Cauliflower, cooked, from fresh, NS as to fat added in cooking*
75214020	Cauliflower, cooked, NS as to form, fat added in cooking*
75214021	Cauliflower, cooked, from fresh, fat added in cooking*
75214022	Cauliflower, cooked, from frozen, fat added in cooking*
75215000	Celery, cooked, NS as to fat added in cooking*
75215020	Celery, cooked, fat added in cooking*
75215120	Fennel bulb, cooked, fat added in cooking*
75216000	Corn, cooked, NS as to form, NS as to color, NS as to fat added in cooking*
75216003	Corn, cooked, from canned, NS as to color, NS as to fat added in cooking*
75216020	Corn, cooked, NS as to form, NS as to color, fat added in cooking*
75216021	Corn, cooked, from fresh, NS as to color, fat added in cooking*

75216022	Corn, cooked, from frozen, NS as to color, fat added in cooking*
75216023	Corn, cooked, from canned, NS as to color, fat added in cooking*
75216100	Corn, yellow, cooked, NS as to form, NS as to fat added in cooking*
75216101	Corn, yellow, cooked, from fresh, NS as to fat added in cooking*
75216102	Corn, yellow, cooked, from frozen, NS as to fat added in cooking*
75216103	Corn, yellow, cooked, from canned, NS as to fat added in cooking*
75216120	Corn, yellow, cooked, NS as to form, fat added in cooking*
75216121	Corn, yellow, cooked, from fresh, fat added in cooking*
75216122	Corn, yellow, cooked, from frozen, fat added in cooking*
75216123	Corn, yellow, cooked, from canned, fat added in cooking*
75216180	Corn, yellow and white, cooked, NS as to form, fat added in cooking*
75216181	Corn, yellow and white, cooked, from fresh, fat added in cooking*
75216182	Corn, yellow and white, cooked, from frozen, fat added in cooking*
75216183	Corn, yellow and white, cooked, from canned, fat added in cooking*
75216190	Corn, yellow, NS as to form, cream style, fat added in cooking*
75216193	Corn, yellow, from canned, cream style, fat added in cooking*
75216200	Corn, white, cooked, NS as to form, NS as to fat added in cooking*
75216201	Corn, white, cooked, from fresh, NS as to fat added in cooking*
75216220	Corn, white, cooked, NS as to form, fat added in cooking*
75216221	Corn, white, cooked, from fresh, fat added in cooking*
75216222	Corn, white, cooked, from frozen, fat added in cooking*
75216223	Corn, white, cooked, from canned, fat added in cooking*
75216300	Corn, yellow, canned, low sodium, NS as to fat added in cooking*
75216320	Corn, yellow, canned, low sodium, fat added in cooking*
75216720	Cucumber, cooked, fat added in cooking*
75217000	Eggplant, cooked, NS as to fat added in cooking*
75217020	Eggplant, cooked, fat added in cooking*
75217520	Hominy, cooked, fat added in cooking*
75218400	Leek, cooked, NS as to fat added in cooking*
75219000	Mushrooms, cooked, NS as to form, NS as to fat added in cooking*
75219001	Mushrooms, cooked, from fresh, NS as to fat added in cooking*
75219020	Mushrooms, cooked, NS as to form, fat added in cooking*
75219021	Mushrooms, cooked, from fresh, fat added in cooking*
75219022	Mushrooms, cooked, from frozen, fat added in cooking*
75219023	Mushrooms, cooked, from canned, fat added in cooking*
75220000	Okra, cooked, NS as to form, NS as to fat added in cooking*
75220001	Okra, cooked, from fresh, NS as to fat added in cooking*
75220020	Okra, cooked, NS as to form, fat added in cooking*
75220021	Okra, cooked, from fresh, fat added in cooking*
75220022	Okra, cooked, from frozen, fat added in cooking*
75221000	Onions, mature, cooked, NS as to form, NS as to fat added in cooking*

75221001	Onions, mature, cooked, from fresh, NS as to fat added in cooking*
75221020	Onions, mature, cooked or sauteed, NS as to form, fat added in cooking*
75221021	Onions, mature, cooked or sauteed, from fresh, fat added in cooking*
75221022	Onions, mature, cooked or sauteed, from frozen, fat added in cooking*
75221040	Onion, young green, cooked, NS as to form, NS as to fat added in cooking*
75221061	Onion, young green, cooked, from fresh, fat added in cooking*
75222020	Parsnips, cooked, fat added in cooking*
75223000	Peas, cowpeas, field peas, or blackeye peas (not dried), cooked, NS as to form, NS as to fat added in cooking*
75223001	Peas, cowpeas, field peas, or blackeye peas (not dried), cooked, from fresh, NS as to fat added in cooking*
75223002	Peas, cowpeas, field peas, or blackeye peas (not dried), cooked, from frozen, NS as to fat added in cooking*
75223003	Peas, cowpeas, field peas, or blackeye peas (not dried), cooked, from canned, NS as to fat added in cooking*
75223020	Peas, cowpeas, field peas, or blackeye peas (not dried), cooked, NS as to form, fat added in cooking*
75223021	Peas, cowpeas, field peas, or blackeye peas (not dried), cooked, from fresh, fat added in cooking*
75223022	Peas, cowpeas, field peas, or blackeye peas (not dried), cooked, from frozen, fat added in cooking*
75223023	Peas, cowpeas, field peas, or blackeye peas (not dried), cooked, from canned, fat added in cooking*
75224010	Peas, green, cooked, NS as to form, NS as to fat added in cooking*
75224011	Peas, green, cooked, from fresh, NS as to fat added in cooking*
75224012	Peas, green, cooked, from frozen, NS as to fat added in cooking*
75224013	Peas, green, cooked, from canned, NS as to fat added in cooking*
75224030	Peas, green, cooked, NS as to form, fat added in cooking*
75224031	Peas, green, cooked, from fresh, fat added in cooking*
75224032	Peas, green, cooked, from frozen, fat added in cooking*
75224033	Peas, green, cooked, from canned, fat added in cooking*
75224130	Peas, green, canned, low sodium, fat added in cooking*
75226000	Peppers, green, cooked, NS as to fat added in cooking*
75226020	Peppers, green, cooked, fat added in cooking*
75226040	Peppers, red, cooked, NS as to fat added in cooking*
75226060	Peppers, red, cooked, fat added in cooking*
75226110	Peppers, hot, cooked, NS as to form, fat added in cooking*
75226111	Peppers, hot, cooked, from fresh, fat added in cooking*
75226113	Peppers, hot, cooked, from canned, fat added in cooking*
75227110	Radish, Japanese (daikon), cooked, fat added in cooking*
75228000	Rutabaga, cooked, NS as to fat added in cooking*
75228020	Rutabaga, cooked, fat added in cooking*
75231000	Snowpea (pea pod), cooked, NS as to form, NS as to fat added in cooking*
75231020	Snowpea (pea pod), cooked, NS as to form, fat added in cooking*
75231021	Snowpea (pea pod), cooked, from fresh, fat added in cooking*

75231022	Snowpea (pea pod), cooked, from frozen, fat added in cooking*
75233000	Squash, summer, cooked, NS as to form, NS as to fat added in cooking*
75233001	Squash, summer, cooked, from fresh, NS as to fat added in cooking*
75233020	Squash, summer, cooked, NS as to form, fat added in cooking*
75233021	Squash, summer, cooked, from fresh, fat added in cooking*
75233022	Squash, summer, cooked, from frozen, fat added in cooking*
75233210	Squash, spaghetti, cooked, fat added in cooking*
75234000	Turnip, cooked, NS as to form, NS as to fat added in cooking*
75234001	Turnip, cooked, from fresh, NS as to fat added in cooking*
75234021	Turnip, cooked, from fresh, fat added in cooking*
75301120	Beans, lima and corn (succotash), cooked, fat added in cooking*
75302045	Beans, string, green, with almonds, cooked, fat added in cooking*
75302210	Beans, green string, with onions, fat added in cooking*
75302500	Beans, green, and potatoes, cooked, NS as to fat added in cooking*
75302510	Beans, green, and potatoes, cooked, fat added in cooking*
75307000	Green peppers and onions, cooked, fat added in cooking*
75311000	Mixed vegetables (corn, lima beans, peas, green beans, and carrots), cooked, NS as to form, NS as to fat added in cooking*
75311002	Mixed vegetables (corn, lima beans, peas, green beans, and carrots), cooked, from frozen, NS as to fat added in cooking*
75311003	Mixed vegetables (corn, lima beans, peas, green beans, and carrots), cooked, from canned, NS as to fat added in cooking*
75311020	Mixed vegetables (corn, lima beans, peas, green beans, and carrots), cooked, NS as to form, fat added in cooking*
75311022	Mixed vegetables (corn, lima beans, peas, green beans, and carrots), cooked, from frozen, fat added in cooking*
75311023	Mixed vegetables (corn, lima beans, peas, green beans, and carrots), cooked, from canned, fat added in cooking*
75311120	Mixed vegetables (corn, lima beans, peas, green beans, and carrots), canned, low sodium, fat added in cooking*
75315000	Peas and corn, cooked, NS as to fat added in cooking*
75315020	Peas and corn, cooked, fat added in cooking*
75315120	Peas and onions, cooked, fat added in cooking*
75315305	Peas and potatoes, cooked, NS as to fat added in cooking*
75315310	Peas and potatoes, cooked, fat added in cooking*
75316020	Squash, summer, and onions, cooked, fat added in cooking*
75316050	Ratatouille*
75317000	Vegetables, stew type (including potatoes, carrots, onions, celery) cooked, NS as to fat added in cooking*
75317010	Vegetables, stew type (including potatoes, carrots, onions, celery) cooked, fat added in cooking*
75330100	Vegetable combination (including carrots, broccoli, and/or dark-green leafy), cooked, no sauce, NS as to fat added in cooking*
75330120	Vegetable combination (including carrots, broccoli, and/or dark-green leafy), cooked, no sauce, fat added in cooking*
75330130	Vegetable combination (excluding carrots, broccoli, and dark-green leafy), cooked, no sauce, NS as to fat added in cooking*

75330150	Vegetable combination (excluding carrots, broccoli, and dark-green leafy), cooked, no sauce, fat added in cooking*
75340000	Vegetable combinations, Oriental style, (broccoli, green pepper, water chestnut, etc) cooked, NS as to fat added in cooking*
75340020	Vegetable combinations, Oriental style, (broccoli, green pepper, water chestnuts, etc), cooked, fat added in cooking*
75340100	Vegetable combinations (broccoli, carrots, corn, cauliflower, etc.), cooked, NS as to fat added in cooking*
75340120	Vegetable combinations (broccoli, carrots, corn, cauliflower, etc.), cooked, fat added in cooking*
75340150	Vegetable combination (green beans, broccoli, onions, mushrooms), cooked, fat added in cooking*
75340160	Vegetable and pasta combinations with cream or cheese sauce (broccoli, pasta, carrots, corn, zucchini, peppers, cauliflower, peas, etc.), cooked*
75400500	Artichokes, stuffed*
75403012	Beans, string, green, from frozen, creamed or with cheese sauce*
75403200	Beans, string, green, cooked, Szechuan-style, fat added in cooking*
75405010	Beets with Harvard sauce*
75411010	Corn, scalloped or pudding*
75411020	Corn fritter*
75412010	Eggplant, batter-dipped, fried*
75412060	Eggplant parmesan casserole, regular*
75414020	Mushrooms, stuffed*
75414030	Mushrooms, batter-dipped, fried*
75414500	Okra, batter-dipped, fried*
75415020	Onion rings, NS as to form, batter-dipped, baked or fried*
75415022	Onion rings, from frozen, batter-dipped, baked or fried*
75418020	Squash, summer, casserole with tomato and cheese*
75418060	Squash, summer, souffle*
75439500	Chop suey, meatless, no noodles*
75440100	Vegetable combination (including carrots, broccoli, and/or dark-green leafy), cooked, with soy-based sauce*
75440170	Vegetable sticks, breaded (including corn, carrots, and green beans)*
75440200	Vegetable tempura*
75440400	Vegetables, dipped in chick-pea flour batter, (pakora), fried*
75440600	Vegetable curry*
75450600	Vegetable combination (including carrots, broccoli, and/or dark-green leafy), cooked, with butter sauce*
75460800	Vegetable combinations (including carrots, broccoli, and/or dark-green leafy), cooked, with butter sauce and pasta*
75601200	Cabbage soup*
75601210	Cabbage with meat soup*
75602010	Cauliflower soup, cream of, prepared with milk*
75604010	Corn soup, cream of, prepared with milk*
75604020	Corn soup, cream of, prepared with water*
75608100	Onion soup, French*

75647000	Seaweed soup*
75649110	Vegetable soup, home recipe*
75649150	Vegetable noodle soup, home recipe*
75651000	Minestrone soup, home recipe*
75651150	Vegetable noodle soup, canned, reduced sodium, prepared with water or ready-to-serve*
75652010	Vegetable beef soup, home recipe*
75652040	Vegetable beef soup with noodles or pasta, home recipe*
75652050	Vegetable beef soup with rice, home recipe*
75656060	Vegetable beef soup, chunky style*
77205610	Ripe plantain meat pie, Puerto Rican style (Pinon)*
77230210	Cassava Pasteles, Puerto Rican style (Pasteles de yuca)*
77272010	Puerto Rican pasteles (Pasteles de masa)*
77316010	Stuffed cabbage, with meat, Puerto Rican style (Repollo relleno con carne)*
77316510	Stuffed cabbage, with meat and rice, Syrian dish, Puerto Rican style (Repollo relleno con carne y con arroz; Arabe Mihsy Melful)*
77316600	Eggplant and meat casserole*
81100500	Butter, NFS
81101000	Butter, stick, salted
81101010	Butter, whipped, tub, salted
81101100	Butter, stick, unsalted
81101110	Butter, whipped, tub, unsalted
81101500	Light butter, stick, salted
81101520	Light butter, whipped, tub, salted
81102000	Margarine, NFS
81102010	Margarine, stick, salted
81102020	Margarine, tub, salted
81103020	Margarine, whipped, tub, salted
81103030	Margarine, stick, unsalted
81103040	Margarine-like spread, stick, salted
81103041	Margarine-like spread, made with yogurt, stick, salted
81103060	Margarine, tub, unsalted
81103080	Margarine-like spread, tub, salted
81103090	Margarine-like spread, liquid, salted
81103100	Margarine-like spread, stick, unsalted
81103120	Margarine-like spread, tub, unsalted
81103140	Margarine-like spread, tub, sweetened
81104010	Margarine-like spread, reduced calorie, about 40% fat, tub, salted
81104011	Margarine-like spread, reduced calorie, about 40% fat, made with yogurt, tub, salted
81104020	Margarine-like spread, reduced calorie, about 40% fat, stick, salted
81104050	Margarine-like spread, reduced calorie, about 20% fat, tub, salted
81104100	Margarine-like spread, fat free, tub, salted
81104110	Margarine-like spread, fat free, liquid, salted

81104510	Vegetable oil-butter spread, tub, salted
81104560	Vegetable oil-butter spread, reduced calorie, tub, salted
81105010	Butter-margarine blend, stick, salted
81105020	Butter-margarine blend, tub, salted
81105500	Butter-vegetable oil blend
81106010	Butter replacement, fat-free powder
81203000	Shortening, NS as to vegetable or animal
81322000	Honey butter*
82101000	Vegetable oil, NFS
82101500	Coconut oil
82102000	Corn oil
82103500	Flaxseed oil
82104000	Olive oil
82105000	Peanut oil
82105500	Rapeseed oil
82106000	Safflower oil
82107000	Sesame oil
91301040	Buttered blends syrup*
91304010	Topping, butterscotch or caramel*
91304300	Topping, chocolate, hard coating*
91361020	Fruit sauce*
91361040	Plain dessert sauce*
91718000	Honey-combed hard candy with peanut butter*
91718200	Chocolate-flavored sprinkles*
91735000	Pralines*
91760500	Truffles*

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Dressings for salads

Food Code	Description
27510950	Reuben sandwich (corned beef sandwich with sauerkraut and cheese), with spread*
27520165	Bacon, chicken fillet (breaded, fried), and tomato club with lettuce and spread*
27540210	Wrap sandwich filled with chicken strips (breaded, fried), cheese, lettuce, and spread*
27540300	Wrap sandwich filled with chicken strips (broiled), cheese, lettuce, and spread*
58127500	Vegetable submarine sandwich*
58134640	Tortellini, cheese-filled, meatless, with vinaigrette dressing*
58148500	Pasta or macaroni salad with oil and vinegar-type dressing*
58148550	Pasta or macaroni salad with meat*
75141000	Cabbage salad or coleslaw, with dressing*
75141100	Cabbage salad or coleslaw with apples and/or raisins, with dressing*

75141200	Cabbage salad or coleslaw with pineapple, with dressing*
75302080	Bean salad, yellow and/or green string beans*
83100100	Salad dressing, NFS
83101000	Blue or roquefort cheese dressing
83101500	Bacon dressing (hot)
83102000	Caesar dressing
83103000	Coleslaw dressing
83103500	Feta Cheese Dressing
83104000	French dressing
83105000	Fruit dressing, made with fruit juice and cream
83105100	Fruit dressing, made with honey, oil, and water
83105500	Honey mustard dressing
83106000	Italian dressing, made with vinegar and oil
83109000	Russian dressing
83112000	Green Goddess dressing
83112500	Creamy dressing, made with sour cream and/or buttermilk and oil
83112900	Milk, vinegar, and sugar dressing
83112950	Poppy seed dressing
83112960	Peppercorn Dressing
83112980	Celery seed dressing
83112990	Sesame dressing
83113000	Sweet and sour dressing
83114000	Thousand Island dressing
83115000	Yogurt dressing
83200100	Salad dressing, low-calorie, NFS
83201000	Blue or roquefort cheese dressing, low-calorie
83201050	Blue or roquefort cheese dressing, reduced calorie
83201200	Blue or roquefort cheese dressing, reduced calorie, fat-free, cholesterol-free
83202000	French dressing, low-calorie
83202010	French dressing, reduced calorie, fat-free, cholesterol-free
83202020	French dressing, reduced calorie
83203000	Caesar dressing, low-calorie
83204500	Honey mustard dressing, reduced calorie
83205000	Italian dressing, low calorie
83205450	Italian dressing, reduced calorie
83205500	Italian dressing, reduced calorie, fat-free
83206000	Russian dressing, low-calorie
83207000	Thousand Island dressing, low-calorie
83207100	Thousand Island dressing, reduced calorie, fat-free, cholesterol-free
83208000	Vinegar, sugar, and water dressing
83208500	Korean dressing or marinade

83210000	Creamy dressing, made with sour cream and/or buttermilk and oil, diet, NS as to low or reduced calorie
83210050	Creamy dressing made with sour cream and/or buttermilk and oil, low calorie
83210100	Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie
83210200	Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie, fat-free, cholesterol-free
83210250	Creamy dressing, made with sour cream and/or buttermilk and oil, reduced calorie, cholesterol-free

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Mayonnaise, sandwich spreads, and mayonnaise-type dressings

Food Code	Description
14640000	Cheese sandwich*
27250040	Crab cake*
27416250	Beef salad*
27420020	Ham or pork salad*
27446200	Chicken or turkey salad*
27446205	Chicken or turkey salad with nuts and/or fruits*
27446220	Chicken or turkey salad with egg*
27450010	Crab salad*
27450020	Lobster salad*
27450030	Salmon salad*
27450060	Tuna salad*
27450070	Shrimp salad*
27450080	Seafood salad*
27450090	Tuna salad with cheese*
27450100	Tuna salad with egg*
27450130	Crab salad made with imitation crab*
27500050	Sandwich, NFS*
27510230	Cheeseburger, with mayonnaise or salad dressing and tomatoes, on bun*
27510250	Cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing, on bun*
27510280	Double cheeseburger (2 patties), with mayonnaise or salad dressing, on bun*
27510340	Double cheeseburger (2 patties), with mayonnaise or salad dressing and tomatoes, on bun*
27510350	Cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun*
27510355	Cheeseburger, 1/3 lb meat, with mayonnaise or salad dressing, tomato and/or catsup on bun*
27510370	Double cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun*
27510380	Triple cheeseburger (3 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes, on bun*
27510425	Double bacon cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun*
27510430	Double bacon cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes, on bun*

27510435	Double bacon cheeseburger (2 patties,1/3 lb meat each), with mayonnaise or salad dressing, on bun*
27510440	Bacon cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun*
27510520	Hamburger, with mayonnaise or salad dressing and tomatoes, on bun*
27510550	Double hamburger (2 patties), with mayonnaise or salad dressing and tomatoes, on double-decker bun*
27510560	Hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun*
27510670	Double hamburger (2 patties), with mayonnaise or salad dressing and tomatoes, on bun*
27510690	Double hamburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes and/or catsup, on double-decker bun*
27513040	Roast beef submarine sandwich, with lettuce, tomato and spread*
27513041	Roast beef submarine sandwich, with cheese, lettuce, tomato and spread*
27520130	Bacon, chicken, and tomato club sandwich, with lettuce and spread*
27520135	Bacon, chicken, and tomato club sandwich, with cheese, lettuce and spread*
27520150	Bacon, lettuce, and tomato sandwich with spread*
27520166	Bacon, chicken fillet (breaded, fried), and tomato club sandwich with cheese, lettuce and spread*
27520300	Ham sandwich, with spread*
27520320	Ham and cheese sandwich, with lettuce and spread*
27520350	Ham and cheese sandwich, with spread, grilled*
27520370	Hot ham and cheese sandwich, on bun*
27520390	Ham and cheese submarine sandwich, on multigrain roll, with lettuce, tomato and spread*
27540110	Chicken sandwich, with spread*
27540120	Chicken salad or chicken spread sandwich*
27540150	Chicken fillet (breaded, fried) sandwich with lettuce, tomato and spread*
27540170	Chicken patty sandwich, miniature, with spread*
27540190	Chicken patty sandwich, with lettuce and spread*
27540230	Chicken patty sandwich with cheese, on wheat bun, with lettuce, tomato and spread*
27540240	Chicken fillet, (broiled), sandwich, on whole wheat roll, with lettuce, tomato and spread*
27540260	Chicken fillet, broiled, sandwich, on oat bran bun, with lettuce, tomato, spread*
27540290	Chicken submarine sandwich, with lettuce, tomato, and spread*
27540291	Chicken submarine sandwich, with cheese, lettuce, tomato, and spread*
27540310	Turkey sandwich, with spread*
27540350	Turkey submarine sandwich, with cheese, lettuce, tomato and spread*
27541000	Turkey, ham, and roast beef club sandwich*
27541001	Turkey, ham, and roast beef club sandwich with cheese, lettuce, tomato, and spread*
27550720	Tuna salad sandwich*
27550750	Tuna salad submarine sandwich, with lettuce and tomato*
27550751	Tuna salad submarine sandwich, with cheese, lettuce and tomato*
27560910	Submarine, cold cut sandwich, with lettuce and tomato*
32102000	Egg, deviled*
32103000	Egg salad*
58148110	Macaroni or pasta salad*

58148120	Macaroni or pasta salad with egg*
58148130	Macaroni or pasta salad with tuna*
58148140	Macaroni or pasta salad with crab meat*
58148150	Macaroni or pasta salad with shrimp*
58148160	Macaroni or pasta salad with tuna and egg*
58148170	Macaroni or pasta salad with chicken*
58148180	Macaroni or pasta salad with cheese*
63401010	Apple salad with dressing*
63401020	Apple and cabbage salad with dressing*
63402950	Fruit salad (excluding citrus fruits) with salad dressing or mayonnaise*
63403010	Fruit salad (including citrus fruits) with salad dressing or mayonnaise*
63412010	Pear salad with dressing*
63413010	Pineapple salad with dressing*
71601010	Potato salad with egg*
71603010	Potato salad*
73101110	Carrots, raw, salad*
73101210	Carrots, raw, salad with apples*
75140500	Broccoli salad with cauliflower, cheese, bacon bits, and dressing*
75145000	Seven-layer salad (lettuce salad made with a combination of onion, celery, green pepper, peas, mayonnaise, cheese, eggs, and/or bacon)*
75416500	Pea salad*
75416600	Pea salad with cheese*
83100200	Salad dressing, NFS, for sandwiches
83107000	Mayonnaise, regular
83107200	Mayonnaise, made with tofu
83108000	Mayonnaise, imitation
83108100	Mayonnaise, imitation, cholesterol free
83110000	Mayonnaise-type salad dressing
83110010	Mayonnaise-type salad dressing, cholesterol-free
83203250	Mayonnaise-type salad dressing, fat-free
83204000	Mayonnaise, low-calorie or diet
83204020	Mayonnaise, reduced calorie or diet, cholesterol-free
83204050	Mayonnaise-type salad dressing, low-calorie or diet
83204060	Mayonnaise-type salad dressing, low-calorie or diet, cholesterol-free

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Fruit juices and Fruit nectars

Food Code	Description
42404010	Coconut water, canned or bottled
61201020	Grapefruit juice, NS as to form
61201220	Grapefruit juice, canned, bottled or in a carton

61201620	Grapefruit juice, frozen (reconstituted with water)
61210000	Orange juice, NFS
61210220	Orange juice, canned, bottled or in a carton
61210250	Orange juice, with calcium added, canned, bottled or in a carton
61210620	Orange juice, frozen (reconstituted with water)
61210820	Orange juice, frozen, with calcium added (reconstituted with water)
61213000	Tangerine juice, NFS
61213220	Tangerine juice, canned
61213800	Fruit juice blend, including citrus, 100% juice
61213900	Fruit juice blend, including citrus, 100% juice, with calcium added
64100100	Fruit juice, NFS
64100110	Fruit juice blend, 100% juice, with added Vitamin C
64100200	Fruit juice blend, with cranberry, 100% juice
64101010	Apple cider
64104010	Apple juice
64104600	Blackberry juice
64105400	Cranberry juice, unsweetened
64116020	Grape juice
64120010	Papaya juice
64121000	Passion fruit juice
64124020	Pineapple juice
64126000	Pomegranate juice
64132010	Prune juice
64132500	Strawberry juice
64133100	Watermelon juice
64134000	Fruit smoothie drink, made with fruit or fruit juice only (no dairy products)
64200100	Fruit nectar, NFS
64201010	Apricot nectar
64201500	Banana nectar
64202010	Cantaloupe nectar
64203020	Guava nectar
64204010	Mango nectar
64205010	Peach nectar
64210010	Papaya nectar
64213010	Passion fruit nectar
64215010	Pear nectar
64221010	Soursop (Guanabana) nectar
92512090	Pina Colada, nonalcoholic*
93301032	Cape Cod*
93301115	Mimosa*
93301139	Salty Dog*

93301140	Screwdriver*
93301141	Seabreeze*
93301200	Pina Colada*
93301320	Tequila Sunrise*
93404500	Sangria*
93404600	Sangria, Puerto Rican style*
93504100	Rum cooler*

* Only component of proposed food category of food was applied in analysis

Meat, poultry and fish dry coating mixes, dry seasoning mixes

Food Code	Description
20000000	Meat, NFS*
20000200	Ground meat, NFS*
21000100	Beef, NS as to cut, cooked, NS as to fat eaten*
21000110	Beef, NS as to cut, cooked, lean and fat eaten*
21000120	Beef, NS as to cut, cooked, lean only eaten*
21001000	Steak, NS as to type of meat, cooked, NS as to fat eaten*
21001010	Steak, NS as to type of meat, cooked, lean and fat eaten*
21001020	Steak, NS as to type of meat, cooked, lean only eaten*
21003000	Beef, NS as to cut, fried, NS to fat eaten*
21101000	Beef steak, NS as to cooking method, NS as to fat eaten*
21101010	Beef steak, NS as to cooking method, lean and fat eaten*
21101020	Beef steak, NS as to cooking method, lean only eaten*
21101110	Beef steak, broiled or baked, NS as to fat eaten*
21101120	Beef steak, broiled or baked, lean and fat eaten*
21101130	Beef steak, broiled or baked, lean only eaten*
21102110	Beef steak, fried, NS as to fat eaten*
21102120	Beef steak, fried, lean and fat eaten*
21102130	Beef steak, fried, lean only eaten*
21103110	Beef steak, breaded or floured, baked or fried, NS as to fat eaten*
21103120	Beef steak, breaded or floured, baked or fried, lean and fat eaten*
21103130	Beef steak, breaded or floured, baked or fried, lean only eaten*
21104110	Beef steak, battered, fried, NS as to fat eaten*
21104120	Beef steak, battered, fried, lean and fat eaten*
21104130	Beef steak, battered, fried, lean only eaten*
21105110	Beef steak, braised, NS as to fat eaten*
21105120	Beef steak, braised, lean and fat eaten*
21105130	Beef steak, braised, lean only eaten*
21301000	Beef, oxtails, cooked*
21302000	Beef, neck bones, cooked*

21304000	Beef, shortribs, cooked, NS as to fat eaten*
21304110	Beef, shortribs, cooked, lean and fat eaten*
21304120	Beef, shortribs, cooked, lean only eaten*
21304200	Beef, shortribs, barbecued, with sauce, NS as to fat eaten*
21304210	Beef, shortribs, barbecued, with sauce, lean and fat eaten*
21304220	Beef, shortribs, barbecued, with sauce, lean only eaten*
21305000	Beef, cow head, cooked*
21401000	Beef, roast, roasted, NS as to fat eaten*
21401110	Beef, roast, roasted, lean and fat eaten*
21401120	Beef, roast, roasted, lean only eaten*
21407000	Beef, pot roast, braised or boiled, NS as to fat eaten*
21407110	Beef, pot roast, braised or boiled, lean and fat eaten*
21407120	Beef, pot roast, braised or boiled, lean only eaten*
21410000	Beef, stew meat, cooked, NS as to fat eaten*
21410120	Beef, stew meat, cooked, lean only eaten*
21416000	Corned beef, cooked, NS as to fat eaten*
21416110	Corned beef, cooked, lean and fat eaten*
21416120	Corned beef, cooked, lean only eaten*
21417100	Beef brisket, cooked, NS as to fat eaten*
21417110	Beef brisket, cooked, lean and fat eaten*
21417120	Beef brisket, cooked, lean only eaten*
21420100	Beef, sandwich steak (flaked, formed, thinly sliced)*
21500100	Ground beef or patty, cooked, NS as to regular, lean, or extra lean*
21500110	Ground beef, meatballs, meat only, cooked, NS as to regular, lean, or extra lean*
21500200	Ground beef or patty, breaded, cooked*
21500300	Ground beef patty, cooked (for fast food sandwiches)*
21501000	Ground beef, regular, cooked*
21501200	Ground beef, lean, cooked*
21501300	Ground beef, extra lean, cooked*
21501350	Ground beef, 90% - 94% lean, cooked*
21501360	Ground beef, 95% or more lean, cooked*
21540100	Ground beef with textured vegetable protein, cooked*
21602000	Beef, dried, chipped, uncooked*
21602010	Beef, dried, chipped, cooked in fat*
21602100	Beef jerky*
21603000	Beef, pastrami (beef, smoked, spiced)*
22000100	Pork, NS as to cut, cooked, NS as to fat eaten*
22000110	Pork, NS as to cut, cooked, lean and fat eaten*
22000120	Pork, NS as to cut, cooked, lean only eaten*
22000200	Pork, NS as to cut, fried, NS as to fat eaten*
22000210	Pork, NS as to cut, fried, lean and fat eaten*

22000220	Pork, NS as to cut, fried, lean only eaten*
22000300	Pork, NS as to cut, breaded or floured, fried, NS as to fat eaten*
22000310	Pork, NS as to cut, breaded or floured, fried, lean and fat eaten*
22000320	Pork, NS as to cut, breaded or floured, fried, lean only eaten*
22002000	Pork, ground or patty, cooked*
22002100	Pork, ground or patty, breaded, cooked*
22002800	Pork jerky*
22101000	Pork chop, NS as to cooking method, NS as to fat eaten*
22101010	Pork chop, NS as to cooking method, lean and fat eaten*
22101020	Pork chop, NS as to cooking method, lean only eaten*
22101100	Pork chop, broiled or baked, NS as to fat eaten*
22101110	Pork chop, broiled or baked, lean and fat eaten*
22101120	Pork chop, broiled or baked, lean only eaten*
22101130	Pork chop, breaded or floured, broiled or baked, NS as to fat eaten*
22101140	Pork chop, breaded or floured, broiled or baked, lean and fat eaten*
22101150	Pork chop, breaded or floured, broiled or baked, lean only eaten*
22101200	Pork chop, fried, NS as to fat eaten*
22101210	Pork chop, fried, lean and fat eaten*
22101220	Pork chop, fried, lean only eaten*
22101300	Pork chop, breaded or floured, fried, NS as to fat eaten*
22101310	Pork chop, breaded or floured, fried, lean and fat eaten*
22101320	Pork chop, breaded or floured, fried, lean only eaten*
22101400	Pork chop, battered, fried, NS as to fat eaten*
22101410	Pork chop, battered, fried, lean and fat eaten*
22101420	Pork chop, battered, fried, lean only eaten*
22101500	Pork chop, stewed, NS as to fat eaten*
22101510	Pork chop, stewed, lean and fat eaten*
22101520	Pork chop, stewed, lean only eaten*
22107000	Pork chop, smoked or cured, cooked, NS as to fat eaten*
22107010	Pork chop, smoked or cured, cooked, lean and fat eaten*
22107020	Pork chop, smoked or cured, cooked, lean only eaten*
22201010	Pork steak or cutlet, NS as to cooking method, lean and fat eaten*
22201020	Pork steak or cutlet, NS as to cooking method, lean only eaten*
22201050	Pork steak or cutlet, battered, fried, NS as to fat eaten*
22201060	Pork steak or cutlet, battered, fried, lean and fat eaten*
22201110	Pork steak or cutlet, broiled or baked, lean and fat eaten*
22201120	Pork steak or cutlet, broiled or baked, lean only eaten*
22201200	Pork steak or cutlet, fried, NS as to fat eaten*
22201210	Pork steak or cutlet, fried, lean and fat eaten*
22201220	Pork steak or cutlet, fried, lean only eaten*
22201300	Pork steak or cutlet, breaded or floured, broiled or baked, NS as to fat eaten*

22201320	Pork steak or cutlet, breaded or floured, broiled or baked, lean only eaten*
22201400	Pork steak or cutlet, breaded or floured, fried, NS as to fat eaten*
22201410	Pork steak or cutlet, breaded or floured, fried, lean and fat eaten*
22201420	Pork steak or cutlet, breaded or floured, fried, lean only eaten*
22210300	Pork, tenderloin, cooked, NS as to cooking method*
22210310	Pork, tenderloin, breaded, fried*
22210350	Pork, tenderloin, braised*
22210400	Pork, tenderloin, baked*
22210450	Pork, tenderloin, battered, fried*
22300120	Ham, fried, NS as to fat eaten*
22300130	Ham, fried, lean and fat eaten*
22300140	Ham, fried, lean only eaten*
22300160	Ham, breaded or floured, fried, lean and fat eaten*
22301000	Ham, fresh, cooked, NS as to fat eaten*
22311000	Ham, smoked or cured, cooked, NS as to fat eaten*
22311010	Ham, smoked or cured, cooked, lean and fat eaten*
22311020	Ham, smoked or cured, cooked, lean only eaten*
22311220	Ham, smoked or cured, low sodium, cooked, lean only eaten*
22311450	Ham, prosciutto*
22400100	Pork roast, NS as to cut, cooked, NS as to fat eaten*
22400110	Pork roast, NS as to cut, cooked, lean and fat eaten*
22400120	Pork roast, NS as to cut, cooked, lean only eaten*
22401000	Pork roast, loin, cooked, NS as to fat eaten*
22401010	Pork roast, loin, cooked, lean and fat eaten*
22401020	Pork roast, loin, cooked, lean only eaten*
22411000	Pork roast, shoulder, cooked, NS as to fat eaten*
22411010	Pork roast, shoulder, cooked, lean and fat eaten*
22411020	Pork roast, shoulder, cooked, lean only eaten*
22421010	Pork roast, smoked or cured, cooked, lean and fat eaten*
22421020	Pork roast, smoked or cured, cooked, lean only eaten*
22431000	Pork roll, cured, fried*
22701000	Pork, spareribs, cooked, NS as to fat eaten*
22701010	Pork, spareribs, cooked, lean and fat eaten*
22701020	Pork, spareribs, cooked, lean only eaten*
22701030	Pork, spareribs, barbecued, with sauce, NS as to fat eaten*
22701040	Pork, spareribs, barbecued, with sauce, lean and fat eaten*
22701050	Pork, spareribs, barbecued, with sauce, lean only eaten*
22704010	Pork, cracklings, cooked*
22705010	Pork ears, tail, head, snout, miscellaneous parts, cooked*
22706010	Pork, neck bones, cooked*
22707010	Pork, pig's feet, cooked*

22708010	Pork, pig's hocks, cooked*
22709010	Pork skin, rinds, deep-fried*
22709110	Pork skin, boiled*
23000100	Lamb, NS as to cut, cooked*
23101010	Lamb chop, NS as to cut, cooked, lean and fat eaten*
23101020	Lamb chop, NS as to cut, cooked, lean only eaten*
23104000	Lamb, loin chop, cooked, NS as to fat eaten*
23104010	Lamb, loin chop, cooked, lean and fat eaten*
23104020	Lamb, loin chop, cooked, lean only eaten*
23108020	Lamb, shoulder, cooked, lean only eaten*
23110050	Lamb, ribs, cooked, lean and fat eaten*
23120100	Lamb, roast, cooked, NS as to fat eaten*
23120110	Lamb, roast, cooked, lean and fat eaten*
23120120	Lamb, roast, cooked, lean only eaten*
23132000	Lamb, ground or patty, cooked*
23150100	Goat, boiled*
23150200	Goat, fried*
23150250	Goat, baked*
23150300	Goat ribs, cooked*
23200100	Veal, NS as to cut, cooked, NS as to fat eaten*
23200120	Veal, NS as to cut, cooked, lean only eaten*
23203030	Veal chop, fried, lean only eaten*
23203110	Veal chop, broiled, lean and fat eaten*
23204030	Veal cutlet or steak, NS as to cooking method, lean only eaten*
23204210	Veal cutlet or steak, broiled, lean and fat eaten*
23204220	Veal cutlet or steak, broiled, lean only eaten*
23205010	Veal cutlet or steak, fried, NS as to fat eaten*
23205030	Veal cutlet or steak, fried, lean only eaten*
23210030	Veal, roasted, lean only eaten*
23220010	Veal, ground or patty, cooked*
23220020	Mock chicken legs, cooked*
23310000	Rabbit, NS as to domestic or wild, cooked*
23311120	Rabbit, NS as to domestic or wild, breaded, fried*
23321000	Venison/deer, NFS*
23321100	Venison/deer, roasted*
23321200	Venison/deer steak, cooked, NS as to cooking method*
23321900	Venison/deer jerky*
23322100	Deer bologna*
23322350	Venison/deer ribs, cooked*
23322400	Venison/deer, stewed*
23323100	Moose, cooked*

23323500	Bear, cooked*
23326100	Bison, cooked*
23333100	Squirrel, cooked*
24100000	Chicken, NS as to part and cooking method, NS as to skin eaten*
24100010	Chicken, NS as to part and cooking method, skin eaten*
24100020	Chicken, NS as to part and cooking method, skin not eaten*
24102000	Chicken, NS as to part, roasted, broiled, or baked, NS as to skin eaten*
24102010	Chicken, NS as to part, roasted, broiled, or baked, skin eaten*
24102020	Chicken, NS as to part, roasted, broiled, or baked, skin not eaten*
24103000	Chicken, NS as to part, stewed, NS as to skin eaten*
24103010	Chicken, NS as to part, stewed, skin eaten*
24103020	Chicken, NS as to part, stewed, skin not eaten*
24107000	Chicken, NS as to part, coated, baked or fried, prepared with skin, NS as to skin/coating eaten*
24107010	Chicken, NS as to part, coated, baked or fried, prepared with skin, skin/coating eaten*
24107020	Chicken, NS as to part, coated, baked or fried, prepared with skin, skin/coating not eaten*
24107040	Chicken, NS as to part, coated, baked or fried, prepared skinless, NS as to coating eaten*
24107050	Chicken, NS as to part, coated, baked or fried, prepared skinless, coating eaten*
24107060	Chicken, NS as to part, coated, baked or fried, prepared skinless, coating not eaten*
24120100	Chicken, breast, NS as to cooking method, NS as to skin eaten*
24120110	Chicken, breast, NS as to cooking method, skin eaten*
24120120	Chicken, breast, NS as to cooking method, skin not eaten*
24122100	Chicken, breast, roasted, broiled, or baked, NS as to skin eaten*
24122110	Chicken, breast, roasted, broiled, or baked, skin eaten*
24122120	Chicken, breast, roasted, broiled, or baked, skin not eaten*
24123100	Chicken, breast, stewed, NS as to skin eaten*
24123110	Chicken, breast, stewed, skin eaten*
24123120	Chicken, breast, stewed, skin not eaten*
24127100	Chicken, breast, coated, baked or fried, prepared with skin, NS as to skin/coating eaten*
24127110	Chicken, breast, coated, baked or fried, prepared with skin, skin/coating eaten*
24127120	Chicken, breast, coated, baked or fried, prepared with skin, skin/coating not eaten*
24127140	Chicken, breast, coated, baked or fried, prepared skinless, NS as to coating eaten*
24127150	Chicken, breast, coated, baked or fried, prepared skinless, coating eaten*
24127160	Chicken, breast, coated, baked or fried, prepared skinless, coating not eaten*
24130200	Chicken, leg (drumstick and thigh), NS as to cooking method, NS as to skin eaten*
24130210	Chicken, leg (drumstick and thigh), NS as to cooking method, skin eaten*
24130220	Chicken, leg (drumstick and thigh), NS as to cooking method, skin not eaten*
24132200	Chicken, leg (drumstick and thigh), roasted, broiled, or baked, NS as to skin eaten*
24132210	Chicken, leg (drumstick and thigh), roasted, broiled, or baked, skin eaten*
24132220	Chicken, leg (drumstick and thigh), roasted, broiled, or baked, skin not eaten*
24133210	Chicken, leg (drumstick and thigh), stewed, skin eaten*
24133220	Chicken, leg (drumstick and thigh), stewed, skin not eaten*

24137200	Chicken, leg (drumstick and thigh), coated, baked or fried, prepared with skin, NS as to skin/coating eaten*
24137210	Chicken, leg (drumstick and thigh), coated, baked or fried, prepared with skin, skin/coating eaten*
24137220	Chicken, leg (drumstick and thigh), coated, baked or fried, prepared with skin, skin/coating not eaten*
24137250	Chicken, leg (drumstick and thigh), coated, baked or fried, prepared skinless, coating eaten*
24137260	Chicken, leg (drumstick and thigh), coated, baked or fried, prepared skinless, coating not eaten*
24140200	Chicken, drumstick, NS as to cooking method, NS as to skin eaten*
24140210	Chicken, drumstick, NS as to cooking method, skin eaten*
24140220	Chicken, drumstick, NS as to cooking method, skin not eaten*
24142200	Chicken, drumstick, roasted, broiled, or baked, NS as to skin eaten*
24142210	Chicken, drumstick, roasted, broiled, or baked, skin eaten*
24142220	Chicken, drumstick, roasted, broiled, or baked, skin not eaten*
24143200	Chicken, drumstick, stewed, NS as to skin eaten*
24143210	Chicken, drumstick, stewed, skin eaten*
24143220	Chicken, drumstick, stewed, skin not eaten*
24147200	Chicken, drumstick, coated, baked or fried, prepared with skin, NS as to skin/coating eaten*
24147210	Chicken, drumstick, coated, baked or fried, prepared with skin, skin/coating eaten*
24147220	Chicken, drumstick, coated, baked or fried, prepared with skin, skin/coating not eaten*
24147240	Chicken, drumstick, coated, baked or fried, prepared skinless, NS as to coating eaten*
24147250	Chicken, drumstick, coated, baked or fried, prepared skinless, coating eaten*
24147260	Chicken, drumstick, coated, baked or fried, prepared skinless, coating not eaten*
24150200	Chicken, thigh, NS as to cooking method, NS as to skin eaten*
24150210	Chicken, thigh, NS as to cooking method, skin eaten*
24150220	Chicken, thigh, NS as to cooking method, skin not eaten*
24152200	Chicken, thigh, roasted, broiled, or baked, NS as to skin eaten*
24152210	Chicken, thigh, roasted, broiled, or baked, skin eaten*
24152220	Chicken, thigh, roasted, broiled, or baked, skin not eaten*
24153200	Chicken, thigh, stewed, NS as to skin eaten*
24153210	Chicken, thigh, stewed, skin eaten*
24153220	Chicken, thigh, stewed, skin not eaten*
24157200	Chicken, thigh, coated, baked or fried, prepared with skin, NS as to skin/coating eaten*
24157210	Chicken, thigh, coated, baked or fried, prepared with skin, skin/coating eaten*
24157220	Chicken, thigh, coated, baked or fried, prepared with skin, skin/coating not eaten*
24157240	Chicken, thigh, coated, baked or fried, prepared skinless, NS as to coating eaten*
24157250	Chicken, thigh, coated, baked or fried, prepared skinless, coating eaten*
24157260	Chicken, thigh, coated, baked or fried, prepared skinless, coating not eaten*
24160100	Chicken, wing, NS as to cooking method, NS as to skin eaten*
24160110	Chicken, wing, NS as to cooking method, skin eaten*
24160120	Chicken, wing, NS as to cooking method, skin not eaten*
24162100	Chicken, wing, roasted, broiled, or baked, NS as to skin eaten*

24162110	Chicken, wing, roasted, broiled, or baked, skin eaten*
24162120	Chicken, wing, roasted, broiled, or baked, skin not eaten*
24163110	Chicken, wing, stewed, skin eaten*
24163120	Chicken, wing, stewed, skin not eaten*
24167100	Chicken, wing, coated, baked or fried, prepared with skin, NS as to skin/coating eaten*
24167110	Chicken, wing, coated, baked or fried, prepared with skin, skin/coating eaten*
24167120	Chicken, wing, coated, baked or fried, prepared with skin, skin/coating not eaten*
24201000	Turkey, NFS*
24201010	Turkey, light meat, cooked, NS as to skin eaten*
24201020	Turkey, light meat, cooked, skin not eaten*
24201030	Turkey, light meat, cooked, skin eaten*
24201050	Turkey, light meat, breaded, baked or fried, NS as to skin eaten*
24201060	Turkey, light meat, breaded, baked or fried, skin not eaten*
24201070	Turkey, light meat, breaded, baked or fried, skin eaten*
24201110	Turkey, light meat, roasted, NS as to skin eaten*
24201120	Turkey, light meat, roasted, skin not eaten*
24201130	Turkey, light meat, roasted, skin eaten*
24201210	Turkey, dark meat, roasted, NS as to skin eaten*
24201220	Turkey, dark meat, roasted, skin not eaten*
24201230	Turkey, dark meat, roasted, skin eaten*
24201310	Turkey, light and dark meat, roasted, NS as to skin eaten*
24201320	Turkey, light and dark meat, roasted, skin not eaten*
24201330	Turkey, light and dark meat, roasted, skin eaten*
24201350	Turkey, light or dark meat, battered, fried, NS as to skin eaten*
24201370	Turkey, light or dark meat, battered, fried, skin eaten*
24201400	Turkey, light or dark meat, stewed, NS as to skin eaten*
24201410	Turkey, light or dark meat, stewed, skin not eaten*
24201420	Turkey light or dark meat, stewed, skin eaten*
24201500	Turkey, light or dark meat, smoked, cooked, NS as to skin eaten*
24201520	Turkey, light or dark meat, smoked, cooked, skin not eaten*
24202010	Turkey, drumstick, cooked, skin not eaten*
24202020	Turkey, drumstick, cooked, skin eaten*
24202060	Turkey, drumstick, roasted, skin not eaten*
24202070	Turkey, drumstick, roasted, skin eaten*
24202120	Turkey, drumstick, smoked, cooked, skin eaten*
24202460	Turkey, thigh, cooked, skin eaten*
24202500	Turkey, thigh, cooked, skin not eaten*
24202600	Turkey, neck, cooked*
24203000	Turkey, wing, cooked, NS as to skin eaten*
24203010	Turkey, wing, cooked, skin not eaten*
24203020	Turkey, wing, cooked, skin eaten*

24203120	Turkey, wing, smoked, cooked, skin eaten*
24205000	Turkey, tail, cooked*
24300100	Duck, cooked, NS as to skin eaten*
24300110	Duck, cooked, skin eaten*
24300120	Duck, cooked, skin not eaten*
24301000	Duck, roasted, NS as to skin eaten*
24301010	Duck, roasted, skin eaten*
24301020	Duck, roasted, skin not eaten*
24302010	Duck, pressed, Chinese*
24400010	Cornish game hen, cooked, skin eaten*
24400020	Cornish game hen, cooked, skin not eaten*
24401010	Cornish game hen, roasted, skin eaten*
24401020	Cornish game hen, roasted, skin not eaten*
24403100	Quail, cooked*
24404100	Pheasant, cooked*
26100100	Fish, NS as to type, raw*
26100110	Fish, NS as to type, cooked, NS as to cooking method*
26100120	Fish, NS as to type, baked or broiled*
26100130	Fish, NS as to type, breaded or battered, baked*
26100140	Fish, NS as to type, floured or breaded, fried*
26100150	Fish, NS as to type, battered, fried*
26100160	Fish, NS as to type, steamed*
26100170	Fish, NS as to type, dried*
26100190	Fish, NS as to type, smoked*
26100210	Fish stick, patty, or fillet, NS as to type, cooked, NS as to cooking method*
26100220	Fish stick, patty, or fillet, NS as to type, baked or broiled*
26100230	Fish stick, patty, or fillet, NS as to type, breaded or battered, baked*
26100240	Fish stick, patty, or fillet, NS as to type, floured or breaded, fried*
26100250	Fish stick, patty, or fillet, NS as to type, battered, fried*
26101110	Anchovy, cooked, NS as to cooking method*
26105120	Carp, baked or broiled*
26105140	Carp, floured or breaded, fried*
26107110	Catfish, cooked, NS as to cooking method*
26107120	Catfish, baked or broiled*
26107130	Catfish, breaded or battered, baked*
26107140	Catfish, floured or breaded, fried*
26107150	Catfish, battered, fried*
26107160	Catfish, steamed or poached*
26109110	Cod, cooked, NS as to cooking method*
26109120	Cod, baked or broiled*
26109130	Cod, breaded or battered, baked*

26109140	Cod, floured or breaded, fried*
26109150	Cod, battered, fried*
26109160	Cod, steamed or poached*
26109170	Cod, dried, salted*
26109180	Cod, dried, salted, salt removed in water*
26111120	Croaker, baked or broiled*
26111130	Croaker, breaded or battered, baked*
26111140	Croaker, floured or breaded, fried*
26111160	Croaker, steamed or poached*
26113110	Eel, cooked, NS as to cooking method*
26115110	Flounder, cooked, NS as to cooking method*
26115120	Flounder, baked or broiled*
26115130	Flounder, breaded or battered, baked*
26115140	Flounder, floured or breaded, fried*
26115150	Flounder, battered, fried*
26115160	Flounder, steamed or poached*
26117120	Haddock, baked or broiled*
26117130	Haddock, breaded or battered, baked*
26117140	Haddock, floured or breaded, fried*
26117150	Haddock, battered, fried*
26117160	Haddock, steamed or poached*
26119110	Herring, cooked, NS as to cooking method*
26119120	Herring, baked or broiled*
26119140	Herring, floured or breaded, fried*
26119160	Herring, pickled, in cream sauce*
26119180	Herring, pickled*
26119190	Herring, smoked, kippered*
26121110	Mackerel, cooked, NS as to cooking method*
26121120	Mackerel, baked or broiled*
26121140	Mackerel, floured or breaded, fried*
26125120	Ocean perch, baked or broiled*
26125140	Ocean perch, floured or breaded, fried*
26125150	Ocean perch, battered, fried*
26125160	Ocean perch, steamed or poached*
26127120	Perch, baked or broiled*
26127130	Perch, breaded or battered, baked*
26127140	Perch, floured or breaded, fried*
26127150	Perch, battered, fried*
26127160	Perch, steamed or poached*
26129120	Pike, baked or broiled*
26129140	Pike, floured or breaded, fried*

26131100	Pompano, raw*
26131110	Pompano, cooked, NS as to cooking method*
26131120	Pompano, baked or broiled*
26131140	Pompano, floured or breaded, fried*
26131160	Pompano, steamed or poached*
26133110	Porgy, cooked, NS as to cooking method*
26133120	Porgy, baked or broiled*
26133140	Porgy, floured or breaded, fried*
26133150	Porgy, battered, fried*
26133160	Porgy, steamed or poached*
26137100	Salmon, raw*
26137110	Salmon, cooked, NS as to cooking method*
26137120	Salmon, baked or broiled*
26137140	Salmon, floured or breaded, fried*
26137150	Salmon, battered, fried*
26137160	Salmon, steamed or poached*
26137190	Salmon, smoked*
26139110	Sardines, cooked*
26139190	Sardines, skinless, boneless, packed in water*
26141110	Sea bass, cooked, NS as to cooking method*
26141120	Sea bass, baked or broiled*
26141130	Sea bass, breaded or battered, baked*
26141140	Sea bass, floured or breaded, fried*
26141160	Sea bass, steamed or poached*
26143120	Shark, baked or broiled*
26147110	Sturgeon, cooked, NS as to cooking method*
26149120	Swordfish, baked or broiled*
26149140	Swordfish, floured or breaded, fried*
26149160	Swordfish, steamed or poached*
26151120	Trout, baked or broiled*
26151140	Trout, floured or breaded, fried*
26151150	Trout, battered, fried*
26151190	Trout, smoked*
26153100	Tuna, fresh, raw*
26153110	Tuna, fresh, cooked, NS as to cooking method*
26153120	Tuna, fresh, baked or broiled*
26153140	Tuna, fresh, floured or breaded, fried*
26153160	Tuna, fresh, steamed or poached*
26157120	Whiting, baked or broiled*
26157130	Whiting, breaded or battered, baked*
26157140	Whiting, floured or breaded, fried*

26157150	Whiting, battered, fried*
26158000	Tilapia, cooked, NS as to cooking method*
26158010	Tilapia, baked or broiled*
26158020	Tilapia, breaded or battered, baked*
26158030	Tilapia, floured or breaded, fried*
26158040	Tilapia, battered, fried*
26203110	Frog legs, NS as to cooking method*
26205160	Octopus, steamed*
26207110	Roe, shad, cooked*
26213120	Squid, baked, broiled*
26213140	Squid, breaded, fried*
26213160	Squid, steamed or boiled*
26213170	Squid, dried*
26303100	Clams, raw*
26303110	Clams, cooked, NS as to cooking method*
26303120	Clams, baked or broiled*
26303140	Clams, floured or breaded, fried*
26303150	Clams, battered, fried*
26303160	Clams, steamed or boiled*
26305110	Crab, cooked, NS as to cooking method*
26305120	Crab, baked or broiled*
26305160	Crab, hard shell, steamed*
26307140	Crab, soft shell, floured or breaded, fried*
26309140	Crayfish, floured or breaded, fried*
26309160	Crayfish, boiled or steamed*
26311110	Lobster, cooked, NS as to cooking method*
26311120	Lobster, baked or broiled*
26311160	Lobster, steamed or boiled*
26313110	Mussels, cooked, NS as to cooking method*
26313160	Mussels, steamed or poached*
26315100	Oysters, raw*
26315110	Oysters, cooked, NS as to cooking method*
26315120	Oysters, baked or broiled*
26315130	Oysters, steamed*
26315140	Oysters, floured or breaded, fried*
26315150	Oysters, battered, fried*
26315190	Oysters, smoked*
26317110	Scallops, cooked, NS as to cooking method*
26317120	Scallops, baked or broiled*
26317130	Scallops, steamed or boiled*
26317140	Scallops, floured or breaded, fried*

26317150	Scallops, battered, fried*
26319110	Shrimp, cooked, NS as to cooking method*
26319120	Shrimp, baked or broiled*
26319130	Shrimp, steamed or boiled*
26319140	Shrimp, floured, breaded, or battered, fried*
26319170	Shrimp, dried*
26321110	Snails, cooked, NS as to cooking method*
27111000	Beef with tomato-based sauce (mixture)*
27111050	Spaghetti sauce with beef or meat other than lamb or mutton, homemade-style*
27111100	Beef goulash*
27111200	Beef burgundy (beef bourguignonne)*
27111300	Mexican style beef stew, no potatoes, tomato-based sauce (mixture) (Carne guisada sin papas)*
27111310	Mexican style beef stew, no potatoes, with chili peppers, tomato-based sauce (mixture) (Carne guisada con chile)*
27111400	Chili con carne, NS as to beans*
27111410	Chili con carne with beans*
27111420	Chili con carne without beans*
27111430	Chili con carne, NS as to beans, with cheese*
27111440	Chili con carne with beans and cheese*
27111500	Beef sloppy joe (no bun)*
27112000	Beef with gravy (mixture)*
27112010	Salisbury steak with gravy (mixture)*
27113000	Beef with cream or white sauce (mixture)*
27113100	Beef stroganoff*
27113200	Creamed chipped or dried beef*
27113300	Swedish meatballs with cream or white sauce (mixture)*
27114000	Beef with (mushroom) soup (mixture)*
27115000	Beef with soy-based sauce (mixture)*
27115100	Steak teriyaki with sauce (mixture)*
27116100	Beef curry*
27116200	Beef with barbecue sauce (mixture)*
27116300	Beef with sweet and sour sauce (mixture)*
27116350	Stewed, seasoned, ground beef, Mexican style (Picadillo de carne de rez)*
27116400	Steak tartare (raw ground beef and egg)*
27118110	Meatballs, Puerto Rican style (Albondigas guisadas)*
27118120	Stewed seasoned ground beef, Puerto Rican style (Picadillo guisado, picadillo de carne)*
27118180	Puerto Rican style beef stew, meat with gravy (potatoes reported separately)*
27120020	Ham or pork with gravy (mixture)*
27120030	Ham or pork with barbecue sauce (mixture)*
27120060	Sweet and sour pork*
27120080	Ham stroganoff*

27120090	Ham or pork with (mushroom) soup (mixture)*
27120100	Ham or pork with tomato-based sauce (mixture)*
27120130	Mexican style pork stew, no potatoes, tomato-based sauce (mixture) (cerdo guisado sin papas)*
27120150	Pork or ham with soy-based sauce (mixture)*
27120250	Frankfurters or hot dogs with tomato-based sauce (mixture)*
27121000	Pork with chili and tomatoes (mixture) (Puerco con chile)*
27121010	Stewed pork, Puerto Rican style*
27121410	Chili con carne with beans, made with pork*
27130040	Spaghetti sauce with lamb or mutton, homemade-style*
27130100	Lamb curry*
27133010	Stewed goat, Puerto Rican style (Cabrito en fricase, chilindron de chivo)*
27135010	Veal with gravy (mixture)*
27135050	Veal Marsala*
27135110	Veal parmigiana*
27136050	Venison/deer with tomato-based sauce (mixture)*
27136100	Chili con carne with venison/deer and beans*
27141000	Chicken or turkey cacciatore*
27141030	Spaghetti sauce with poultry, home-made style*
27141050	Stewed chicken with tomato-based sauce, Mexican style (mixture) (Pollo guisado con tomate)*
27141500	Chili con carne with chicken or turkey and beans*
27142100	Chicken or turkey fricassee*
27142200	Turkey with gravy (mixture)*
27143000	Chicken or turkey with cream sauce (mixture)*
27144000	Chicken or turkey with (mushroom) soup (mixture)*
27145000	Chicken or turkey teriyaki (chicken or turkey with soy-based sauce)*
27146000	Chicken or turkey with barbecue sauce (mixture), skin eaten*
27146010	Chicken or turkey with barbecue sauce (mixture), skin not eaten*
27146050	Chicken wing with hot pepper sauce*
27146100	Sweet and sour chicken or turkey*
27146150	Chicken curry*
27146160	Chicken with mole sauce*
27146200	Chicken or turkey with cheese sauce (mixture)*
27146250	Chicken or turkey cordon bleu*
27146300	Chicken or turkey parmigiana*
27146350	Lemon chicken, Chinese style*
27146400	Chicken kiev*
27150010	Fish with cream or white sauce, not tuna or lobster (mixture)*
27150030	Crab imperial*
27150060	Lobster newburg*
27150070	Lobster with butter sauce (mixture)*

27150100	Shrimp, curried*
27150110	Shrimp cocktail (shrimp with cocktail sauce)*
27150120	Tuna with cream or white sauce (mixture)*
27150130	Seafood newburg*
27150160	Shrimp with lobster sauce (mixture)*
27150170	Sweet and sour shrimp*
27150190	Lobster sauce (broth-based)*
27150200	Oyster sauce (white sauce-based)*
27150210	Fish sauce (bagoong)*
27150230	Shrimp scampi*
27150310	Fish with tomato-based sauce (mixture)*
27150320	Fish curry*
27150330	Mussels with tomato-based sauce (mixture)*
27150350	Sardines with tomato-based sauce (mixture)*
27150370	Sardines with mustard sauce (mixture)*
27150410	Shrimp teriyaki (shrimp with soy-based sauce) (mixture)*
27150510	Scallops with cheese sauce (mixture)*
27151030	Marinated fish (Ceviche)*
27151040	Crabs in tomato-based sauce, Puerto Rican style (mixture) (Salmorejo de jueyes)*
27151050	Shrimp in garlic sauce, Puerto Rican style (mixture) (Camarones al ajillo)*
27151070	Stewed codfish, Puerto Rican style, no potatoes (potatoes reported separately)*
27160010	Meat with barbecue sauce, NS as to type of meat (mixture)*
27160100	Meatballs, NS as to type of meat, with sauce (mixture)*
27162010	Meat with tomato-based sauce (mixture)*
27162060	Spaghetti sauce with meat and vegetables, homemade-style*
27162500	Stewed, seasoned, ground beef and pork, Mexican style (Picadillo de carne de rez y puerco)*
27211000	Beef and potatoes, no sauce (mixture)*
27211100	Beef stew with potatoes, tomato-based sauce (mixture)*
27211110	Mexican style beef stew with potatoes, tomato-based sauce (mixture) (Carne guisada con papas)*
27211150	Beef goulash with potatoes*
27211190	Beef and potatoes with cream sauce, white sauce or mushroom soup-based sauce (mixture)*
27211200	Beef stew with potatoes, gravy*
27211300	Beef (roast) hash*
27211400	Corned beef hash*
27211500	Beef and potatoes with cheese sauce (mixture)*
27211550	Stewed, seasoned, ground beef with potatoes, Mexican style (Picadillo de carne de rez con papas)*
27212000	Beef and noodles, no sauce (mixture)*
27212050	Beef and macaroni with cheese sauce (mixture)*
27212100	Beef and noodles with tomato-based sauce (mixture)*
27212120	Chili con carne with beans and macaroni*

27212150	Beef goulash with noodles*
27212200	Beef and noodles with gravy (mixture)*
27212300	Beef and noodles with cream or white sauce (mixture)*
27212350	Beef stroganoff with noodles*
27212400	Beef and noodles with (mushroom) soup (mixture)*
27213000	Beef and rice, no sauce (mixture)*
27213100	Beef and rice with tomato-based sauce (mixture)*
27213150	Chili con carne with beans and rice*
27213200	Beef and rice with gravy (mixture)*
27213300	Beef and rice with cream sauce (mixture)*
27213500	Beef and rice with soy-based sauce (mixture)*
27213600	Beef and rice with cheese sauce (mixture)*
27214100	Meat loaf made with beef*
27214110	Meat loaf made with beef, with tomato-based sauce*
27218210	Puerto Rican style beef stew with potatoes (Carne guisada con papas)*
27218310	Stewed corned beef, Puerto Rican style ("Corned beef" guisado)*
27220010	Meat loaf made with ham (not luncheon meat)*
27220020	Ham and noodles with cream or white sauce (mixture)*
27220030	Ham and rice with (mushroom) soup (mixture)*
27220080	Ham croquette*
27220110	Pork and rice with tomato-based sauce (mixture)*
27220210	Ham and noodles, no sauce (mixture)*
27220310	Ham or pork and rice, no sauce (mixture)*
27220510	Ham or pork and potatoes with gravy (mixture)*
27220520	Ham or pork and potatoes with cheese sauce (mixture)*
27221100	Stewed pig's feet, Puerto Rican style (Patitas de cerdo guisadas)*
27221150	Mexican style pork stew, with potatoes, tomato-based sauce (mixture) (cerdo guisado con papas)*
27230010	Lamb or mutton loaf*
27231000	Lamb or mutton and potatoes with gravy (mixture)*
27235000	Meat loaf made with venison/deer*
27241010	Chicken or turkey and potatoes with gravy (mixture)*
27242000	Chicken or turkey and noodles, no sauce (mixture)*
27242200	Chicken or turkey and noodles with gravy (mixture)*
27242250	Chicken or turkey and noodles with (mushroom) soup (mixture)*
27242300	Chicken or turkey and noodles with cream or white sauce (mixture)*
27242310	Chicken or turkey and noodles with cheese sauce (mixture)*
27242350	Chicken or turkey tetrazzini*
27242400	Chicken or turkey and noodles, tomato-based sauce (mixture)*
27242500	Chicken or turkey and noodles with soy-based sauce (mixture)*
27243000	Chicken or turkey and rice, no sauce (mixture)*
27243300	Chicken or turkey and rice with cream sauce (mixture)*

27243400	Chicken or turkey and rice with (mushroom) soup (mixture)*
27243500	Chicken or turkey and rice with tomato-based sauce (mixture)*
27243600	Chicken or turkey and rice with soy-based sauce (mixture)*
27246100	Chicken or turkey with dumplings (mixture)*
27246200	Chicken or turkey with stuffing (mixture)*
27246300	Chicken or turkey cake, patty, or croquette*
27246400	Chicken or turkey souffle*
27246500	Meat loaf made with chicken or turkey*
27246505	Meat loaf made with chicken or turkey, with tomato-based sauce*
27250020	Clams, stuffed*
27250030	Codfish ball or cake*
27250040	Crab cake*
27250050	Fish cake or patty, NS as to fish*
27250070	Salmon cake or patty*
27250110	Scallops and noodles with cheese sauce (mixture)*
27250120	Shrimp and noodles, no sauce (mixture)*
27250122	Shrimp and noodles with gravy (mixture)*
27250124	Shrimp and noodles with (mushroom) soup (mixture)*
27250126	Shrimp and noodles with cream or white sauce (mixture)*
27250128	Shrimp and noodles with soy-based sauce (mixture)*
27250130	Shrimp and noodles with cheese sauce (mixture)*
27250132	Shrimp and noodles with tomato sauce (mixture)*
27250160	Tuna cake or patty*
27250210	Clam cake or patty*
27250220	Oyster fritter*
27250250	Flounder with crab stuffing*
27250400	Shrimp cake or patty*
27250410	Shrimp with crab stuffing*
27250450	Shrimp toast, fried*
27250520	Seafood restructured*
27250610	Tuna noodle casserole with cream or white sauce*
27250630	Tuna noodle casserole with (mushroom) soup*
27250810	Fish and rice with tomato-based sauce*
27250820	Fish and rice with cream sauce*
27250900	Fish and noodles with (mushroom) soup*
27260010	Meat loaf, NS as to type of meat*
27260050	Meatballs, with breading, NS as to type of meat, with gravy*
27260080	Meat loaf made with beef and pork*
27260090	Meat loaf made with beef, veal and pork*
27260100	Meat loaf made with beef and pork, with tomato-based sauce*
27260110	Hash, NS as to type of meat*

27311110	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27311120	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27311210	Corned beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27311220	Corned beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27311310	Beef stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce*
27311320	Beef stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce*
27311410	Beef stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy*
27311420	Beef stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy*
27311510	Shepherd's pie with beef*
27311600	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27311605	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27311610	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), (mushroom) soup (mixture)*
27311620	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), (mushroom) soup (mixture)*
27311625	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27311630	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27311635	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), cheese sauce (mixture)*
27311640	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27311645	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)*
27311650	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)*
27313010	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27313020	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27313110	Beef chow mein or chop suey with noodles*
27313160	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)*
27313210	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27313220	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27313320	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), (mushroom) soup (mixture)*
27313410	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27313420	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*

27315010	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27315020	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27315210	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27315220	Beef, rice, and vegetables (excluding carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27315250	Stuffed cabbage rolls with beef and rice*
27315270	Stuffed grape leaves with beef and rice*
27315310	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), (mushroom) soup (mixture)*
27315320	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), (mushroom) soup (mixture)*
27315340	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27315410	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27315420	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27315510	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)*
27315520	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)*
27317010	Beef pot pie*
27320030	Ham or pork, noodles and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27320040	Pork, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27320070	Ham or pork, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27320100	Pork, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27320110	Pork, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27320140	Pork, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27320150	Pork, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27320210	Pork, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27320310	Pork chow mein or chop suey with noodles*
27320320	Pork, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)*
27320330	Pork, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)*
27320340	Pork, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27320410	Ham, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27320450	Ham, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27330010	Shepherd's pie with lamb*

27330030	Lamb or mutton stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy*
27330050	Lamb or mutton, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27330060	Lamb or mutton, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27330110	Lamb or mutton stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy*
27332100	Veal stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce*
27336150	Venison/deer stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce*
27336200	Venison/deer, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27336310	Venison/deer, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27341000	Chicken or turkey, potatoes, corn, and cheese, with gravy*
27341010	Chicken or turkey, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27341020	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27341025	Chicken or turkey, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27341030	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27341035	Chicken or turkey, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27341040	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27341050	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27341055	Chicken or turkey, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27341060	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27341310	Chicken or turkey stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy*
27341320	Chicken or turkey stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy*
27341510	Chicken or turkey stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce*
27341520	Chicken or turkey stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato- based sauce*
27343010	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27343020	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27343410	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27343420	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27343470	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*

27343480	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27343510	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27343520	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27343910	Chicken or turkey chow mein or chop suey with noodles*
27343950	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), cheese sauce (mixture)*
27343960	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27345010	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27345020	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), no sauce (mixture)*
27345210	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27345220	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27345310	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)*
27345320	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), soy-based sauce (mixture)*
27345410	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27345420	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27345440	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), cheese sauce (mixture)*
27345450	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27345510	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27345520	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27347100	Chicken or turkey pot pie*
27347200	Chicken or turkey, stuffing, and vegetables (including carrots, broccoli, and/or dark-green leafy), no sauce (mixture)*
27347210	Chicken or turkey,stuffing, and vegetables (excluding carrots, broccoli, and dark green leafy), no sauce (mixture)*
27347220	Chicken or turkey, stuffing, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27347240	Chicken or turkey, dumplings, and vegetables (including carrots, broccoli, and/or dark green leafy), gravy (mixture)*
27347250	Chicken or turkey, dumplings, and vegetables (excluding carrots, broccoli, and dark green leafy), gravy (mixture)*
27348100	Chicken fricassee, Puerto Rican style (Fricase de pollo)*
27350020	Paella with seafood*
27350030	Seafood stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-base sauce*
27350050	Shrimp chow mein or chop suey with noodles*
27350060	Shrimp creole, with rice*

27350080	Tuna noodle casserole with vegetables, cream or white sauce*
27350110	Bouillabaisse*
27350310	Seafood stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-base sauce*
27350410	Tuna noodle casserole with vegetables and (mushroom) soup*
27360000	Stew, NFS*
27360010	Goulash, NFS*
27360080	Chow mein or chop suey, NS as to type of meat, with noodles*
27360090	Paella, NFS*
27360100	Brunswick stew*
27360120	Chow mein or chop suey, various types of meat, with noodles*
27362000	Stewed tripe, Puerto Rican style, with potatoes (Mondongo)*
27363000	Gumbo with rice (New Orleans type with shellfish, pork, and/or poultry, tomatoes, okra, rice)*
27363100	Jambalaya with meat and rice*
27410210	Beef and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), no sauce (mixture)*
27410220	Beef and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), no sauce (mixture)*
27410250	Beef shish kabob with vegetables, excluding potatoes*
27411100	Beef with vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27411120	Swiss steak*
27411200	Beef with vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27414100	Beef with vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), (mushroom) soup (mixture)*
27414200	Beef with vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), (mushroom) soup (mixture)*
27415100	Beef and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27415120	Beef, tofu, and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27415150	Beef chow mein or chop suey, no noodles*
27415170	Kung Pao beef*
27415200	Beef and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27415220	Beef, tofu, and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27416150	Pepper steak*
27416250	Beef salad*
27416300	Beef taco filling: beef, cheese, tomato, taco sauce*
27416400	Sukiyaki (stir fried beef and vegetables in soy sauce)*
27416450	Beef and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), gravy (mixture)*
27416500	Beef and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), gravy (mixture)*
27418210	Puerto Rican style beef stew with vegetables, excluding potatoes (Carne a la Judia)*

27418310	Corned beef with tomato sauce and onion, Puerto Rican style (mixture)*
27418410	Beef steak with onions, Puerto Rican style (mixture) (Biftec encebollado)*
27420010	Cabbage with ham hocks (mixture)*
27420020	Ham or pork salad*
27420060	Pork and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), no sauce (mixture)*
27420080	Greens with ham or pork (mixture)*
27420160	Moo Shu (Mu Shi) Pork, without Chinese pancake*
27420170	Pork and onions with soy-based sauce (mixture)*
27420200	Pork hash, Hawaiian style-ground pork, vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce*
27420250	Ham and vegetables (including carrots, broccoli, and/or dark- green leafy (no potatoes)), no sauce (mixture)*
27420270	Ham and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), no sauce (mixture)*
27420350	Pork and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), no sauce (mixture)*
27420370	Pork, tofu, and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27420390	Pork chow mein or chop suey, no noodles*
27420400	Pork and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27420410	Pork and vegetables (excluding carrots, broccoli, and dark- green leafy (no potatoes)), tomato-based sauce (mixture)*
27420470	Sausage and peppers, no sauce (mixture)*
27420500	Pork and vegetables (including carrots, broccoli, and/or dark-green leafy), soy-based sauce (mixture)*
27420510	Pork and vegetables (excluding carrots, broccoli, and dark- green leafy), soy-based sauce (mixture)*
27420520	Pork shish kabob with vegetables, excluding potatoes*
27422010	Pork chop stewed with vegetables, Puerto Rican style (mixture) (Chuletas a la jardinera)*
27430610	Lamb shish kabob with vegetables, excluding potatoes*
27440110	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), no sauce (mixture)*
27440120	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), no sauce (mixture)*
27440130	Chicken or turkey shish kabob with vegetables, excluding potatoes*
27442110	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), gravy (mixture)*
27442120	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), gravy (mixture)*
27443110	Chicken or turkey a la king with vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), cream, white, or soup-based sauce*
27443120	Chicken or turkey a la king with vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), cream, white, or soup-based sauce*
27443150	Chicken or turkey divan*
27445110	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27445120	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)*

27445125	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27445130	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27445150	General Tso (General Gau) chicken*
27445180	Moo Goo Gai Pan*
27445220	Kung pao chicken*
27445250	Almond chicken*
27446100	Chicken or turkey chow mein or chop suey, no noodles*
27446200	Chicken or turkey salad*
27446205	Chicken or turkey salad with nuts and/or fruits*
27446220	Chicken or turkey salad with egg*
27446300	Chicken or turkey garden salad (chicken and/or turkey, tomato and/or carrots, other vegetables), no dressing*
27446310	Chicken or turkey garden salad (chicken and/or turkey, other vegetables excluding tomato and carrots), no dressing*
27446315	Chicken or turkey garden salad with bacon (chicken and/or turkey, bacon, cheese, lettuce and/or greens, tomato and/or carrots, other vegetables), no dressing*
27446320	Chicken or turkey (breaded, fried) garden salad with bacon (chicken and/or turkey, bacon, cheese, lettuce and/or greens, tomato and/or carrots, other vegetables), no dressing*
27446355	Oriental chicken or turkey garden salad with crispy noodles (chicken and/or turkey, lettuce, fruit, nuts, crispy noodles), no dressing*
27446360	Chicken or turkey caesar garden salad (chicken and/or turkey, lettuce, tomato, cheese), no dressing*
27446400	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), cheese sauce (mixture)*
27446410	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), cheese sauce (mixture)*
27450010	Crab salad*
27450020	Lobster salad*
27450030	Salmon salad*
27450040	Shrimp chow mein or chop suey, no noodles*
27450060	Tuna salad*
27450070	Shrimp salad*
27450080	Seafood salad*
27450090	Tuna salad with cheese*
27450100	Tuna salad with egg*
27450120	Shrimp garden salad (shrimp, lettuce, eggs, vegetables excluding tomato and carrots), no dressing*
27450130	Crab salad made with imitation crab*
27450180	Seafood garden salad with seafood, lettuce, vegetables excluding tomato and carrots, no dressing*
27450400	Shrimp and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), no sauce (mixture)*
27450405	Shrimp and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), no sauce (mixture)*
27450410	Shrimp and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)*

27450420	Shrimp and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27450430	Shrimp shish kabob with vegetables, excluding potatoes*
27450450	Shrimp creole, no rice*
27450470	Kung Pao shrimp*
27450510	Tuna casserole with vegetables and (mushroom) soup, no noodles*
27450610	Shellfish mixture and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce*
27450660	Shellfish mixture and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), (mushroom) soup (mixture)*
27450700	Fish and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27450710	Fish and vegetables (excluding carrots, broccoli, and dark- green leafy (no potatoes)), tomato-based sauce (mixture)*
27450740	Fish and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27450750	Fish and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), soy-based sauce (mixture)*
27451030	Lobster creole, Puerto Rican style (Langosta a la criolla)*
27460010	Chow mein or chop suey, NS as to type of meat, no noodles*
27460510	Antipasto with ham, fish, cheese, vegetables*
27460750	Liver, beef or calves, and onions*
27464000	Gumbo, no rice (New Orleans type with shellfish, pork, and/or poultry, tomatoes, okra)*
27500050	Sandwich, NFS*
27500200	Wrap sandwich, filled with meat, poultry, or fish, vegetables, and cheese*
27500300	Wrap sandwich, filled with meat, poultry, or fish, and vegetables*
27510110	Beef barbecue sandwich or Sloppy Joe, on bun*
27510130	Beef barbecue submarine sandwich, on bun*
27510210	Cheeseburger, plain, on bun*
27510230	Cheeseburger, with mayonnaise or salad dressing and tomatoes, on bun*
27510250	Cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing, on bun*
27510260	Cheeseburger, 1/4 lb meat, with mushrooms in sauce, on bun*
27510280	Double cheeseburger (2 patties), with mayonnaise or salad dressing, on bun*
27510300	Double cheeseburger (2 patties), with mayonnaise or salad dressing, on double-decker bun*
27510310	Cheeseburger with tomato and/or catsup, on bun*
27510311	Cheeseburger, 1 oz meat, plain, on miniature bun*
27510320	Cheeseburger, 1/4 lb meat, with tomato and/or catsup, on bun*
27510330	Double cheeseburger (2 patties), with tomato and/or catsup, on bun*
27510340	Double cheeseburger (2 patties), with mayonnaise or salad dressing and tomatoes, on bun*
27510350	Cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun*
27510355	Cheeseburger, 1/3 lb meat, with mayonnaise or salad dressing, tomato and/or catsup on bun*
27510360	Cheeseburger with mayonnaise or salad dressing, tomato and bacon, on bun*
27510370	Double cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun*
27510375	Double cheeseburger (2 patties, 1/4 lb meat each), with tomato and/or catsup, on bun*

27510380	Triple cheeseburger (3 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes, on bun*
27510390	Double bacon cheeseburger (2 patties, 1/4 lb meat each), on bun*
27510400	Bacon cheeseburger, 1/4 lb meat, with tomato and/or catsup, on bun*
27510410	Chiliburger, on bun*
27510420	Taco burger, on bun*
27510425	Double bacon cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun*
27510430	Double bacon cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes, on bun*
27510435	Double bacon cheeseburger (2 patties,1/3 lb meat each), with mayonnaise or salad dressing, on bun*
27510440	Bacon cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun*
27510480	Cheeseburger (hamburger with cheese sauce), 1/4 lb meat, with grilled onions, on rye bun*
27510500	Hamburger, plain, on bun*
27510510	Hamburger, with tomato and/or catsup, on bun*
27510520	Hamburger, with mayonnaise or salad dressing and tomatoes, on bun*
27510540	Double hamburger (2 patties), with tomato and/or catsup, on bun*
27510550	Double hamburger (2 patties), with mayonnaise or salad dressing and tomatoes, on double-decker bun*
27510560	Hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun*
27510600	Hamburger, 1 oz meat, plain, on miniature bun*
27510610	Hamburger, 1 oz meat, with tomato and/or catsup, on miniature bun*
27510620	Hamburger, 1/4 lb meat, with tomato and/or catsup, on bun*
27510670	Double hamburger (2 patties), with mayonnaise or salad dressing and tomatoes, on bun*
27510680	Double hamburger (2 patties, 1/4 lb meat each), with tomato and/or catsup, on bun*
27510690	Double hamburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes and/or catsup, on double-decker bun*
27510700	Meatball and spaghetti sauce submarine sandwich*
27515020	Steak and cheese submarine sandwich, with lettuce and tomato*
27515050	Fajita-style beef sandwich with cheese, on pita bread, with lettuce and tomato*
27515070	Steak and cheese submarine sandwich, with fried peppers and onions, on roll*
27515080	Steak sandwich, plain, on biscuit*
27516010	Gyro sandwich (pita bread, beef, lamb, onion, condiments), with tomato and spread*
27520130	Bacon, chicken, and tomato club sandwich, with lettuce and spread*
27520135	Bacon, chicken, and tomato club sandwich, with cheese, lettuce and spread*
27520165	Bacon, chicken fillet (breaded, fried), and tomato club with lettuce and spread*
27520166	Bacon, chicken fillet (breaded, fried), and tomato club sandwich with cheese, lettuce and spread*
27520500	Pork sandwich, on white roll, with onions, dill pickles and barbecue sauce*
27520520	Pork sandwich*
27540110	Chicken sandwich, with spread*
27540130	Chicken barbecue sandwich*
27540140	Chicken fillet (breaded, fried) sandwich*
27540145	Chicken fillet (breaded, fried) sandwich on biscuit*

27540150	Chicken fillet (breaded, fried) sandwich with lettuce, tomato and spread*
27540170	Chicken patty sandwich, miniature, with spread*
27540180	Chicken patty sandwich or biscuit*
27540190	Chicken patty sandwich, with lettuce and spread*
27540200	Fajita-style chicken sandwich with cheese, on pita bread, with lettuce and tomato*
27540210	Wrap sandwich filled with chicken strips (breaded, fried), cheese, lettuce, and spread*
27540230	Chicken patty sandwich with cheese, on wheat bun, with lettuce, tomato and spread*
27540235	Chicken fillet, broiled, sandwich with lettuce, tomato, and spread*
27540240	Chicken fillet, (broiled), sandwich, on whole wheat roll, with lettuce, tomato and spread*
27540250	Chicken fillet, broiled, sandwich with cheese, on whole wheat roll, with lettuce, tomato and non-mayonaise type spread*
27540260	Chicken fillet, broiled, sandwich, on oat bran bun, with lettuce, tomato, spread*
27540270	Chicken fillet, broiled, sandwich, with lettuce, tomato, and non-mayonnaise type spread*
27540280	Chicken fillet, broiled, sandwich with cheese, on bun, with lettuce, tomato and spread*
27560300	Corn dog (frankfurter or hot dog with cornbread coating)*
28101000	Frozen dinner, NFS*
28110000	Beef dinner, NFS (frozen meal)*
28110150	Beef with vegetable (diet frozen meal)*
28110220	Sirloin, chopped, with gravy, mashed potatoes, vegetable (frozen meal)*
28110270	Sirloin beef with gravy, potatoes, vegetable (frozen meal)*
28110300	Salisbury steak dinner, NFS (frozen meal)*
28110310	Salisbury steak with gravy, potatoes, vegetable (frozen meal)*
28110330	Salisbury steak with gravy, whipped potatoes, vegetable, dessert (frozen meal)*
28110350	Salisbury steak with gravy, potatoes, vegetable, dessert (frozen meal, large meat portion)*
28110370	Salisbury steak with gravy, macaroni and cheese, vegetable (frozen meal)*
28110380	Salisbury steak with gravy, macaroni and cheese (frozen meal)*
28110390	Salisbury steak, potatoes, vegetable, dessert (diet frozen meal)*
28110510	Beef, sliced, with gravy, potatoes, vegetable (frozen meal)*
28110620	Beef short ribs, boneless, with barbecue sauce, potatoes, vegetable (frozen meal)*
28110640	Meatballs, Swedish, in sauce, with noodles (frozen meal)*
28110660	Meatballs, Swedish, in gravy, with noodles (diet frozen meal)*
28113110	Salisbury steak, baked, with tomato sauce, vegetable (diet frozen meal)*
28113140	Beef with spaetzle or rice, vegetable (frozen meal)*
28133110	Veal, breaded, with spaghetti, in tomato sauce (frozen meal)*
28140100	Chicken dinner, NFS (frozen meal)*
28140150	Chicken divan (frozen meal)*
28140320	Chicken and noodles with vegetable, dessert (frozen meal)*
28140710	Chicken, fried, with potatoes, vegetable (frozen meal)*
28140720	Chicken patty, or nuggets, boneless, breaded, potatoes, vegetable (frozen meal)*
28140730	Chicken patty, breaded, with tomato sauce and cheese, fettuccine alfredo, vegetable (frozen meal)*
28140740	Chicken patty, or nuggets, boneless, breaded, with pasta and tomato sauce, fruit, dessert (frozen meal)*

28140810	Chicken, fried, with potatoes, vegetable, dessert (frozen meal)*
28141010	Chicken, fried, with potatoes, vegetable, dessert (frozen meal, large meat portion)*
28141050	Chicken patty parmigiana, breaded, with vegetable (diet frozen meal)*
28141201	Teriyaki chicken with rice and vegetable (diet frozen meal)*
28141250	Chicken with rice-vegetable mixture (diet frozen meal)*
28141300	Chicken with rice and vegetable, reduced fat and sodium (diet frozen meal)*
28141600	Chicken a la king with rice (frozen meal)*
28141610	Chicken and vegetables in cream or white sauce (diet frozen meal)*
28143010	Chicken and vegetable entree with rice, Oriental (frozen meal)*
28143020	Chicken and vegetable entree with rice, Oriental (diet frozen meal)*
28143030	Chicken and vegetable entree, oriental (diet frozen meal)*
28143080	Chicken with noodles and cheese sauce (diet frozen meal)*
28143110	Chicken cacciatore with noodles (diet frozen meal)*
28143130	Chicken and vegetable entree with noodles (frozen meal)*
28143150	Chicken and vegetable entree with noodles (diet frozen meal)*
28143170	Chicken in cream sauce with noodles and vegetable (frozen meal)*
28143180	Chicken in butter sauce with potatoes and vegetable (diet frozen meal)*
28143190	Chicken in mushroom sauce, white and wild rice, vegetable (frozen meal)*
28143200	Chicken in soy-based sauce, rice and vegetables (frozen meal)*
28143210	Chicken in orange sauce with almond rice (diet frozen meal)*
28143220	Chicken in barbecue sauce, with rice, vegetable and dessert, reduced fat and sodium (diet frozen meal)*
28144100	Chicken and vegetable entree with noodles and cream sauce (frozen meal)*
28145000	Turkey dinner, NFS (frozen meal)*
28145100	Turkey with dressing, gravy, vegetable and fruit (diet frozen meal)*
28145110	Turkey with vegetable, stuffing (diet frozen meal)*
28145210	Turkey with gravy, dressing, potatoes, vegetable (frozen meal)*
28145610	Turkey with gravy, dressing, potatoes, vegetable, dessert (frozen meal, large meat portion)*
28150000	Fish dinner, NFS (frozen meal)*
28150210	Haddock with chopped spinach (diet frozen meal)*
28150220	Flounder with chopped broccoli (diet frozen meal)*
28150510	Fish in lemon-butter sauce with starch item, vegetable (frozen meal)*
28150650	Fish, breaded, or fish sticks, with pasta, vegetable and dessert (frozen meal)*
28152030	Seafood newburg with rice, vegetable (frozen meal)*
28152050	Shrimp with rice, vegetable (frozen meal)*
28154010	Shrimp and vegetables in sauce with noodles (diet frozen meal)*
28160310	Meat loaf with potatoes, vegetable (frozen meal)*
28160650	Stuffed green pepper (frozen meal)*
28160710	Stuffed cabbage, with meat and tomato sauce (diet frozen meal)*
58100100	Burrito with beef, no beans*
58100110	Burrito with beef and beans*
58100120	Burrito with beef, beans, and cheese*

58100130	Burrito with beef and cheese, no beans*
58100140	Burrito with beef, beans, cheese, and sour cream*
58100150	Burrito with beef and potato, no beans*
58100155	Burrito with beef, rice, and cheese*
58100160	Burrito with beef, beans, rice, and cheese*
58100180	Burrito with pork and beans*
58100200	Burrito with chicken, no beans*
58100210	Burrito with chicken and beans*
58100240	Burrito with chicken, NFS*
58100245	Burrito with chicken, beans, cheese, and sour cream*
58100250	Burrito with chicken, rice, and cheese*
58100255	Burrito with chicken, beans, rice, and cheese*
58100410	Burrito with beef, cheese, and sour cream*
58101230	Flauta with beef*
58101240	Flauta with chicken*
58101300	Taco or tostada with beef, cheese and lettuce*
58101310	Taco or tostada with beef, lettuce, tomato and salsa*
58101320	Taco or tostada with beef, cheese, lettuce, tomato and salsa*
58101350	Soft taco with beef, cheese, lettuce, tomato and sour cream*
58101400	Soft taco with beef, cheese, and lettuce*
58101450	Soft taco with chicken, cheese, and lettuce*
58101460	Soft taco with chicken, cheese, lettuce, tomato and sour cream*
58101510	Taco or tostada with chicken or turkey, lettuce, tomato and salsa*
58101520	Taco or tostada with chicken, cheese, lettuce, tomato and salsa*
58101530	Soft taco with beef, cheese, lettuce, tomato and salsa*
58101540	Taco or tostada with fish, lettuce, tomato, salsa*
58101610	Soft taco with bean, cheese, lettuce, and tomato and/or salsa*
58101615	Soft taco with bean, cheese, lettuce, tomato and/or salsa, and sour cream*
58101710	Taco or tostada with beans, meatless, with lettuce, tomato and salsa*
58101720	Taco or tostada with beans and cheese, meatless, with lettuce, tomato and salsa*
58101730	Taco or tostada with beans, cheese, meat, lettuce, tomato and salsa*
58101800	Ground beef with tomato sauce and taco seasonings on a cornbread crust*
58101820	Mexican casserole made with ground beef, beans, tomato sauce, cheese, taco seasonings, and corn chips*
58101830	Mexican casserole made with ground beef, tomato sauce, cheese, taco seasonings, and corn chips*
58101910	Taco or tostada salad with beef and cheese, corn chips*
58101930	Taco or tostada salad with beef, beans and cheese, fried flour tortilla*
58103130	Tamale with chicken*
58104080	Nachos with beef, beans, cheese, and sour cream*
58104130	Nachos with beef, beans, and cheese*
58104140	Nachos with beef and cheese*

58104180	Nachos with beef, beans, cheese, tomatoes, sour cream and onions*
58104250	Nachos with chicken or turkey and cheese*
58104280	Chalupa with beef, cheese, lettuce, tomato and sour cream*
58104290	Chalupa with beef, cheese, lettuce, tomato and salsa*
58104320	Chalupa with chicken, cheese, lettuce, tomato and sour cream*
58104340	Chalupa with chicken, cheese, lettuce, tomato and salsa*
58104450	Chimichanga with beef and tomato*
58104500	Chimichanga with beef, beans, lettuce and tomato*
58104510	Chimichanga with beef, cheese, lettuce and tomato*
58104530	Chimichanga with chicken and cheese*
58104550	Chimichanga with chicken, sour cream, lettuce and tomato, no cheese*
58104830	Taquitos with chicken*
58105000	Fajita with chicken and vegetables*
58105050	Fajita with beef and vegetables*
58116130	Empanada, Mexican turnover, filled with chicken and vegetables*
58306010	Beef enchilada dinner, NFS (frozen meal)*
58306020	Beef enchilada, chili gravy, rice, refried beans (frozen meal)*
58306100	Chicken enchilada (diet frozen meal)*
58306150	Chicken enchilada with salsa, rice, vegetable, and dessert (diet frozen meal)*
74410110	Puerto Rican seasoning with ham*

* Only component of proposed food category of food was applied in analysis

Chewing gum

Food Code	Description
91800100	Chewing gum, NFS
91801000	Chewing gum, sugared
91802000	Chewing gum, sugarless

Major main entrée sauces

Food Code	Description
14650160	Alfredo sauce
27111000	Beef with tomato-based sauce (mixture)*
27111300	Mexican style beef stew, no potatoes, tomato-based sauce (mixture) (Carne guisada sin papas)*
27111310	Mexican style beef stew, no potatoes, with chili peppers, tomato-based sauce (mixture) (Carne guisada con chile)*
27116100	Beef curry*
27120080	Ham stroganoff*
27120100	Ham or pork with tomato-based sauce (mixture)*

27120110	Sausage with tomato-based sauce (mixture)*
27120130	Mexican style pork stew, no potatoes, tomato-based sauce (mixture) (cerdo guisado sin papas)*
27120250	Frankfurters or hot dogs with tomato-based sauce (mixture)*
27130040	Spaghetti sauce with lamb or mutton, homemade-style*
27130100	Lamb curry*
27135110	Veal parmigiana*
27136050	Venison/deer with tomato-based sauce (mixture)*
27141000	Chicken or turkey cacciatore*
27141030	Spaghetti sauce with poultry, home-made style*
27141050	Stewed chicken with tomato-based sauce, Mexican style (mixture) (Pollo guisado con tomate)*
27146150	Chicken curry*
27146300	Chicken or turkey parmigiana*
27150190	Lobster sauce (broth-based)*
27150200	Oyster sauce (white sauce-based)*
27150310	Fish with tomato-based sauce (mixture)*
27150320	Fish curry*
27150330	Mussels with tomato-based sauce (mixture)*
27150350	Sardines with tomato-based sauce (mixture)*
27151040	Crabs in tomato-based sauce, Puerto Rican style (mixture) (Salmorejo de jueyes)*
27162010	Meat with tomato-based sauce (mixture)*
27162060	Spaghetti sauce with meat and vegetables, homemade-style*
27211100	Beef stew with potatoes, tomato-based sauce (mixture)*
27211110	Mexican style beef stew with potatoes, tomato-based sauce (mixture) (Carne guisada con papas)*
27211190	Beef and potatoes with cream sauce, white sauce or mushroom soup-based sauce (mixture)*
27212100	Beef and noodles with tomato-based sauce (mixture)*
27212150	Beef goulash with noodles*
27213100	Beef and rice with tomato-based sauce (mixture)*
27214110	Meat loaf made with beef, with tomato-based sauce*
27220110	Pork and rice with tomato-based sauce (mixture)*
27220120	Sausage and rice with tomato-based sauce (mixture)*
27221150	Mexican style pork stew, with potatoes, tomato-based sauce (mixture) (cerdo guisado con papas)*
27242350	Chicken or turkey tetrazzini*
27242400	Chicken or turkey and noodles, tomato-based sauce (mixture)*
27243500	Chicken or turkey and rice with tomato-based sauce (mixture)*
27246505	Meat loaf made with chicken or turkey, with tomato-based sauce*
27250110	Scallops and noodles with cheese sauce (mixture)*
27250130	Shrimp and noodles with cheese sauce (mixture)*
27250132	Shrimp and noodles with tomato sauce (mixture)*
27250810	Fish and rice with tomato-based sauce*

27260100	Meat loaf made with beef and pork, with tomato-based sauce*
27311310	Beef stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce*
27311320	Beef stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce*
27311625	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27311630	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27313210	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27313220	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27315210	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27315220	Beef, rice, and vegetables (excluding carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27320070	Ham or pork, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27320080	Sausage, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce*
27320090	Sausage, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce*
27320100	Pork, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27320110	Pork, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27320340	Pork, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27330060	Lamb or mutton, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27332100	Veal stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce*
27336150	Venison/deer stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce*
27336310	Venison/deer, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27341035	Chicken or turkey, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27341040	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27341055	Chicken or turkey, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27341060	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27341510	Chicken or turkey stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce*
27341520	Chicken or turkey stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato- based sauce*
27343470	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27343480	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*

27343510	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27343520	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27345410	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27345420	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), cream sauce, white sauce, or mushroom soup-based sauce (mixture)*
27345510	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-based sauce (mixture)*
27345520	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-based sauce (mixture)*
27350030	Seafood stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), tomato-base sauce*
27350310	Seafood stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), tomato-base sauce*
27411100	Beef with vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27411200	Beef with vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27418310	Corned beef with tomato sauce and onion, Puerto Rican style (mixture)*
27420400	Pork and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27420410	Pork and vegetables (excluding carrots, broccoli, and dark- green leafy (no potatoes)), tomato-based sauce (mixture)*
27420460	Sausage and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27445125	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27445130	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27450700	Fish and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), tomato-based sauce (mixture)*
27450710	Fish and vegetables (excluding carrots, broccoli, and dark- green leafy (no potatoes)), tomato-based sauce (mixture)*
27510700	Meatball and spaghetti sauce submarine sandwich*
28113110	Salisbury steak, baked, with tomato sauce, vegetable (diet frozen meal)*
28133110	Veal, breaded, with spaghetti, in tomato sauce (frozen meal)*
28140730	Chicken patty, breaded, with tomato sauce and cheese, fettuccine alfredo, vegetable (frozen meal)*
28140740	Chicken patty, or nuggets, boneless, breaded, with pasta and tomato sauce, fruit, dessert (frozen meal)*
28160710	Stuffed cabbage, with meat and tomato sauce (diet frozen meal)*
58101800	Ground beef with tomato sauce and taco seasonings on a cornbread crust*
58126150	Turnover, meat- and cheese-filled, tomato-based sauce*
58126300	Turnover, meat- and cheese-filled, tomato-based sauce, lower in fat*
58130011	Lasagna with meat*
58130013	Lasagna with meat, canned*
58130020	Lasagna with meat and spinach*
58130140	Lasagna with chicken or turkey*

58130150	Lasagna, with chicken or turkey, and spinach*
58130310	Lasagna, meatless*
58130320	Lasagna, meatless, with vegetables*
58131110	Ravioli, NS as to filling, with tomato sauce*
58131320	Ravioli, meat-filled, with tomato sauce or meat sauce*
58131323	Ravioli, meat-filled, with tomato sauce or meat sauce, canned*
58131520	Ravioli, cheese-filled, with tomato sauce*
58131523	Ravioli, cheese-filled, with tomato sauce, canned*
58131530	Ravioli, cheese-filled, with meat sauce*
58131610	Ravioli, cheese and spinach filled, with tomato sauce*
58132110	Spaghetti with tomato sauce, meatless*
58132113	Pasta with tomato sauce and cheese, canned*
58132310	Spaghetti with tomato sauce and meatballs or spaghetti with meat sauce or spaghetti with meat sauce and meatballs*
58132313	Pasta with tomato sauce and meat or meatballs, canned*
58132340	Spaghetti with tomato sauce and vegetables*
58132350	Spaghetti with tomato sauce, meatless, whole wheat noodles*
58132360	Spaghetti with tomato sauce and meatballs, whole wheat noodles or spaghetti with meat sauce, whole wheat noodles or spaghetti with meat sauce and meatballs, whole wheat noodles*
58132450	Spaghetti with tomato sauce, meatless, made with spinach noodles*
58132460	Spaghetti with tomato sauce and meatballs made with spinach noodles, or spaghetti with meat sauce made with spinach noodles, or spaghetti with meat sauce and meatballs made with spinach noodles*
58132710	Spaghetti with tomato sauce and frankfurters or hot dogs*
58132910	Spaghetti with tomato sauce and chicken or turkey*
58133120	Manicotti, cheese-filled, with tomato sauce, meatless*
58133130	Manicotti, cheese-filled, with meat sauce*
58133140	Manicotti, vegetable- and cheese-filled, with tomato sauce, meatless*
58134120	Stuffed shells, cheese-filled, with tomato sauce, meatless*
58134130	Stuffed shells, cheese-filled, with meat sauce*
58134210	Stuffed shells, with chicken, with tomato sauce*
58134620	Tortellini, cheese-filled, meatless, with tomato sauce*
58134623	Tortellini, cheese-filled, meatless, with tomato sauce, canned*
58134710	Tortellini, spinach-filled, with tomato sauce*
58146100	Pasta with tomato sauce, meatless*
58146110	Pasta with meat sauce*
58146120	Pasta with cheese and meat sauce*
58146150	Pasta with cheese and tomato sauce, meatless*
58146300	Pasta, whole wheat, with meat sauce*
58147110	Macaroni or noodles with beans or lentils and tomato sauce*
58160220	Rice with vegetables, tomato-based sauce (mixture)*
58161310	Rice, brown, with tomato sauce*

58301020	Lasagna with cheese and sauce (diet frozen meal)*
58301030	Veal lasagna (diet frozen meal)*
58301050	Lasagna with cheese and meat sauce (diet frozen meal)*
58301080	Lasagna with cheese and meat sauce, reduced fat and sodium (diet frozen meal)*
58301110	Vegetable lasagna (frozen meal)*
58301150	Zucchini lasagna (diet frozen meal)*
58302050	Beef and noodles with meat sauce and cheese (diet frozen meal)*
58302060	Spaghetti or noodles with beef in tomato-based sauce, lowfat, reduced sodium (diet frozen meal)*
58302080	Noodles with vegetables in tomato-based sauce (diet frozen meal)*
58304010	Spaghetti and meatballs dinner, NFS (frozen meal)*
58304050	Spaghetti with meat and mushroom sauce (diet frozen meal)*
58304060	Spaghetti with meat sauce (diet frozen meal)*
58304200	Ravioli, cheese-filled, with tomato sauce (diet frozen meal)*
58304230	Ravioli, cheese-filled, with vegetable and fruit (frozen meal)*
73111400	Carrots in tomato sauce*
74403010	Tomato sauce
74404010	Spaghetti sauce, meatless
74404020	Spaghetti sauce with vegetables, homemade-style
74404030	Spaghetti sauce with meat, canned, no extra meat added
74404050	Spaghetti sauce, meatless, low sodium
74404060	Spaghetti sauce, meatless, fat free
74415110	Puerto Rican seasoning with ham and tomato sauce*
75306010	Eggplant in tomato sauce, cooked, fat not added in cooking*
75316010	Zucchini with tomato sauce, cooked, fat not added in cooking*
75316050	Ratatouille*
75412060	Eggplant parmesan casserole, regular*
75412070	Eggplant with cheese and tomato sauce*
75440300	Vegetable combinations (including carrots, broccoli, and/or dark-green leafy), cooked, with tomato sauce*
75440310	Vegetable combinations (excluding carrots, broccoli, and dark-green leafy), cooked, with tomato sauce*

* Only component of proposed food category of food was applied in analysis

Minor main entrée sauces

Food Code	Description
13411000	White sauce, milk sauce
13412000	Milk gravy, quick gravy
14620300	Topping from cheese pizza*
14620310	Topping from vegetable pizza*
14620320	Topping from meat pizza*
14650100	Cheese sauce

26119160	Herring, pickled, in cream sauce*
27111050	Spaghetti sauce with beef or meat other than lamb or mutton, homemade-style*
27112000	Beef with gravy (mixture)*
27112010	Salisbury steak with gravy (mixture)*
27113000	Beef with cream or white sauce (mixture)*
27113300	Swedish meatballs with cream or white sauce (mixture)*
27118180	Puerto Rican style beef stew, meat with gravy (potatoes reported separately)*
27120020	Ham or pork with gravy (mixture)*
27120120	Sausage gravy
27135010	Veal with gravy (mixture)*
27142000	Chicken with gravy (mixture)*
27142100	Chicken or turkey fricassee*
27142200	Turkey with gravy (mixture)*
27143000	Chicken or turkey with cream sauce (mixture)*
27146160	Chicken with mole sauce*
27146200	Chicken or turkey with cheese sauce (mixture)*
27146250	Chicken or turkey cordon bleu*
27146350	Lemon chicken, Chinese style*
27150010	Fish with cream or white sauce, not tuna or lobster (mixture)*
27150070	Lobster with butter sauce (mixture)*
27150120	Tuna with cream or white sauce (mixture)*
27150130	Seafood newburg*
27150160	Shrimp with lobster sauce (mixture)*
27150210	Fish sauce (bagoong)*
27150510	Scallops with cheese sauce (mixture)*
27151050	Shrimp in garlic sauce, Puerto Rican style (mixture) (Camarones al ajillo)*
27160100	Meatballs, NS as to type of meat, with sauce (mixture)*
27211200	Beef stew with potatoes, gravy*
27211500	Beef and potatoes with cheese sauce (mixture)*
27212050	Beef and macaroni with cheese sauce (mixture)*
27212200	Beef and noodles with gravy (mixture)*
27212300	Beef and noodles with cream or white sauce (mixture)*
27213200	Beef and rice with gravy (mixture)*
27213300	Beef and rice with cream sauce (mixture)*
27213600	Beef and rice with cheese sauce (mixture)*
27220020	Ham and noodles with cream or white sauce (mixture)*
27220170	Sausage and rice with cheese sauce (mixture)*
27220190	Sausage and noodles with cream or white sauce (mixture)*
27220510	Ham or pork and potatoes with gravy (mixture)*
27220520	Ham or pork and potatoes with cheese sauce (mixture)*
27231000	Lamb or mutton and potatoes with gravy (mixture)*

27241010	Chicken or turkey and potatoes with gravy (mixture)*
27242200	Chicken or turkey and noodles with gravy (mixture)*
27242300	Chicken or turkey and noodles with cream or white sauce (mixture)*
27242310	Chicken or turkey and noodles with cheese sauce (mixture)*
27243300	Chicken or turkey and rice with cream sauce (mixture)*
27250122	Shrimp and noodles with gravy (mixture)*
27250126	Shrimp and noodles with cream or white sauce (mixture)*
27250610	Tuna noodle casserole with cream or white sauce*
27250820	Fish and rice with cream sauce*
27260050	Meatballs, with breading, NS as to type of meat, with gravy*
27311410	Beef stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy*
27311420	Beef stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy*
27311600	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27311605	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27311635	Beef, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), cheese sauce (mixture)*
27311640	Beef, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27313410	Beef, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27313420	Beef, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27315340	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27315410	Beef, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27315420	Beef, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27320030	Ham or pork, noodles and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27320120	Sausage, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27320130	Sausage, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27320140	Pork, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27320150	Pork, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27330030	Lamb or mutton stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy*
27330050	Lamb or mutton, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27330110	Lamb or mutton stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy*
27336200	Venison/deer, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27341000	Chicken or turkey, potatoes, corn, and cheese, with gravy*

27341025	Chicken or turkey, potatoes, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27341030	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27341050	Chicken or turkey, potatoes, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27341310	Chicken or turkey stew with potatoes and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy*
27341320	Chicken or turkey stew with potatoes and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy*
27343410	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27343420	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27343950	Chicken or turkey, noodles, and vegetables (including carrots, broccoli, and/or dark-green leafy), cheese sauce (mixture)*
27343960	Chicken or turkey, noodles, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27345210	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27345220	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), gravy (mixture)*
27345440	Chicken or turkey, rice, and vegetables (including carrots, broccoli, and/or dark-green leafy), cheese sauce (mixture)*
27345450	Chicken or turkey, rice, and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture)*
27347220	Chicken or turkey, stuffing, and vegetables (including carrots, broccoli, and/or dark-green leafy), gravy (mixture)*
27347240	Chicken or turkey, dumplings, and vegetables (including carrots, broccoli, and/or dark green leafy), gravy (mixture)*
27347250	Chicken or turkey, dumplings, and vegetables (excluding carrots, broccoli, and dark green leafy), gravy (mixture)*
27350080	Tuna noodle casserole with vegetables, cream or white sauce*
27416300	Beef taco filling: beef, cheese, tomato, taco sauce*
27416450	Beef and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), gravy (mixture)*
27416500	Beef and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), gravy (mixture)*
27442110	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), gravy (mixture)*
27442120	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), gravy (mixture)*
27445180	Moo Goo Gai Pan*
27446400	Chicken or turkey and vegetables (including carrots, broccoli, and/or dark-green leafy (no potatoes)), cheese sauce (mixture)*
27446410	Chicken or turkey and vegetables (excluding carrots, broccoli, and dark-green leafy (no potatoes)), cheese sauce (mixture)*
27510480	Cheeseburger (hamburger with cheese sauce), 1/4 lb meat, with grilled onions, on rye bun*
27560330	Frankfurter or hot dog, with cheese, plain, on bun*
28110150	Beef with vegetable (diet frozen meal)*
28110220	Sirloin, chopped, with gravy, mashed potatoes, vegetable (frozen meal)*
28110270	Sirloin beef with gravy, potatoes, vegetable (frozen meal)*

28110300	Salisbury steak dinner, NFS (frozen meal)*
28110310	Salisbury steak with gravy, potatoes, vegetable (frozen meal)*
28110330	Salisbury steak with gravy, whipped potatoes, vegetable, dessert (frozen meal)*
28110350	Salisbury steak with gravy, potatoes, vegetable, dessert (frozen meal, large meat portion)*
28110370	Salisbury steak with gravy, macaroni and cheese, vegetable (frozen meal)*
28110380	Salisbury steak with gravy, macaroni and cheese (frozen meal)*
28110390	Salisbury steak, potatoes, vegetable, dessert (diet frozen meal)*
28110510	Beef, sliced, with gravy, potatoes, vegetable (frozen meal)*
28110640	Meatballs, Swedish, in sauce, with noodles (frozen meal)*
28110660	Meatballs, Swedish, in gravy, with noodles (diet frozen meal)*
28113140	Beef with spaetzle or rice, vegetable (frozen meal)*
28140150	Chicken divan (frozen meal)*
28140320	Chicken and noodles with vegetable, dessert (frozen meal)*
28141050	Chicken patty parmigiana, breaded, with vegetable (diet frozen meal)*
28141600	Chicken a la king with rice (frozen meal)*
28141610	Chicken and vegetables in cream or white sauce (diet frozen meal)*
28143080	Chicken with noodles and cheese sauce (diet frozen meal)*
28143110	Chicken cacciatore with noodles (diet frozen meal)*
28143130	Chicken and vegetable entree with noodles (frozen meal)*
28143170	Chicken in cream sauce with noodles and vegetable (frozen meal)*
28143190	Chicken in mushroom sauce, white and wild rice, vegetable (frozen meal)*
28143210	Chicken in orange sauce with almond rice (diet frozen meal)*
28144100	Chicken and vegetable entree with noodles and cream sauce (frozen meal)*
28145000	Turkey dinner, NFS (frozen meal)*
28145100	Turkey with dressing, gravy, vegetable and fruit (diet frozen meal)*
28145110	Turkey with vegetable, stuffing (diet frozen meal)*
28145210	Turkey with gravy, dressing, potatoes, vegetable (frozen meal)*
28145610	Turkey with gravy, dressing, potatoes, vegetable, dessert (frozen meal, large meat portion)*
28150510	Fish in lemon-butter sauce with starch item, vegetable (frozen meal)*
28154010	Shrimp and vegetables in sauce with noodles (diet frozen meal)*
28500000	Gravy, poultry
28500010	Gravy, meat or poultry, with wine
28500040	Gravy, beef or meat
28500050	Gravy, giblet
28500070	Gravy, beef or meat, home recipe
28500080	Gravy, poultry, home recipe
28500100	Gravy, mushroom
28501110	Gravy, poultry, fat free
28510010	Gravy or sauce, poultry-based from Puerto Rican-style chicken fricasse
28510030	Gravy, meat-based, from Puerto-Rican style beef stew
28520000	Gravy or sauce, Chinese (soy sauce, stock or bouillon, cornstarch)

28520100	Oyster-flavored sauce
28522000	Mole poblano (sauce)
28522050	Mole verde (sauce)
32105150	Egg omelet or scrambled egg, with cheese, beans, tomatoes, and chili sauce*
32105180	Huevos rancheros*
41205100	Black bean sauce
41811950	Swiss steak, with gravy, meatless*
42204050	Peanut sauce
42204100	Brown nut gravy, meatless
43103100	Sesame sauce
55502000	Flour and water gravy
58100600	Enchilada with chicken, tomato-based sauce*
58100620	Enchilada with chicken, beans, and cheese, tomato- based sauce*
58100630	Enchilada with chicken and cheese, no beans, tomato- based sauce*
58100900	Enchilada with seafood, tomato-based sauce*
58101820	Mexican casserole made with ground beef, beans, tomato sauce, cheese, taco seasonings, and corn chips*
58101830	Mexican casserole made with ground beef, tomato sauce, cheese, taco seasonings, and corn chips*
58106200	Pizza, cheese, prepared from frozen, thin crust*
58106205	Pizza, cheese, prepared from frozen, thick crust*
58106210	Pizza, cheese, NS as to type of crust*
58106220	Pizza, cheese, thin crust*
58106225	Pizza, cheese, regular crust*
58106230	Pizza, cheese, thick crust*
58106240	Pizza, extra cheese, NS as to type of crust*
58106250	Pizza, extra cheese, thin crust*
58106255	Pizza, extra cheese, regular crust*
58106260	Pizza, extra cheese, thick crust*
58106300	Pizza, cheese, with vegetables, prepared from frozen, thin crust*
58106305	Pizza, cheese with vegetables, prepared from frozen, thick crust*
58106310	Pizza, cheese, with vegetables, NS as to type of crust*
58106320	Pizza, cheese, with vegetables, thin crust*
58106325	Pizza, cheese, with vegetables, regular crust*
58106330	Pizza, cheese, with vegetables, thick crust*
58106345	Pizza with cheese and extra vegetables, thin crust*
58106347	Pizza with cheese and extra vegetables, regular crust*
58106350	Pizza with cheese and extra vegetables, thick crust*
58106358	Pizza, cheese, with fruit, thin crust*
58106359	Pizza, cheese, with fruit, regular crust*
58106360	Pizza, cheese, with fruit, thick crust*
58106411	Pizza with chicken, thin crust*

58106412	Pizza with chicken, regular crust*
58106413	Pizza with chicken, thick crust*
58106441	Pizza with chicken and vegetables, thin crust*
58106442	Pizza with chicken and vegetables, regular crust*
58106443	Pizza with chicken and vegetables, thick crust*
58106462	Pizza with chicken and fruit, regular crust*
58106500	Pizza with meat, prepared from frozen, thin crust*
58106505	Pizza with meat, prepared from frozen, thick crust*
58106540	Pizza with pepperoni, NS as to type of crust*
58106550	Pizza with pepperoni, thin crust*
58106555	Pizza with pepperoni, regular crust*
58106560	Pizza with pepperoni, thick crust*
58106610	Pizza with meat other than pepperoni, NS as to type of crust*
58106620	Pizza with meat other than pepperoni, thin crust*
58106625	Pizza with meat other than pepperoni, regular crust*
58106630	Pizza with meat other than pepperoni, thick crust*
58106640	Pizza with extra meat, NS as to type of crust*
58106650	Pizza with extra meat, thin crust*
58106655	Pizza with extra meat, regular crust*
58106660	Pizza with extra meat, thick crust*
58106700	Pizza with meat and vegetables, prepared from frozen, thin crust*
58106705	Pizza with meat and vegetables, prepared from frozen, thick crust*
58106710	Pizza with meat and vegetables, NS as to type of crust*
58106720	Pizza with meat and vegetables, thin crust*
58106725	Pizza with meat and vegetables, regular crust*
58106730	Pizza with meat and vegetables, thick crust*
58106733	Pizza with extra meat and extra vegetables, prepared from frozen, thin crust*
58106734	Pizza with extra meat and extra vegetables, prepared from frozen, thick crust*
58106735	Pizza with extra meat and extra vegetables, NS as to type of crust*
58106736	Pizza with extra meat and extra vegetables, thin crust*
58106737	Pizza with extra meat and extra vegetables, thick crust*
58106738	Pizza with extra meat and extra vegetables, regular crust*
58106750	Pizza with meat and fruit, thin crust*
58106755	Pizza with meat and fruit, regular crust*
58106760	Pizza with meat and fruit, thick crust*
58106820	Pizza with beans and vegetables, thin crust*
58106830	Pizza with beans and vegetables, thick crust*
58106910	Pizza with seafood, thin crust*
58106915	Pizza with seafood, regular crust*
58107030	Pizza, no cheese, NS as to type of crust*
58107050	Pizza, no cheese, thin crust*

58107060	Pizza, no cheese, regular crust*
58107100	Pizza, no cheese, thick crust*
58108050	Pizza rolls*
58116110	Meat turnover, Puerto Rican style (Pastelillo de carne; Empanadilla)*
58120110	Crepes, filled with meat, fish, or poultry, with sauce*
58126130	Turnover, meat- and cheese-filled, no gravy*
58126270	Turnover, chicken- or turkey-, and cheese-filled, no gravy*
58126310	Turnover, chicken, with gravy*
58128000	Biscuit with gravy*
58131120	Ravioli, NS as to filling, with cream sauce*
58131330	Ravioli, meat-filled, with cream sauce*
58131535	Ravioli, cheese-filled, with cream sauce*
58131600	Ravioli, cheese and spinach-filled, with cream sauce*
58132800	Spaghetti with clam sauce, NS as to red or white*
58132820	Spaghetti with white clam sauce*
58134660	Tortellini, cheese-filled, with cream sauce*
58145115	Macaroni or noodles with cheese, from boxed mix with already prepared cheese sauce*
58145140	Macaroni or noodles with cheese and tomato*
58146130	Pasta with carbonara sauce*
58146200	Pasta, meat-filled, with gravy, canned*
58147100	Pasta with pesto sauce*
58147340	Macaroni, creamed, with cheese and tuna*
58147350	Macaroni, creamed, with vegetables*
58161300	White rice with tomato sauce*
58163110	Rice with gravy*
58302000	Macaroni and cheese (diet frozen meal)*
58303100	Rice, with broccoli, cheese sauce (frozen side dish)*
58304220	Rigatoni with meat sauce and cheese (diet frozen meal)*
58305250	Pasta with vegetable and cheese sauce (diet frozen meal)*
58306020	Beef enchilada, chili gravy, rice, refried beans (frozen meal)*
71507040	White potato, stuffed, baked, peel not eaten, stuffed with broccoli and cheese sauce*
71507050	White potato, stuffed, baked, peel not eaten, stuffed with meat in cream sauce*
71508040	White potato, stuffed, baked, peel eaten, stuffed with broccoli and cheese sauce*
71508120	White potato, stuffed with ham, broccoli and cheese sauce, baked, peel eaten*
72125230	Spinach, NS as to form, creamed*
72125231	Spinach, from fresh, creamed*
72125232	Spinach, from frozen, creamed*
72125233	Spinach, from canned, creamed*
72125250	Spinach, cooked, NS as to form, with cheese sauce*
72125251	Spinach, cooked, from fresh, with cheese sauce*
72125252	Spinach, cooked, from frozen, with cheese sauce*

72125253	Spinach, cooked, from canned, with cheese sauce*
72201230	Broccoli, cooked, NS as to form, with cheese sauce*
72201231	Broccoli, cooked, from fresh, with cheese sauce*
72201232	Broccoli, cooked, from frozen, with cheese sauce*
72201240	Broccoli, cooked, NS as to form, with mushroom sauce*
72201242	Broccoli, cooked, from frozen, with mushroom sauce*
72201250	Broccoli, cooked, NS as to form, with cream sauce*
72201251	Broccoli, cooked, from fresh, with cream sauce*
72201252	Broccoli, cooked, from frozen, with cream sauce*
72202020	Broccoli casserole (broccoli, rice, cheese, and mushroom sauce)*
73102230	Carrots, cooked, NS as to form, creamed*
73102231	Carrots, cooked, from fresh, creamed*
73102252	Carrots, cooked, from frozen, with cheese sauce*
73111031	Peas and carrots, from fresh, creamed*
74402310	Green tomato-chile sauce, raw (Salsa de tomate verde cruda)
74406100	Steak sauce, tomato-base
74406500	Cocktail sauce
75340160	Vegetable and pasta combinations with cream or cheese sauce (broccoli, pasta, carrots, corn, zucchini, peppers, cauliflower, peas, etc.), cooked*
75401010	Asparagus, NS as to form, creamed or with cheese sauce*
75401011	Asparagus, from fresh, creamed or with cheese sauce*
75401012	Asparagus, from frozen, creamed or with cheese sauce*
75402020	Beans, lima, immature, cooked, NS as to form, with mushroom sauce*
75403010	Beans, string, green, NS as to form, creamed or with cheese sauce*
75403011	Beans, string, green, from fresh, creamed or with cheese sauce*
75403012	Beans, string, green, from frozen, creamed or with cheese sauce*
75403013	Beans, string, green, from canned, creamed or with cheese sauce*
75403020	Beans, string, green, cooked, NS as to form, with mushroom sauce*
75403023	Beans, string, green, cooked, from canned, with mushroom sauce*
75405010	Beets with Harvard sauce*
75407010	Cabbage, creamed*
75409010	Cauliflower, NS as to form, creamed*
75409011	Cauliflower, from fresh, creamed*
75409012	Cauliflower, from frozen, creamed*
75410010	Celery, creamed*
75411030	Corn, cooked, NS as to form, with cream sauce, made with milk*
75414010	Mushrooms, NS as to form, creamed*
75414011	Mushrooms, from fresh, creamed*
75414013	Mushrooms, from canned, creamed*
75415011	Onions, from fresh, creamed*
75417010	Peas, NS as to form, creamed*
75417011	Peas, from fresh, creamed*

75418040	Squash, summer, casserole, with cheese sauce*
75440500	Vegetable combinations (including carrots, broccoli, and/or dark-green leafy), cooked, with cheese sauce*
75440510	Vegetable combinations (excluding carrots, broccoli, and dark-green leafy), cooked, with cheese sauce*
75450500	Vegetable combination (including carrots, broccoli, and/or dark-green leafy), cooked, with cream sauce*
75450510	Vegetable combination (excluding carrots, broccoli, and dark-green leafy), cooked, with cream sauce*
81301000	Garlic sauce
81301020	Lemon-butter sauce
81302070	Pesto sauce

* Only component of proposed food category of food was applied in analysis

Major condiments (Catsup only)

27111500	Beef sloppy joe (no bun)*
27315250	Stuffed cabbage rolls with beef and rice*
27510230	Cheeseburger, with mayonnaise or salad dressing and tomatoes, on bun*
27510300	Double cheeseburger (2 patties), with mayonnaise or salad dressing, on double-decker bun*
27510310	Cheeseburger with tomato and/or catsup, on bun*
27510320	Cheeseburger, 1/4 lb meat, with tomato and/or catsup, on bun*
27510330	Double cheeseburger (2 patties), with tomato and/or catsup, on bun*
27510350	Cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun*
27510355	Cheeseburger, 1/3 lb meat, with mayonnaise or salad dressing, tomato and/or catsup on bun*
27510360	Cheeseburger with mayonnaise or salad dressing, tomato and bacon, on bun*
27510375	Double cheeseburger (2 patties, 1/4 lb meat each), with tomato and/or catsup, on bun*
27510400	Bacon cheeseburger, 1/4 lb meat, with tomato and/or catsup, on bun*
27510425	Double bacon cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun*
27510440	Bacon cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun*
27510510	Hamburger, with tomato and/or catsup, on bun*
27510520	Hamburger, with mayonnaise or salad dressing and tomatoes, on bun*
27510540	Double hamburger (2 patties), with tomato and/or catsup, on bun*
27510560	Hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun*
27510610	Hamburger, 1 oz meat, with tomato and/or catsup, on miniature bun*
27510620	Hamburger, 1/4 lb meat, with tomato and/or catsup, on bun*
27510680	Double hamburger (2 patties, 1/4 lb meat each), with tomato and/or catsup, on bun*
27510690	Double hamburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing and tomatoes and/or catsup, on double-decker bun*
27560340	Frankfurter or hot dog, with catsup and/or mustard, on bun*
28160650	Stuffed green pepper (frozen meal)*
32202045	Egg, cheese, and steak on bagel*

32202120	Egg, cheese and sausage on bagel*
41207030	Beans, dry, cooked with ground beef*
41208100	Beans, dry, cooked with pork*
58123110	Sweet bread dough, filled with meat, steamed*
74401010	Tomato catsup
74401110	Tomato catsup, low sodium
74402010	Tomato chili sauce (catsup-type)

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Barbecue sauce, hollandaise sauce, tartar sauce and other dipping sauces

12350000	Dip, sour cream base
12350020	Dip, sour cream base, reduced calorie
12350100	Spinach dip, sour cream base
14620100	Dip, cream cheese base
14620120	Shrimp dip, cream cheese base
14620150	Dip, cheese with chili pepper (chili con queso)
14620200	Dip, cheese base other than cream cheese
21304200	Beef, shortribs, barbecued, with sauce, NS as to fat eaten*
21304210	Beef, shortribs, barbecued, with sauce, lean and fat eaten*
21304220	Beef, shortribs, barbecued, with sauce, lean only eaten*
22701030	Pork, spareribs, barbecued, with sauce, NS as to fat eaten*
22701040	Pork, spareribs, barbecued, with sauce, lean and fat eaten*
22701050	Pork, spareribs, barbecued, with sauce, lean only eaten*
27111500	Beef sloppy joe (no bun)*
27116200	Beef with barbecue sauce (mixture)*
27116300	Beef with sweet and sour sauce (mixture)*
27120030	Ham or pork with barbecue sauce (mixture)*
27120060	Sweet and sour pork*
27146000	Chicken or turkey with barbecue sauce (mixture), skin eaten*
27146010	Chicken or turkey with barbecue sauce (mixture), skin not eaten*
27146100	Sweet and sour chicken or turkey*
27150170	Sweet and sour shrimp*
27160010	Meat with barbecue sauce, NS as to type of meat (mixture)*
27510110	Beef barbecue sandwich or Sloppy Joe, on bun*
27510130	Beef barbecue submarine sandwich, on bun*
27510420	Taco burger, on bun*
27520500	Pork sandwich, on white roll, with onions, dill pickles and barbecue sauce*
27540130	Chicken barbecue sandwich*
27540250	Chicken fillet, broiled, sandwich with cheese, on whole wheat roll, with lettuce, tomato and non-mayonaise type spread*

27540270	Chicken fillet, broiled, sandwich, with lettuce, tomato, and non-mayonnaise type spread*
27550000	Fish sandwich, on bun, with spread*
27550100	Fish sandwich, on bun, with cheese and spread*
27560340	Frankfurter or hot dog, with catsup and/or mustard, on bun*
28110620	Beef short ribs, boneless, with barbecue sauce, potatoes, vegetable (frozen meal)*
41205050	Bean dip, made with refried beans
41205070	Hummus
41207030	Beans, dry, cooked with ground beef*
41208100	Beans, dry, cooked with pork*
58100155	Burrito with beef, rice, and cheese*
58100240	Burrito with chicken, NFS*
58100245	Burrito with chicken, beans, cheese, and sour cream*
58100250	Burrito with chicken, rice, and cheese*
58100255	Burrito with chicken, beans, rice, and cheese*
58101310	Taco or tostada with beef, lettuce, tomato and salsa*
58101510	Taco or tostada with chicken or turkey, lettuce, tomato and salsa*
58101520	Taco or tostada with chicken, cheese, lettuce, tomato and salsa*
58101540	Taco or tostada with fish, lettuce, tomato, salsa*
58101710	Taco or tostada with beans, meatless, with lettuce, tomato and salsa*
58101720	Taco or tostada with beans and cheese, meatless, with lettuce, tomato and salsa*
58101730	Taco or tostada with beans, cheese, meat, lettuce, tomato and salsa*
58104290	Chalupa with beef, cheese, lettuce, tomato and salsa*
58104340	Chalupa with chicken, cheese, lettuce, tomato and salsa*
74402100	Salsa, NFS
74402110	Salsa, red, uncooked
74402150	Salsa, red, cooked, not homemade
74402260	Enchilada sauce, green
74402300	Salsa made with fruit
74402350	Green tomato-chile sauce, cooked (Salsa verde, NFS)
74405010	Tomato relish
74406010	Barbecue sauce
75410550	Jalapeno pepper, stuffed with cheese, breaded or battered, fried*
75412030	Eggplant dip
75506010	Mustard
75506100	Mustard sauce
81302010	Hollandaise sauce
81302050	Tartar sauce
91361010	Sweet and sour sauce

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Snack foods

Food Code	Description
41410015	Soy chips
44201000	Carob chips
54401010	Salty snacks, corn or cornmeal base, nuts or nuggets, toasted
54401020	Salty snacks, corn or cornmeal base, corn chips, corn-cheese chips
54401050	Salty snacks, corn or cornmeal base, corn puffs and twists; corn-cheese puffs and twists
54401080	Salty snacks, corn or cornmeal base, tortilla chips
54401090	Salty snacks, corn or cornmeal base, corn chips, corn-cheese chips, unsalted
54401100	Salty snacks, corn or cornmeal base, tortilla chips, light (baked with less oil)
54401120	Salty snacks, corn or cornmeal base, tortilla chips, fat free, made with Olean
54401150	Salty snacks, corn or cornmeal base, tortilla chips, lowfat, baked without fat
54401170	Salty snacks, corn or cornmeal base, tortilla chips, lowfat, baked without fat, unsalted
54401210	Salty snacks, corn based puffs and twists, cheese puffs and twists, lowfat
54402080	Salty snacks, corn or cornmeal base, tortilla chips, unsalted
54402200	Salty snack mixture, mostly corn or cornmeal based, with pretzels, without nuts
54402500	Salty snacks, wheat- and corn-based chips
54402600	Salty snacks, multigrain, chips
54402700	Pita chips
54403050	Popcorn, flavored
54403110	Popcorn, sugar syrup or caramel-coated
54403120	Popcorn, sugar syrup or caramel-coated, with nuts
54406200	Shrimp chips (tapioca base)
54408000	Pretzels, NFS
54408010	Pretzels, hard
54408020	Pretzels, soft
54408030	Pretzel, hard, unsalted
54408040	Pretzels, soft, unsalted
54408200	Pretzel, hard, chocolate-coated
54408250	Pretzel, yogurt-covered
54408300	Pretzels, cheese-filled
54420010	Multigrain mixture, pretzels, cereal and/or crackers, nuts
54420100	Oriental party mix, with peanuts, sesame sticks, chili rice crackers and fried green peas
54420200	Multigrain mixture, bread sticks, sesame nuggets, pretzels, rye chips
54430010	Yogurt chips
54440010	Bagel chip
58101910	Taco or tostada salad with beef and cheese, corn chips*
58104080	Nachos with beef, beans, cheese, and sour cream*
58104090	Nachos with cheese and sour cream*
58104100	Nachos with cheese, meatless, no beans*
58104110	Nachos with beans, no cheese*
58104120	Nachos with beans and cheese*

58104130	Nachos with beef, beans, and cheese*
58104140	Nachos with beef and cheese*
58104180	Nachos with beef, beans, cheese, tomatoes, sour cream and onions*
58104250	Nachos with chicken or turkey and cheese*
62101300	Apple chips
62107200	Banana chips
71201010	White potato, chips
71201015	White potato chips, regular cut
71201020	White potato chips, ruffled, rippled, or crinkle cut
71201050	White potato, chips, reduced fat
71201080	White potato, chips, fat free
71201090	White potato chips, fat free, made with Olean
71201100	White potato, chips, restructured
71201200	White potato, chips, restructured, reduced fat and reduced sodium
71201210	White potato, chips, restructured, fat free, made with Olean
71201250	White potato, chips, restructured, baked
71202000	White potato, chips, unsalted
71202100	White potato, chips, unsalted, reduced fat
71205000	White potato, sticks
71211000	White potato skins, chips
71220000	Vegetable chips
71905410	Plantain chips
71980200	Taro chips
73410210	Sweet potato, chips

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Vegetable juice

27111100	Beef goulash*
27211150	Beef goulash with potatoes*
27315270	Stuffed grape leaves with beef and rice*
27360010	Goulash, NFS*
28350120	Crab soup, tomato-base*
73105010	Carrot juice
74301100	Tomato juice
74301150	Tomato juice, low sodium
74302000	Tomato juice cocktail
74303000	Tomato and vegetable juice, mostly tomato
74303100	Tomato and vegetable juice, mostly tomato, low sodium
74304000	Tomato juice with clam or beef juice*
74402250	Enchilada sauce, red*

74501010	Tomato aspic*
75132000	Mixed vegetable juice (vegetables other than tomato)
75132100	Celery juice
75200700	Aloe vera juice
78101000	Vegetable and fruit juice blend, 100% juice, with high vitamin C plus added vitamin E and vitamin A
93301030	Bloody Mary*

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Appendix B

Food	Variety	Study Note	Concentration Hydroxytyrosol (mg/kg)	Citation
Olives	Green in Brine	1. Spanish style green olives in brine	450	Blekas et al. 2002 [Table 2]
Olives	Green in Brine	2. Spanish style green olives in brine	371	Blekas et al. 2002 [Table 2]
Olives	Green in Brine	3. Spanish style green olives in brine	499	Blekas et al. 2002 [Table 2]
Olives	Green in Brine	4. Spanish style green olives in brine	513	Blekas et al. 2002 [Table 2]
Olives	Green in Brine	5. Spanish style green olives in brine	287	Blekas et al. 2002 [Table 2]
Olives	Green in Brine	6. Spanish style green olives in brine	233	Blekas et al. 2002 [Table 2]
Olives	Green in Brine	7. Spanish style green olives in brine	169	Blekas et al. 2002 [Table 2]
Olives	Green in Brine	8. Spanish style pitted green olives stuffed with red pepper in brine	43	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	9. Greek style black in brine	219	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	10. Greek style black in brine	101	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	11. Greek style black in brine	204	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	12. Greek style black in brine	339	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	13. Greek style black in brine	209	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	14. Greek style black in brine	0	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	15. Kalamata in brine	475	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	16. Kalamata in brine	431	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	17. Kalamata in brine	761	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	18. Kalamata in brine	591	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	19. Kalamata in brine	254	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	20. Kalamata in brine	462	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	21. Kalamata in brine	395	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	22. Kalamata in brine	343	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	23. Kalamata in brine	388	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	24. black olives in dry salt	63	Blekas et al. 2002 [Table 2]
Olives	Black in Brine	25. black olives in dry salt	78	Blekas et al. 2002 [Table 2]
Olive oil	Extra Virgin	Extra Virgin Olive Oil A	160.5	Romero et al 2012 [Table 1]
Olive oil	Extra Virgin	Extra Virgin Olive Oil B	201.1	Romero et al 2012 [Table 1]
Olive oil	Extra Virgin	Extra Virgin Olive Oil C	63.3	Romero et al 2012 [Table 1]
Olive oil	Oil	Mild Flavored olive oil	5	Romero et al 2012 [Figure 6-estimated value]
Olive oil	Oil	Intensely Flavored olive oil	12	Romero et al 2012 [Figure 6-estimated value]
Olive oil	Extra Virgin	Extra virgin olive oil	110	Romero et al 2012 [Figure 6-estimated value]
Olive oil	Extra Virgin	Arbequina extra virgin olive oil	82	Romero et al 2012 [Figure 6-estimated value]
Olive oil	Extra Virgin	Manzanilla extra virgin olive oil	108	Romero et al 2012 [Figure 6-estimated value]

Food	Variety	Study Note	Concentration Hydroxytyrosol (mg/kg)	Citation
Olive oil	Extra Virgin	Hojiblanca extra virgin olive oil	85	Romero et al 2012 [Figure 6-estimated value]
Olive oil	Extra Virgin	Picual extra virgin olive oil	145	Romero et al 2012 [Figure 6-estimated value]
Olive oil	Extra Virgin	Olio bari	25.08	Mazzotti et al. 2012 [Table 1]
Olive oil	Extra Virgin	Olio bio	24.93	Mazzotti et al. 2012 [Table 1]
Olive oil	Extra Virgin	Olio 41	13.74	Mazzotti et al. 2012 [Table 1]
Olive oil	Extra Virgin	Olio gabro 3	6.51	Mazzotti et al. 2012 [Table 1]
Olive oil	Extra Virgin	Olio gabro 4	4.02	Mazzotti et al. 2012 [Table 1]
Olive oil	Extra Virgin	Olio carolea	9.3	Mazzotti et al. 2012 [Table 1]