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July 14, 2017

Dr. Susan Carlson
Director, Division of Biotechnology and GRAS Notice Review
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Subject: GRAS Notification – Rice Bran Wax

Dear Dr. Carlson:

On behalf of The J.M. Smucker Co., ToxStrategies, Inc. (its agent) is submitting, for FDA review, a copy of the GRAS notification as required. The enclosed document provides notice of a claim that the food ingredient, rice bran wax, 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, for addition to select foods as a texturizer.

If you have any questions or require additional information, please do not hesitate to contact me at 630-352-0303, or dschmitt@toxstrategies.com.

Sincerely,

(b) (6)

Donald F. Schmitt, M.P.H.
Senior Managing Scientist

GRAS Determination of Rice Bran Wax for Use in Specified Food Products

JULY 14, 2017

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GRAS Determination of Rice Bran Wax for Use in Specified Food Products

SUBMITTED BY:

The J.M. Smucker Co.
1 Strawberry Lane
Orrville, OH 44667

SUBMITTED TO:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
HFS-200
5100 Paint Branch Parkway
College Park MD 20740-3835

CONTACT FOR TECHNICAL OR OTHER INFORMATION

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JULY 14, 2017

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List of Acronyms

ADI	Acceptable Daily Intake
ANS	Scientific Panel on Food Additives and Nutrient Sources (EFSA)
AOAC	Association of Official Agricultural Chemists
bw	body weight
C	Celsius
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
cfu	colony-forming units
cGMP	current Good Manufacturing Practice
CIR	Cosmetic Ingredient Review
CONTAM	Panel on Contaminants in Food (EFSA)
EDI	estimated daily intake
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency (US)
EC	European Commission
F	Fahrenheit
FAO	Food and Agriculture Organization of the United Nations
FCC	Food Chemicals Codex
FDA	Food and Drug Administration
FD&C	Federal Food, Drug, and Cosmetic Act
FDRL	Food and Drug Research Laboratory
FOIA	Freedom of Information Act
g	gram
GI	gastrointestinal
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe
GRN	GRAS Notification
INS	International Number System
JAOCA	Journal of Association of Official Agricultural Chemists
JECFA	Joint FAO/WHO Expert Committee on Food Additives
kg	kilogram
LD_{50}	median lethal dose
LOQ	limit of quantification
max	maximum
meq	millequivalent
mg	milligram
ml	milliliter
µM	micromolar.
MOE	margin of exposure
ND	not detectable
NET-NID	National Eating Trends-Nutrient Intake Database
NHANES	National Health and Examination Survey

NLM	National Library of Medicine
NOAEL	no-observed-adverse-effect level
°	degrees
PCB	polychlorinated biphenyls
PCR	polymerase chain reaction
ppm	parts per million
REACH	Registration, Evaluation, and Authorisation of Chemicals
SCF	Scientific Committee on Food
TGA	Australian Therapeutic Goods Administration
US	United States
U.S.C	United States Code
USDA	U.S. Department of Agriculture
USP	U.S. Pharmacopeia
WWEIA	What We Eat in America
WHO	World Health Organization

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§ 170.225 Part 1, GRAS Notice: Signed Statements and Certification

(1) GRAS Notice Submission

The J.M. Smucker Company (Smucker), through its agent ToxStrategies, Inc., hereby notifies the U.S. Food and Drug Administration (FDA) of the submission of a Generally Recognized as Safe (GRAS) notice for rice bran wax, and that the use of rice bran wax described below and which meets the specifications described herein is exempt from pre-market approval requirements of the Federal Food, Drug, and Cosmetic Act, because Smucker has determined that such use is Generally Recognized as Safe (GRAS) through scientific procedures.

(2) Name and Address

The J.M. Smucker Co.
1 Strawberry Lane
Orrville, OH 44667

(3) Name of Notified Substance

The name of the substance that is the subject of this GRAS determination is rice bran wax. Rice bran wax is a hard, crystalline vegetable wax obtained from rice husks. The rice bran wax is processed from rice bran oil obtained from rice husks, and is not hydrogenated. It primarily consists of high molecular weight monoesters ranging from C48 to C64.

(4) Intended Use in Food

Smucker proposes to use rice bran wax as a texturizing agent solely in peanut butter used in bar-form products. The intended use will allow peanut butter to be the primary ingredient in nutritional/snack bars with a similar form and texture to granola bars and nutritional/energy bars. The amount used will not exceed the amount reasonably required to accomplish its intended technical effect.

(5) Statutory Basis for GRAS Determination

The J.M. Smucker Company (Smucker), through its agent ToxStrategies, Inc., hereby notifies the FDA of the submission of a GRAS notice for rice bran wax, which meets the specifications described herein and has been determined to be GRAS through scientific procedures in accordance with § 170.30(a) and (b).

(6) Premarket Approval Statement

Smucker further asserts that the use of rice bran wax in food, as described below, is exempt from the pre-market approval requirements of the Federal Food, Drug, and

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Cosmetic Act, based on a conclusion that the notified substance is GRAS under the conditions of its intended use.

(7) Availability of Information

The data and information that serve as the basis for this GRAS determination, as well any information that has become available since the GRAS determination, will be sent to the FDA on request, or are available for the FDA's review and copying during customary business hours from ToxStrategies, Inc., Naperville, IL.

(8) Data and Information Confidentiality Statement

None of the data and information in the GRAS notice is exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552.

(9) GRAS Notice Certification

To the best of our knowledge, the GRAS notice is a complete, representative, and balanced submission. Smucker is not aware of any information that would be inconsistent with a finding that the proposed use of rice bran wax in food that meets appropriate specifications and is used according to current Good Manufacturing Practices (cGMP), is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

(10) Name/Position of Notifier

(b) (6)

Donald F. Schmitt, M.P.H.
Senior Managing Scientist
ToxStrategies, Inc.
Agent for Smucker

07/14/2017
Date

(11) FSIS Statement

Not applicable.

§ 170.230 Part 2, Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

Identity

Rice bran wax is a hard, crystalline vegetable wax obtained from rice husks. It primarily consists of high molecular weight monoesters ranging from C48 to C64. See Appendix A for Gas Chromatographs identifying peaks for this ingredient. Rice bran wax is typically yellow to light brown in color with a melting point of 75 - 85.5°C. The rice bran wax under review is processed from rice bran oil obtained from rice husks, and is not hydrogenated.

Common or Chemical Names

The ingredient under consideration is referred to as *Oryza sativa* (rice) bran wax, rice bran wax, or rice bran wax beads. The Chemical Abstracts Service (CAS) number for rice bran wax is 8016-60-2. The International Numbering System (INS) or E number is 908.

Manufacturing Process

The rice bran wax that is the subject of this GRAS determination originates from rice husks. The rice bran wax is manufactured following current cGMP for food. The flow diagram of the manufacturing process presented in Figure 1 follows the narrative description below and results in an ingredient in compliance with the manufacturer's and Food Chemicals Codex (FCC) specifications.

The starting material, crude rice bran wax, is weighed and added to a clean melt tank and melted. During this process, settling separates out the non-rice bran wax solids. Next, the melted rice bran wax is transferred to a tank containing one or more safe and suitable decoloring agents, and the wax is mixed and recirculated in the tank. Prior to continuing on to the filter process, a filter medium consisting of common and approved processing aids used in food manufacturing processes (see Table 1) is added. Once the filtering medium is adequately incorporated, the mixture is sent through the filter press and then back into the tank until the wax becomes clear. Once the wax is clear, a sample is collected and sent to the laboratory for aesthetics (color and odor) testing. If the wax does not meet aesthetics specifications, it is pumped into another tank, and cooling water is turned on, a safe and suitable decoloring agent is added, and the temperature is raised in a controlled manner in order to remove the decoloring agent. A sample is again collected and tested for compliance with aesthetic (color/odor) specifications. If the wax meets the aesthetic specification (either with the first or second lab result), it is filtered through a cartridge filter and sent on to the pastillating step (i.e., process of pelleting into uniform half spheres). If the wax is tested twice and fails, it is discarded. Once pastillated, the wax is sampled for quality testing, packaged, and labeled. The finished ingredient that passes

all quality control measures is released for sale and placed into inventory. If a sample fails established quality parameters, the wax is discarded.

Table 1. Processing aids

Processing Aid	**CAS No.**	**CFR Reference**
Activated Carbon	7440-44-0	21 CFR §173.25; 21 CFR §173.165
Silicon Dioxide	7631-86-9	21 CFR §172.480
Citric Acid	77-92-9	21 CFR §184.1033
Bentonite	1302-78-9	21 CFR §170.3
Diatomaceous Earth	68855-54-9, 91053-39-3, or 61790-53-2	21 CFR §172.820; 21 CFR §172.886

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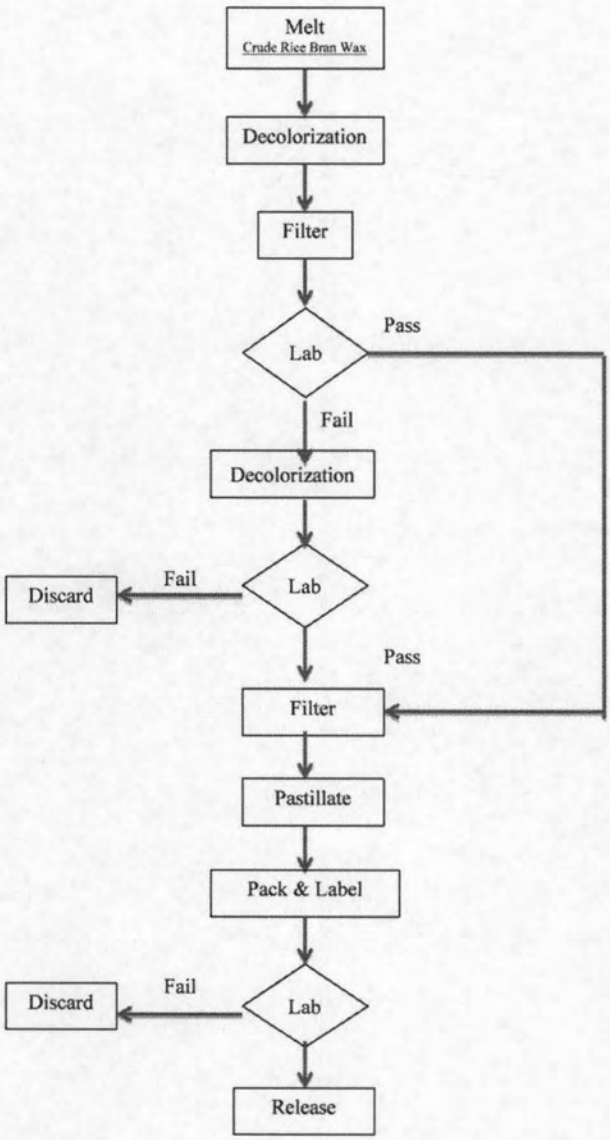

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Figure 1. Process flow diagram

Product Specifications

Food-grade specifications and the assays/methods used for the analysis of rice bran wax (wax #224P) are presented in Table 2 below. A comparison of three non-consecutive lots of rice bran wax to the specifications below can be found in Table 3. The specification for total arsenic in Table 2 is 0.2 ppm, and all analyzed lots were below the limit of quantitation for total arsenic of 10 ppb. Given a projected 90th percentile intake of rice bran wax of approximately 0.1-0.2 grams per day (see Table 6) and applying the limit of quantification (LOQ) of 10 ppb (10 µg/kg) as being present in rice bran wax, the estimated daily total arsenic intake is approximately 0.001–0.002 µg/person/day, and the inorganic arsenic intake a small percentage of that estimate. Therefore, the intake of total and inorganic arsenic from the intended use of rice bran wax is negligible and would not be expected to contribute to the background dietary intake of arsenic. In addition, inorganic arsenic is water soluble, and thus, the manufacturing process of rice bran wax will remove most of the inorganic arsenic. It should be noted that numerous other analyses of the final ingredient are conducted but are not included in the ingredient specifications (e.g., other physical/chemical properties, trace component analyses including additional pesticides, mycotoxins, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and dioxin-like polychlorinated biphenyls [PCBs]). Additional tests for other quality measures and contaminants are included in Table 4. Analytical results for the three non-consecutive lots of rice bran wax are provided in Appendix B.

Table 2. Ingredient specification for rice bran wax

Parameter	Specification	Assay/Analytical Method
Melting point	75.0 – 85.5 °C	USP 741, Class II
Acid value	≤ 13	USP 401
Saponification value	75 - 120	USP 401
Peroxide value	≤ 20 meq/kg	Koster Keunen 205
Gas chromatography	Conforms to Standard	Koster Keunen 208
Iodine value	≤ 20.0	USP 401
Color	Yellow to Light Brown	Visual
Total arsenic	0.2 ppm max	AOAC 984.27 Mod[1]., 2015.01 Mod[2], 993.14 Mod.
Cadmium	0.4 ppm max	AOAC 984.27 Mod[1]., 2015.01 Mod[2], 993.14 Mod.
Lead	0.2 ppm max	AOAC 984.27 Mod[1]., 2015.01 Mod[2], 993.14 Mod.
Mercury	0.1 ppm max	AOAC 984.27 Mod[1]., 2015.01 Mod[2], 993.14 Mod.
Hexane	1 ppm max	GC Headspace

[1]Modified method

[2]Analysis performed with an open vessel microwave system with a hot plate digestion process, followed by analysis on ICP-MS. A specific spike is incorporated for the heavy metal being analyzed (e.g., arsenic). In addition, one internal standard (rhodium 203) is incorporated. An arsenic spike is incorporated for every batch of wax and justifies the digestion efficiency; also a blank sample is used to show there is no contamination, and an internal standard incorporated to monitor for analytical errors.

Table 3. Analytical results of three lots of rice bran wax compared to ingredient specification

Parameter	Specification	Result 1	Result 2	Result 3
		Lot 18940	Lot 20033	Lot 20048
Melting point	75.0 – 85.5 °C	82.0	82.0	82.0
Acid value	≤ 13	1.8	0.6	0.6
Saponification value	75 - 120	78	81	77
Peroxide value	≤ 20 meq/kg	16	2	2
Gas chromatography	Conforms to Standard	Pass	Pass	Pass
Iodine value[a]	≤ 20.0	Pass	Pass	Pass
Color	Yellow to Light Brown	Pass	Pass	Pass
Total arsenic	0.2 ppm max	ND	ND	ND
Cadmium	0.4 ppm max	ND	ND	ND
Lead	0.2 ppm max	0.02	ND	0.01
Mercury	0.1 ppm max	ND	ND	ND
Hexane	1 ppm max	ND	ND	ND

ND=not detected

[a]Iodine value is measured prior to refining on incoming lots; refining will only lower the iodine value. The result is reported as passing since the final value may only be lower than the measured value and the specification for raw incoming wax is ≤20.

Table 4. Quality control parameters or residual contaminants for non-consecutive lots of rice bran wax

Parameter	Result 1	Result 2	Result 3
	Lot 18940	**Lot 20033**	**Lot 20048**
Microbiological			
Aerobic plate count	10 cfu/g	<10 cfu/g	<10 cfu/g
Coliform, plate count	<10 cfu/g	<10 cfu/g	<10 cfu/g
E. Coli, plate count	<10 cfu/g	<10 cfu/g	<10 cfu/g
Listeria genus (PCR)	Negative	Negative	Negative
Mold	<10 cfu/g	<10 cfu/g	<10 cfu/g
Salmonella (PCR)	Negative	Negative	Negative
Yeast	<10 cfu/g	<10 cfu/g	<10 cfu/g
Mycotoxins			
Aflatoxin B_1	ND	ND	ND
Aflatoxin B_2	ND	ND	ND
Aflatoxin G_1	ND	ND	ND
Aflatoxin G_2	ND	ND	ND

ND = not detected

The rice bran wax under consideration is yellow to light brown colored pastillates with a melting point of 75.0–85.5 °C. The USP Food Chemicals Codex (FCC) and 21 CFR § 172.890 contain a specification for rice bran wax and a comparison of the proposed rice bran wax ingredient (wax #224P) and the FCC specification is provided in Table 5. The rice bran wax product under consideration meets FCC specifications, with the exception of melting-point range. Rice bran wax is obtained by winterization/ separation from rice bran oil, and the melting point of the wax is typically determined by the degree of separation between the rice bran oil and the wax. Since the establishment of the FCC specification, methods for separating rice bran wax from rice bran oil have been improved, such that less rice bran oil is now present in the crude rice bran wax. As a result, these improvements can produce slightly increased melting points for rice bran wax.

Table 5. Ingredient specifications compared to FCC specifications for rice bran wax

Parameter	Rice Bran Wax (#224P) Specification	FCC Specification
Melting point	75.0 – 85.5 °C	75.0 – 80.0 °C
Free fatty acids content	<9.2% (equivalent to ≤ 13 acid value)	10% max
Saponification value	75 - 120	75 - 120
Iodine value	≤ 20	≤ 20.0
Lead	0.2 ppm max	3 ppm max

The specifications for rice bran wax also include a parameter for acid value as a substitute for the FCC measurement of percent free fatty acids. Acid value is an FCC-published method for fats and related substances and is appropriate for the indication of the free fatty acid content of rice bran wax. Specifically, acid value is reported to be the milligrams of potassium hydroxide (KOH) required to neutralize 1 gram of material (rice bran wax). Hence, an acid value of 13 (maximum) specifically means that it should require less than 13 mg of KOH to neutralize one gram of rice bran wax (see Appendix B for conversion formula).

The analytical (physical, chemical, and microbiological) results for rice bran wax summarized in the above tables and included in the certificate of analyses in Appendix B confirm that the ingredient meets the proposed analytical specifications and demonstrates the consistency of production. The analytical results also confirm the lack of impurities/contaminants (e.g., heavy metals, pesticides, mycotoxins, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and dioxin-like PCBs).

Stability Data

Rice bran wax is stable at normal storage and use temperatures. Stability tests, based on acid values, have shown that the rice bran wax ingredient has a shelf life of two years past the date of manufacture, if stored under proper conditions. Stability test data can be found in Appendix C.

§ 170.235 Part 3, Dietary Exposure

Purpose

Smucker is proposing to use rice bran wax as a texturizing agent in peanut butter used in bar products. The intended use will allow peanut butter to be the primary ingredient in nutritional/snack bars with a similar form and texture to granola bars and nutritional/energy bars.

Food Uses

The intended use of rice bran wax is solely in peanut butter used in bar products and results in bar-form products with a form and texture similar to granola and nutritional energy bars. There are no proposed uses of rice bran wax in food products under USDA jurisdiction.

Levels of Use

The proposed rice bran wax will be used at levels up to 3%.

Estimated Exposure

The proposed use of rice bran wax is as a texturizing agent solely in peanut butter in bar-form products, allowing peanut butter to be the primary ingredient in granola-based bar products that include cereal bars, breakfast bars, cookies and biscuits, nutritional bars, and energy snack bars with similar form and texture.

The US FDA's Office of Food Additive Safety, in the Center for Food Safety and Applied Nutrition, has performed a dietary exposure estimate of rice bran wax intake from nutritional and energy bars based on its new proposed use in foods using two different approaches (FDA, 2017). The outcome of this assessment was made available to ToxStrategies for review in response to a Freedom of Information Act request (FOI Request No. 2017-4008). While some of the data used in this assessment are proprietary, and therefore not available to the Expert Panel for review, they are appropriate for consideration as "other information available to FDA.[1]"

The first intake estimate determined by FDA was based on two-day average intake data obtained from the What We Eat in America" (WWEIA) National Health and Nutrition Examination Survey (NHANES). The estimates prepared by FDA based on NHANES data for the EDI of rice bran wax were 0.01 and 0.03 g/kg-bw/day, respectively, for the mean and 90th percentile in the population aged 2+ years. However, as stated by FDA

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[1] Per the description provided in *Table 1. Categories of Letters Responding to a GRAS Notice During the Interim Pilot Program* and *Table 20. Categories of Letters Responding to a GRAS Notice under the Final Rule*, presented in the Federal Register Notice of GRAS Final Rule; Substances Generally Recognized as Safe (Implemented on October 17, 2016). 81 FR 54959, August 17, 2016.

(2017) in its memorandum, the available information suggests that the bars included in the assessment are eaten infrequently. As such, the two-day survey data "are likely to significantly overestimate the actual consumption."

In order to prepare a more appropriate estimate of intake, FDA conducted a second assessment using longer term survey data, which more accurately reflect intake of these bars. To do so, 10- to 14-day dietary recall data from the NPD Group, Inc.'s, National Eating Trends-Nutrient Intake Database (NET-NID) were used. Using the longer-term survey data, FDA estimated the daily average mean and 90th percentile dietary intakes of rice bran wax to be 0.003 and 0.005 g/kg-bw/day, respectively, for ages 2+ years. For the 2- to 5-year-old population, the EDIs of rice bran wax were determined to be 0.007 and 0.014 g/kg-bw/day, respectively (Table 6). Importantly, the analysis by FDA included any and all bars, and as such, is very conservative, and results in an overestimate of the actual consumption.

In addition, ToxStrategies, Inc. (ToxStrategies), has conducted an intake assessment incorporating an estimated market share to provide supplemental information related to the mean and 90th percentile daily intake of the ingredient rice bran wax. The results of this intake estimate were similar to that of the FDA described above. It was assumed for the purpose of the estimate that such unique bars would replace 10% of the bars currently consumed, reflecting a very high assumed future market share, in order to produce conservative (high) estimates of potential rice bran wax consumption. The approach and outcome of this supplemental intake assessment are provided in Appendix D. One potential limitation of the method used here for determining the EDI of rice bran wax is the impact of brand loyalty, or the tendency of an individual to repeat the purchase of a specific brand or product (Arcella and Leclerq, 2005; Leclercq et al., 2003). Leclercq and colleagues (2003) have conducted a study to investigate the impact of incorporating indicators of market share and brand loyalty into intake modeling, using intense sweeteners as an example. While the authors concluded that market share information should generally be included in the model, they found that both parameters—market share and brand loyalty—influenced the intake estimates at the 95th percentile. Without the availability of information regarding brand loyalty to incorporate into the analysis for rice bran wax, it is not possible to ascertain whether the EDI may have been over- or underestimated at the 90th percentile.

Table 6. Estimated daily intake for rice bran wax (g/day and g/kg BW/day) at a 3% use level as Reported by FDA (2017)

Nutrition/Snack Bar	EDI *per User* (g/day)		EDI *per User* (g/kg BW/day)	
	Mean	90th Percentile	Mean	90th Percentile
US Population, Ages 2+				
Rice bran wax consumption	0.1	0.2	0.003	0.005
US Population, Ages 2–5				
Rice bran wax consumption	0.1	0.2	0.007	0.014

Background Levels

As stated previously, rice bran wax is permitted as a direct human food additive when used in candy (maximum 50 ppm as a coating), fresh fruits and fresh vegetables (maximum 50 ppm as a coating), and chewing gum (maximum 2.5% as a plasticizing material in gum base) (21 CFR § 172.890).

The background exposure to rice bran wax from its approved uses in gum, candy, and fresh fruit and fresh vegetables is estimated to be approximately 0.1 g/day, about half of which is estimated to come from fresh fruit/vegetables and the other half from chewing gum. The estimate is based on reported consumption levels for chewing gum (approximately 30 mg/kg/day for a 60-kg individual or 1.8 g gum/day), candy (mean intake of approximately 40 g candy/day), and fresh fruit and fresh vegetables (approximately 900 g fruits and vegetables/day) (Revolymer Limited, 2011; Cook, 2011; Orlich et al., 2014; Shumow et al., 2012). Given the approved 2.5% maximum use level in chewing gum, the background exposure estimates for rice bran wax from its use in chewing gum would be higher for heavy users of chewing gum (estimated to be on the order of 2-3x) as compared to mean intake estimates. Therefore, the background exposure to rice bran wax from current approved uses is estimated to be as high as 0.2–0.3 g/day. The non-food use of rice bran wax in lipstick at a concentration of approximately 1% results in an extremely low level of oral consumption and does not add significantly to the background level of exposure to rice bran wax. Loretz et al. (2005) conducted a study of consumers and reported that the mean use of lipstick was 0.024 mg/day. Given a 1% concentration level and complete ingestion of the applied lipstick, the mean daily ingestion of rice bran wax from lipstick would be approximately 0.00024 g/day, or 240 µg/day, much lower than the daily intakes estimated for the current approved uses of rice bran wax. Of note, the 90th percentile estimated exposure from the rice bran wax bar is 0.1–0.2 g/day, similar to the calculated background exposure. Thus, the total contribution of rice bran wax would be insignificant for something as inert as rice bran wax.

We believe this background exposure estimate is extremely conservative given that other waxes are more commonly used as confectionery coatings (e.g., carnauba wax) and as a coating for fruits and vegetables and alternative waxes and plasticizers are approved and used in chewing gum base in the U.S. In addition, it is generally acknowledged that waxes and plasticizers in gum base remain with the gum cud during chewing and are not released and subsequently ingested.

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§ 170.240 Part 4, Self-Limiting Levels of Use

The use of rice bran wax in foods is considered to be self-limiting for technological reasons, such as product texture and/or flavor profile, either of which could affect consumer acceptability.

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§ 170.245 Part 5, Experience Based on Common Use in Food

The statutory basis for our conclusion of GRAS status in the notice is not based on common use in food.

§ 170.250 Part 6, GRAS Narrative

History of Use and Regulatory Approval of Rice Bran Wax

Rice, brown rice, and their derivatives have a long history of human consumption, with rice cultivation documented back to prehistoric times, starting in Asia and eventually spreading across Europe around the sixth century (Burlando and Cornara, 2014). Currently, rice is produced on most continents and serves as a dietary staple for many populations across the world (Burlando and Cornara, 2014). Once harvested, the rice is hulled and the resulting brown rice can be further processed to generate derivatives such as rice bran oil, rice bran extract, and hydrolyzed rice protein. As referenced in the manufacturing process outlined above, rice bran wax comes from the bran, which is the part between the husk and endosperm of rice, and is a byproduct of bran oil (Burlando and Cornara, 2014; Andersen, 2006; Sabale et al., 2007). Rice bran wax is used in food as a release agent, brightener, coatings for confectioneries, chocolates, cakes, and tablets, treatment of vegetables and fruits and as a plasticizing material for chewing gum base.

Rice bran wax (CAS No. 8016-60-2) has been approved for use in various food applications in the US. It is permitted as a direct human food additive (21 CFR §172.890) when used in candy (maximum 50 ppm as a coating), fresh fruits and fresh vegetables (maximum 50 ppm as a coating), and chewing gum (maximum 2.5% in gum when used as a plasticizing material in chewing gum base, 21CFR §172.615). It is also permitted as an indirect food additive as Type VIII in table 1of 176.170(c), at a maximum level of 1.0 percent by weight of the polymer. After reviewing the available safety data, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that rice-derived ingredients, including rice bran wax, are safe as cosmetic ingredients (e.g., 1% in lipstick) in the practices of use and concentrations as described in their safety assessment (Andersen, 2006). In addition, rice bran wax is eligible for use as active ingredients or excipients in listed medicines in Australia, with no restrictions (Australian Government, 2007).

Safety

Introduction

The major components of most plant- and animal-derived waxes are esters of long-chain aliphatic alcohols and acids with carbon chain lengths spanning C16–C40 (Krendlinger et al., 2002; Vali et al., 2005). Rice bran wax is a hard, crystalline vegetable wax obtained from rice husks that primarily consists of high molecular weight monoesters ranging from C48 to C64 (Appendix A). As shown in Table 7, the majority (87%–98%) of the rice bran wax components are these monoesters; the remaining components (2-13% total) of the rice bran wax product consist of free long-chain fatty alcohols, free long-chain fatty acids, or triglycerides from rice bran oil (Table 7; Appendix A). The long-chain fatty acid esters present in plant-based waxes such as rice bran wax are generally thought to be poorly absorbed in the gastrointestinal (GI) tract (EFSA, 2012a,b) as uptake of wax esters decreases as chain length and hydrophobicity increase (Hargrove et al., 2004). While some species have adapted to the use of these esters as energy sources, humans are

thought to be inefficient at this process (Hargrove et al., 2004). When limited hydrolysis of the long-chain fatty monoesters in waxes such as rice bran wax does occur, the resulting long-chain fatty acid and fatty alcohol products have been shown to be incorporated into normal cellular metabolic pathways (Hargrove et al., 2004; Place, 1992).

While some toxicological data are available for rice bran wax, information on its main constituents and other plant-based waxes with similar chemical structures, and thus similar potential for absorption, were also evaluated as part of the GRAS assessment. These oils and waxes are composed of the same primary monoester constituents as rice bran wax, and have been shown to have the same absorption, metabolism, and excretion properties (Table 7). A similar approach has been taken for the evaluation of other plant-based waxes. In 2007, the European Food Safety Authority (EFSA, 2007) applied a similar approach for beeswax, bridging safety data from main constituents and other similar waxes. In this assessment, the EFSA Panel "noted that experimental biochemical and toxicological studies carried out specifically on beeswax were still lacking and considered that the data on beeswax itself were insufficient to establish an Acceptable Daily Intake (ADI). However, the Panel concluded that the safety of beeswax could be assessed, based on the available scientific literature on the main constituents of beeswax and plant waxes showing chemical structural similarities to beeswax, published since the last SCF evaluation." The Panel concluded that "the use of beeswax as an additive for the existing food uses and the proposed new food use is not of safety concern." EFSA also applied a similar approach to candelilla wax in their 2012 assessment (EFSA, 2012c).

Therefore, toxicity studies conducted on carnauba wax, candelilla wax, beeswax, lanolin wax, and jojoba wax (also known as jojoba oil, see Table 7) were identified and deemed suitable for inclusion in the safety assessment of rice bran wax and considered by the Expert Panel in its evaluation. An overview of the composition of the waxes considered in this assessment, including their respective fatty alcohol and fatty acid carbon chain lengths, is presented in Table 7. Jojoba wax consists almost entirely of long-chain monoesters (97%), and is therefore directly comparable to the primary component of rice bran wax (87%–98% monoesters), providing toxicological data specific to this fraction. Carnauba wax, candelilla wax, beeswax, and lanolin wax also have a large fraction of these monoesters and so provide additional safety information related to these components. Importantly, minor components present in rice bran wax (e.g., free fatty alcohols, free fatty acids) are present in one or more of these waxes at higher concentrations, thus providing additional safety information on these constituents. However, these waxes also contain various other constituents not relevant to rice bran wax that may impart toxicities of their own or may be of unknown toxicity. As such, these other waxes are considered appropriate and conservative comparators to rice bran wax, which is purer and consists almost exclusively of esters or their fatty acid and alcohol components, as demonstrated in Table 7.

In addition, chain length and saturation have been shown to predict physio-chemical behavior of waxes and oils, including their potential for toxicity (EFSA, 2007; Maru et al., 2012; Smith et al., 1996). As demonstrated by Smith et al. (1996), the potential for toxicity of waxes decreases with increasing chain length. This paper reports on

subchronic 90-day feeding studies conducted on a variety of waxes (paraffinic in origin) (Smith et al., 1996). In this study, seven white oils and five waxes were administered to male and female Fischer-344 rats in the diet at doses up to 20,000 ppm (equivalent to 1,850 mg/kg-bw/day). The results of these studies demonstrated a decrease in incidence and severity of adverse effects as molecular weight of the various waxes increased. While systemic exposure to lower weight waxes resulted in effects such as increased organ weights and inflammatory changes of the liver and mesenteric lymph nodes. These effects were reduced in severity for other waxes as chain length increased, and no adverse or biological effects were observed following exposure to the highest molecular weight waxes. Of the waxes evaluated in this GRAS assessment, rice bran wax contains the longest alcohol and acid chain lengths and has one of the largest monoester fraction (comparable to jojoba) and thus would be the least bioavailable, positioning it to have the least potential for toxicity. Thus, any negative findings in safety studies conducted with carnauba wax, candelilla wax, beeswax, lanolin wax, or jojoba wax can be confidently extended to the more inert rice bran wax.

Taken together, the available data on these various waxes provides sufficient information to assess the safety of rice bran wax and its constituents for its intended use.

Table 7. Typical composition of the waxes considered in this assessment, including their respective fatty alcohol and fatty acid chain length distributions

Wax	Alcohol and Acid Chain Length Distribution (C-number)	Monoesters (%)	Other (%)	Reference(s)
Rice bran wax [A]	16-40	87-98	Free alcohols (0-13) Free acids (0-13) Triglycerides from rice bran oil (0-13)	Andersen, 2006; Appendix A; Vali et al., 2005; Warth, 1956
Carnauba wax	16-36	38-85	Free alcohols (2-33) Free acids (3-7) Diesters of 4-hydroxycinnamic acid (20-23) Esters of ω-hydroxycarboxylic acids (12-14) Diesters of 4-methoxycinnamic acid (5-7) Free aromatic acids (1) Hydrocarbons (paraffins) (0.3-1) Free ω-hydroxycarboxylic acids (0.5) Triterpene diols (0.4-0.5) Lactides (2-3) Aromatics and/or resins (4.4)	Appendix A; Bagby, 1988; EFSA 2012b; Krendlinger et al., 2002; Warth, 1956
Candelilla wax	22-34	39	Free alcohols (5) Free acids (8) Hydrocarbons (42-50) Lactones (6) Free wax resin acids (8)	Bagby, 1988; EFSA, 2012c; Krendlinger et al., 2002
Beeswax	16-36	40-80	Free alcohols (<0.3-0.6) Free acids (1-18) Paraffins (10–20) Diesters (7-16) Hydroxydiesters (3.9) Hydrocarbons (11-28) Other (4-8)	Bagby, 1988; EFSA, 2007; Krendlinger et al., 2002; JECFA, 2006
Lanolin wax	14-34	48	Free acids (3.5) Sterol esters (33) Free sterols (6) Lactones (3.5) Hydrocarbons (1-2)	Krendlinger et al., 2002; Sengupta and Behera, 2014
Jojoba wax [B]	16-26	97	Free alcohols (1-1.1) Free acids (1) Sterols (<0.5-0.9) Tocopherols (0.05)	Bagby, 1988; Becker, 2008; EPA, 1995; Krendlinger et al., 2002; Miwa, 1971

[A]As rice bran wax is a natural product, its composition can vary. As an example, and as shown in Appendix A, batch #3906 contains 11.68% fatty alcohols and acids, 86.73% monoesters, and 1.29% rice bran oil.

[B]Jojoba oil is typically defined as a "liquid wax" or "liquid wax ester" due to its chemical composition (EPA, 1995; Krendlinger et al., 2002). Composition and chemistry information are combined from references listed in the table for each respective wax. Test materials listed in the Safety Section are as defined by each study author.

Absorption, Distribution, Metabolism, and Excretion (ADME)

Overview

As described above, wax esters are defined as long-chain fatty alcohols esterified to long-chain fatty acids (Krendlinger et al., 2002; Place, 1992). The bioavailability of wax esters and their constituents in the GI tract depends primarily on the rate of intestinal hydrolysis, and less so on potential re-synthesis of esters from free fatty acids or alcohols (Hargrove et al., 2004). Hydrolysis of wax esters requires a pancreatic lipase or other carboxyl esterase; however, this process is slower in mammals compared to other species, rendering it the rate-limiting factor (Place, 1992). This limitation is partially due to the hydrophobic nature of the wax surface, which makes it a poor substrate for the enzymes. As with physical properties of waxes such as melting point, melt viscosity, and hardness, the rate of uptake is thought to decrease as chain length and hydrophobicity increase (Hargrove et al., 2004; Krendlinger et al., 2002). As such, the long-chain fatty acid esters present in plant-based waxes such as rice bran wax and other waxes included here are generally thought to be poorly absorbed in the GI tract (Hargrove et al., 2004; Place, 1992). Any limited hydrolysis of the long-chain fatty monoesters in rice bran wax and other plant-based waxes would result in the corresponding long-chain fatty acid and fatty alcohol products.

Once released from the wax esters, long-chain free fatty acids and alcohols are absorbed by passive membrane permeation; more recent evidence suggests that uptake may also occur via a fatty acid carrier (Hargrove et al., 2004). The resulting free fatty alcohols are then oxidized into the corresponding fatty acids or incorporated into the synthesis of phospholipids; the fatty acids have been shown to be incorporated into normal cellular metabolic pathways (Hargrove et al., 2004). In addition to limited efficiency in hydrolyzing the wax esters, the ability to oxidize to fatty alcohols is also limited in mammals (Place, 1992).

Available Studies

The objective of Hamm (1984) was to determine whether jojoba oil could act as a replacement for conventional edible fats and oils, to reduce the calories in food. To determine the caloric availability, young male Sprague Dawley rats were randomized into groups of 10 animals and fed either a 5-g basal diet or a 5-g basal diet supplemented with either 0.5, 1.0, 2.0, or 3.0 g (equivalent to 10,000, 20,000, 40,000, or 60,000 mg/kg-bw/day, respectively[2]) jojoba oil, corn oil, or trialkoxytricarballylate. The lower dose groups (0.5 and 1.0 g) were tested for 7 days, while the higher dose groups were tested for 4 days. The jojoba oil was reported to be poorly absorbed due to observed excretion of oils; the authors suggested it was resistant to digestion *in vivo*. Additional findings of this study are described in the Repeated Exposure Toxicity section below.

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[2] Equivalent doses calculated based on assuming an animal weight of 0.1 kg and food consumption of 10 g per day per animal (EFSA, 2007, 2012c).

In another study, rats were given oleyl palmitate (C-34 ester) in the diet to investigate effects such as seborrhea; however, information on the digestibility and absorption of the wax esters was also generated (Hansen and Mead, 1965). In two experiments, weanling male rats were fed *ad libitum* for either four weeks or 10 days[3]; control animals were given a standard diet. EFSA (2007, 2012c) has estimated this intake to be 40 or 150 g/kg diet, equivalent to 2,000 mg/kg-bw-day or 7,500 mg/kg-bw/day, respectively. The oleyl palmitate appeared to be poorly absorbed, as evidenced by excretion of intact monoesters, free fatty acids, and free fatty alcohols. Additional findings of this study are described in the Repeated Toxicity section below.

In a digestibility study conducted by Heise et al. (1982), weanling rats were given dietary (1) jojoba wax (12%), (2) corn oil, (3) medium-chain triglycerides (control), (4) 1:1 jojoba wax and corn oil, or (5) 1:1 jojoba wax and triglycerides *ad libitum* for 30 days. The total food intake for the jojoba-wax-only diet was reported to be 517 g/30 days, equivalent to approximately 2.1 g jojoba wax/day. Evaluation at 2 and 4 weeks demonstrated that weight gain of animals on the jojoba-only diet was reduced by ~50% compared to controls; this effect was not seen in other diet groups. The authors suggested that reduced weight gain was due to the poorer digestibility of jojoba wax (41% versus 98% in controls). This was further evident in the amount of fat found in feces as a percent (%) of fecal dry matter (51% for jojoba wax versus 6% in controls).

Vershuren and Nugteren (1989) evaluated the effects of jojoba oil on digestion parameters. Eight-week-old male SPF Wistar rats were divided into two groups of 20 animals that were administered different diets. One group received a dietary mixture of lard/sunflower oil that represented 18% of the total fat content, while the experimental group received a mixture of 9% lard/sunflower oil + 9% jojoba oil. Both groups followed two equal *ad libitum* feeding periods per day—morning and evening. This protocol was modified for the last three days, and after 4 weeks, the rats were given a radioactive retinol marker to measure intestinal transit time and stomach emptying. In a separate group, 10 rats were fed a dietary mixture of 9% lard/sunflower oil + 9% jojoba oil, to study the digestibility and absorption of the oil. Compared to animals on the control diet, the animals decreased their consumption of jojoba oil–supplemented food, resulting in retarded growth in the experimental animals. This was possibly due to reduced palatability of the jojoba oil. Although jojoba oil did not influence intestinal transit time of retinol, retinol absorption appeared to be decreased in the experimental group. The rate of stomach emptying was not affected by the addition of jojoba oil in the diet. Some jojoba oil appeared to be absorbed, with 35% excreted in the feces. Based on the analysis of free fatty acids in the feces, hydrolysis of jojoba oil likely took place after the small intestine. Furthermore, the mucosal cells of the intestine contained jojoba oil, indicating that wax esters were absorbed.

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[3] Other summary documents describe this as 2 weeks; however, according to the publication, rats were giving the standard diet only for the first 4 days of the 2-week period.

The absorption and distribution of jojoba wax was studied in two experiments by Yaron and colleagues (1982a,b). In the first experiment in the first study, ~90 mg ^{14}C-jojoba wax was injected subcutaneously into male mice (n=24); triolein was used as a control (Yaron et al., 1982a). Mice from each group were sacrificed after 1, 8, 15, or 23 days, and the distribution of labeled wax was determined. In the second experiment, two groups of male and female mice (n=5 per sex, per group) were treated as in experiment 1, and were sacrificed after 90 days. The results of this study demonstrated that only a small amount of the injected wax was absorbed initially, but was not detected at 23 days. The majority of ^{14}C was determined to remain in lipid form, with the remainder incorporated primarily into triglycerides and fatty acids.

In another study by the same group (Yaron et al., 1982b), male albino mice were orally administered 0.1 mL of a 25% solution of ^{14}C-labeled jojoba wax in peanut oil and were sacrificed either 1 day (n=10) or 8 days later (n=10). Of the 500,000 dpm administered per mouse, a small amount (ranging from not detected to 7,760 dpm) was found distributed in each of the internal organs evaluated (liver, heart, lungs, spleen, testes, kidneys, muscle, and epididymal fat) and decreased between 1 and 8 days. Thin-layer chromatography showed that the labeled material was incorporated into the body lipids, including triglycerides and phospholipids

Taguchi and Kunimoto (1977) evaluated the acute oral toxicity of jojoba oil in 5-week-old Y-S mice. Four groups of 10 male and 10 female, fasted mice were administered jojoba oil 0.5, 0.75, 1.13, or 1.69 mL/10 g body weight via oral gavage. In this study, the test material was said to be excreted via feces, suggesting it was poorly absorbed.

Animal Toxicological Studies on Rice Bran and Similar Waxes

Acute Oral Toxicity

Eighteen acute oral toxicity studies were identified that reported the LD_{50} value of rice bran wax, similar waxes, or its constituents (Table 8); additional studies or assessments relevant to this endpoint are also listed. The LD_{50} in all cases was found to be greater than the highest dose tested, which in most cases, was >5,000 mg/kg-bw. While not published, a complete summary of the studies of Polar modified rice bran wax and distilled lanolin fatty acids is available for public access; these studies report LD_{50} values in rats of >2,000 and >5,000 mg/kg-bw/day, respectively. Taken together, these studies demonstrate a lack of potential acute oral toxicity of rice bran wax.

Table 8. Available acute oral toxicity studies on rice bran wax, similar waxes, or its constituents

Test Material	Species (strain)	LD_{50}[A] (mg/kg-bw)	Reference	Access Information
Polar modified rice bran wax	Rat (Crl:WI (Han))	>2,000	Unnamed, 2016, as cited in REACH Registration for Polar Modified Rice Bran Wax	https://echa.europa.eu/registration-dossier/-/registered-dossier/18316/7/3/2
Rice bran wax	Mouse	>2,400	Nippon Bio-Test Laboratories, Inc., 1972, as cited in Anderson, 2006	Reviewed by Andersen, 2006
Hydrogenated rice bran wax	Rat (white)	>5,000	Leberco Testing, Inc., 1991a, as cited in Andersen, 2006	Reviewed by Andersen, 2006
Rice bran wax	Rat (albino)	>5,000	Consumer Product Testing Co., 1998f, as cited in Andersen, 2006	Reviewed by Andersen, 2006
Carnauba wax	Not reported	>1100	Liebert, 1984, as cited in EFSA, 2012b	Reviewed by EFSA, 2012b
Carnauba wax (5.6% in a lipstick product)	Rat	>1,120	Anonymous, 1984	Reviewed by EFSA, 2012b
Beeswax	Rat	>5,000	McGee Laboratories, 1974, cited in American College of Toxicology, 1984, as cited in JECFA, 2006	Reviewed by JECFA, 2006
Candelilla wax	Rat	>5,000	JECFA, 1993b, as cited in EFSA, 2012c	Reviewed by EFSA, 2012c
Candelilla wax	Not specified	Not specified ("none of the studies reported any adverse treatment-related toxicological findings")	SCF, 1992, as cited by EFSA, 2012c	Reviewed by EFSA, 2012c

Test Material	Species (strain)	LD_{50}[A] (mg/kg-bw)	Reference	Access Information
Candelilla wax (as a cosmetic ingredient and in cosmetic formulations)	Rat (SD, Long Evans, and undefined)	Not reported	Liebert, 1984, as cited in EFSA 2012c	Reviewed by EFSA, 2012c
Lanolin wax	Rat	48-64 cc/kg	CFTA: Mamstrom Chemicals, as cited in Elder, 1980	Reviewed by Andersen, 2006
Lanolin wax	Rat	>42,700 mg/kg		
Lanolin wax	Rat	>32,000 mg/kg	CTFA: Robinson-Wagner Co., Section D. Lanolin Acid, as cited in Elder, 1980	
Distilled lanolin fatty acids	Rat (Wistar)	>5,000	Unnamed, 1977, as provided in REACH Registration for Fatty Acids, Lanolin	https://echa.europa.eu/registration-dossier/-/registered-dossier/13395/7/3/2
Jojoba oil	Rat	>21.5 mL/kg-bw	Wisniak, J., 1977, as cited in EPA, 1995	Reviewed by EPA, 1995
Jojoba oil	Mouse (Y-S)	>169 mL/kg-bw	Taguchi and Kunimoto, 1977	http://agris.fao.org/agris-search/search.do?recordID=US19780274740
Jojoba oil	Weanling mouse	LD_{20} = 10% dietary (unclear if single dose)	Locke, R.K. to L.J. Lin, FDA memo, 3/22/1978, as cited in EPA, 1995	Reviewed by EPA, 1995
DETUR (97.5% jojoba oil)	Rat (HSD:SD)	>4,924	Data submitted to EPA, 1995 (no further details provided)	Reviewed by EPA, 1995
Jojoba seed wax	Rat (albino SD)	>5,000	Reinhardt and Brown, 1990, as cited in Becker, 2008	Reviewed by Becker, 2008
Jojoba esters	Rat (white)	>5,000		

Test Material	Species (strain)	LD_{50}[A] (mg/kg-bw)	Reference	Access Information
Jojoba esters 15	Rat (white)	>5,000	Leberco Testing, Inc., 1988a, as cited in Becker, 2008	Reviewed by Becker, 2008
Jojoba esters 30	Rat (white)	>5,000	Leberco Testing, Inc., 1988b, as cited in Becker, 2008	
Jojoba esters 60	Rat (white)	>5,000	Leberco Testing, Inc., 1988c, as cited in Becker, 2008	
Jojoba esters 70	Rat (SD)	>5,000	Leberco Testing, Inc., 1988d, as cited in Becker, 2008	

[A]Unless otherwise noted unites are mg/kg-bw

Repeated Exposure Toxicity

A summary of available repeated exposure studies is provided in Table 9.

Carnauba Wax

Rowland et al. (1982) evaluated the subchronic oral toxicity of carnauba wax in rats in a 13-week study. Carnauba wax (0, 1, 5, or 10%, corresponding to 0, 800, 4200, or 8800 mg/kg-bw/day for males and 0, 900, 4600, 10200 mg/kg-bw/day for females, respectively) in the diet resulted in no treatment-related effects including changes in body weight, hematology, serum-enzyme activities, organ weights, or histology. In rats given carnauba wax, some significant but non-treatment-related changes were reported: increased mean food consumption, higher erythrocyte count at week 2 in male rats, changes in urine specific gravity, and changes in organ and relative organ weights. The authors concluded the no-effect level to be 10% in the diet, equivalent to 8,800 and 10,200 mg/kg-bw/day in males and females, respectively. Similarly, EFSA (2012a,b) identified a no-observed-adverse-effect level (NOAEL) of 8,800 mg/kg-bw/day for carnauba wax based on the highest dose tested in males in this study.

No toxicity was observed in beagle dogs administered carnauba wax in the diet (0, 0.1, 0.3, or 1% carnauba wax, equivalent to 25, 75, and 250 mg/kg-bw/day, respectively) for 28 weeks (Parent et al., 1983a). The only significant finding was an increased free fatty acid level in male dogs in all treated groups compared to control animals at 26 weeks. The levels were determined to be within the normal historical range for beagle dogs in the breeding colony, and the authors noted the control dog values were comparatively lower than these historical levels, which likely accounted for the observed difference, as opposed to abnormally increased levels in treated dogs. No other changes were noted in food consumption, body weight, behavior, blood and urine samples, organ weights, examined tissues (gross and microscopic), or biochemical analysis at the end of the study. The EFSA ANS Panel derived a NOAEL of 250 mg/kg-bw/day for carnauba wax based on the highest dose tested in this study.

The EFSA ANS Panel (EFSA, 2012b; also in JECFA, 1993a) also reviewed an unpublished report by Edwards (1998). In this study, rats were administered carnauba wax in the diet at levels of 0, 15, 150, or 1500 mg/kg-bw/day continuously for 90 days; 5 males and 5 females were also placed back on the control diet for another 90 days as a reversibility test. In some carnauba wax-treated animals, non-treatment-related changes included: significant increase in feed intake in the main study; lower chloride or protein concentration, higher albumin/globulin ratio, higher alanine aminotransferase and lactate dehydrogenase activities in 15 and 150 mg/kg-bw/day groups (few differences in reversibility groups); reduction in mean relative thymus weight of male rats (15 and 1500 mg/kg-bw/day groups); increase in mean absolute brain weight of the male rats fed 15 mg/kg-bw/day; higher incidence of liver necrosis in male rats (15 and 150 mg/kg-bw/day groups); and significantly higher incidence of liver vacuolization in the 150 mg/kg-bw/day group (not observed in the 1500 mg/kg-bw/day group). One female in the highest dose group died of a brain hemorrhage on day 52. The EFSA ANS Panel (EFSA, 2012b) determined the NOAEL to be 1500 mg/kg-bw/day for carnauba wax based on the highest dose tested in this study.

Candelilla Wax

Two 8-week studies were reported by Harrisson (1946, 1948, as cited in EFSA, 2012c) in which groups of 12 weanling Wistar rats were administered dietary candelilla wax; no treatment-related effects were observed in either study, including survival, body-weight gains, food and water intake, urinalysis, hematology, and gross pathology. In the first study, female rats received candelilla wax in a gum base mixture at 0, 3%, and 5% (equivalent to 0, 590, and 980 mg/kg bw/day); however, the concentration of the candelilla wax was not provided. In the later study, male and female rats were given a mixture of candelilla wax and a butadiene-styrene polymer; the daily intake of candelilla wax was calculated to be 0, 370, or 1,800 mg/kg-bw/day. The NOAELs were determined by EFSA to be the highest doses tested.

In a separate study by the same author (Harrisson, 1949, as cited in EFSA, 2012c), a different 50/50 candelilla wax and butadiene-styrene polymer mixture was given to male and female Wistar rats for 27 weeks. The 0, 1%, and 5% dietary levels were determined to be equivalent to approximately 0, 370, and 1,800 mg candelilla wax/kg-bw/day, respectively. No significant differences were reported in survival, food and water intake, urinalysis, hematology, or pathology (heart, lung, spleen, kidney, pancreas, small and large intestines, uterus, ovary, prostate, testicle, and seminal vesicle tissue). A decreased body weight gain (described as "slight") was reported for both treatment groups; however, EFSA (2012c) concluded the NOAEL to be the highest dose of 1,800 mg/kg-bw/day.

The daily intake of candelilla wax in a 180-day study conducted in male and female albino rats (n=12 per sex; strain not reported) was calculated to be approximately 2,400 mg/kg-bw/day (Hodge, 1973, as cited in EFSA, 2012c). In this study, candelilla wax, present at 4.1%–6.1% in a gum base, was administered in dietary concentrations

ranging from 10% to 25% for 180 days. No significant differences were reported in survival, body weight gain, food and water intake, urinalysis, or histopathology.

Hodge (1973, as cited in EFSA, 2012c) also conducted a longer term oral study in C57 mice (n=15/sex/group) using a mixture of 25% candelilla wax in a gum base. Mice were administered 0, 0.8%, or 5.0% of the test material for 12–13 months, equivalent to approximately 0, 300, or, 1,900 mg candelilla wax/kg-bw/day, respectively. The only finding reported was an increase in mortality in the highest dose group relative to lower and control groups; however, the cause of death was not identified. EFSA (2012c) concluded the NOAEL to be the highest dose of 1,900 mg/kg-bw/day.

The final rodent study identified with candelilla wax was conducted by Harrisson (1953, as cited in EFSA, 2012c). In this study, male and female Sprague-Dawley rats received dietary candelilla wax (25% in a gum base mixture) for either 19 months or 2 years. No significant differences were reported in food intake, urinalysis, hematology, or histopathology at the highest dose tested of 750 mg candelilla wax/kg-bw/day. Doses administered in the diet were 0.8, 2.0%, or 5%, equivalent to 0, 125, 300, and 750 mg candelilla wax/kg bw/day, respectively. EFSA determined the NOAEL to be 750 mg/kg-gw/day.

A repeated-dose oral toxicity study was also identified in male and female dogs (strain not reported), where candelilla wax (25% in a gum base) was administered for 6 months (Harrisson, 1953, as cited in EFSA, 2012c). Dose levels were reported as 0, 1%, or 10%, equivalent to 0, 60, and 600 mg candelilla wax/kg bw/day, respectively. No significant differences were reported in survival, body-weight gain, urinalysis, hematology, or histopathology.

Lanolin Wax

The repeated oral toxicity of lanolin fatty acids was tested in a GLP-compliant study using OECD Guideline 408 and submitted for the REACH registration dossier for Fatty Acids, Lanolin (Unnamed, 2013). In this study, lanolin fatty acids (CAS # 68424-43-1) were administered to Wistar rats at doses of 100, 300, and 1,000 mg/kg-bw/day for 91 (females) or 92 (males) days. Parameters evaluated included cage side and clinical observations, neurobehavioral examination, body weight, hematology, clinical chemistry, urinalysis, ophthalmoscopic examination, gross necropsy, histopathology, and organ weights. No treatment-related effects were reported, and the NOAEL was determined to be the highest dose tested of 1,000 mg/kg-bw/day.

Jojoba Wax

As described in the ADME section above, a digestibility study was conducted by Heise et al. (1982). The only observed effect in weanling rats given 2,100 mg/kg-bw/day of jojoba wax in the diet for 30 days was decreased weight gain, which the authors attributed to differences in digestibility related to the jojoba wax. This effect was not seen in groups receiving 1:1 jojoba wax and corn oil or 1:1 jojoba wax and triglycerides. The authors

also noted that the inclusion rates of jojoba wax were "purposefully high, yet no detrimental effects other than those related to lower energy availability were apparent."

Jojoba wax was administered to male and female rats via the diet at levels of 2.5, 5.0, or 10.0% (no additional information provided) for 3 months (Stalder et al., 1985). While no pathological abnormalities were found in the liver, increased serum transaminase and alkaline phosphatase activities were reported in both sexes. Decreased weight gain was reported in females only. No other information was provided in this conference abstract.

In the study by Hamm (1984) described in the ADME section above, male rats received the equivalent of 10,000, 20,000, 40,000, or 60,000 mg/kg-bw/day of jojoba oil, corn oil, or trialkoxytricarballylate in the diet for 4 or 7 days. Weight gain in animals supplemented with 0.5 g jojoba oil in 5 g basal diet (equivalent to10,000 mg/kg-bw/day) was not significantly different from those receiving the basal diet, with a mean reduction of 2.2 g observed over 7 days. Rough coats were observed in some animals of the jojoba oil groups; however, similar findings in the control group suggest that this effect was a result of poor nutrition prior to the study. Weakness or depression (no definition provided) was seen in jojoba oil treatment groups higher than 10,000 mg/kg-bw/day. There was also a 10% mortality rate in these three higher jojoba oil dose groups (20,000, 40,000, and 60,000 mg/kg-bw/day); the cause of death was not discussed by the authors. These effects were not observed in the lowest dose group. Oily coats were observed in some animals, which appeared to be a result of anal leakage from undigested oil. Diarrhea was not observed in animals receiving 10,000 mg/kg-bw/day jojoba oil supplementation, but feces were soft, suggesting that the oil did interfere with some digestive process. The low tolerance of the jojoba oil seen in the higher dose groups was suggested to be related to "metabolic disturbances" (related to malabsorption of nutrients) and laxative effects, rather than direct toxicity. This same effect was also noted in this study for trialkoxytricarballylate, another non-digestible, non-absorbable oil. The authors note that the results of this study may indicate the threshold or physiological limit for non-digestible, non-absorbable oils is above 10,000 mg/kg-bw/day.

The Verschuren (1989) study evaluated jojoba oil as a replacement for other conventional dietary fats. Young male and female SPF Wistar rats were divided into eight groups in which their diets had varying amounts of jojoba oil supplement (w/w) as follows: controls, 0% jojoba oil (12 animals each, males and females); 2.2% jojoba oil (10 animals each, males and females); 4.5% (10 animals each, males and females); or 9% (12 animals each, males and females). The total fat in the diet was up to 18%, with a mixture of lard and sunflower-seed oil. Over the 4-week *ad libitum* feeding protocol, all animals appeared in good health, and there were no deaths. Dietary jojoba oil supplementation resulted in dose-dependent increases in feces production and growth retardation in both sexes in the 9% dosing group. Analysis of the feces showed a dose-dependent increase in wax esters, fatty alcohols, and free fatty acids. Absolute weights of organs evaluated, except for the spleen in females, were also decreased, particularly in the higher dose groups. In both sexes, the white blood cell count was significantly increased in the highest treatment group; no other hematological parameters changed significantly. Jojoba oil supplementation resulted in increased activities of certain serum enzyme activities and urea concentration, and was associated negatively with creatine and triacylglycerols.

Low-dose and control groups appeared to have fatty infiltration in the liver; however, no major treatment-related changes were observed in the liver or liver enzymes. No adverse histological effects were observed in the hearts of animals sacrificed after 6 days of the feeding protocol. Following the entire feeding protocol (at 5 weeks), examination of the stomach contents showed that stomachs of rats fed jojoba oil were fuller than controls (no additional description provided). In animals fed 9% jojoba oil, effects typically associated with malabsorption of nutrients and diarrhea were noted (e.g., the enterocytes in the jejenum and ileum had massive vacuolization, the lamina propria was distended, and the number of mitoses in the mucosal layer increased).

Weanling CD-1 mice (10 male, 10 female) received 1% or 2% dietary jojoba oil *ad libitum* for 3 weeks in a study by Verbiscar et al. (1980). Results are also presented for weanling (3 weeks) and adult mice (1 week) receiving 10% dietary jojoba oil; however, details on the methods for these two groups are not provided. Decreased weight gain was observed, starting with the 2% group (statistical analysis not provided). Animals receiving 10% oil were reported to have done "poorly," with 30% mortality reported in the weanling mice (no other mortality reported). The authors suggest that the observed deaths were due to malnutrition due to the inability to absorb nutrients, as opposed to a direct toxicological effect.

Oleyl Palmitate

As discussed in the ADME section above, rats were given 2,000 mg/kg-bw-day or 7,500 mg/kg-bw/day oleyl palmitate in the diet for either 4 weeks or 10 days[4] (Hansen and Mead, 1965). Weight gain was decreased in the oleyl palmitate groups, which was attributed by the authors primarily to issues with palatability. In addition, animals in the highest dose group were reported to have oily skin and fur and/or to exhibit diarrhea.

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[4] Other summary documents describe this as 2 weeks; however, according to the publication, rats were giving the standard diet only for the first 4 days of the 2-week period.

Table 9. Available repeated dose oral toxicity studies on rice bran wax, similar waxes, or its constituents

Test Material	Species (Sex[A])	Duration	Doses Tested (mg/kg-bw/day[B])	NOAEL (mg/kg-bw/day[B])	Reference	Publication and Access Information
Carnauba wax	Rat (M, F)	13 weeks	0, 800, 4200, or 8,800 (M); 0, 900, 4600, 10,200 (F)	8,800 (M); 10,200 (F)	Rowland et al., 1982	https://www.ncbi.nlm.nih.gov/pubmed/6890026
Carnauba wax	Rat (M, F)	90 days	0, 15, 150, or 1,500	1,500	Edwards, 1998	Reviewed by EFSA, 2013b, and JECFA, 1993a
Carnauba wax	Dog	28 weeks	25, 75, or 250	250	Parent et al., 1983a	https://www.ncbi.nlm.nih.gov/pubmed/6681797
Candelilla wax and gum base (composition not given)	Rat (F)	8 weeks	Not available	980 mg mixture/kg-bw/day	Harrisson, 1946	Reviewed by EFSA, 2012c
Candelilla wax (1:1 mixture of candelilla wax and a butadiene-styrene polymer)	Rat (M, F)	8 weeks	0, 370 or 1,800	1,800	Harrisson, 1948	Reviewed by EFSA, 2012c
Candelilla wax (1:1 mixture of candelilla wax and a butadiene-styrene polymer)	Rat (M, F)	27 weeks	0, 370 or 1,800	1,800	Harrisson, 1949	Reviewed by EFSA, 2012c

Test Material	Species (Sex[A])	Duration	Doses Tested (mg/kg-bw/day[B])	NOAEL (mg/kg-bw/day[B])	Reference	Publication and Access Information
Candelilla wax (4.1-6.1% in a gum base)	Rat (M, F)	180 days	2,400	2,400	Hodge, 1973	Reviewed by EFSA, 2012c
Candelilla wax (25% in a gum base)	Mouse (M, F)	12-13 months	0, 300, or 1,900	1,900	Hodge, 1973	Reviewed by EFSA, 2012c
Candelilla wax (25% in a gum base)	Rat (M, F)	19 months or 2 years	0, 125, 300, or 750	750	Harrisson, 1953	Reviewed by EFSA, 2012c
Candelilla wax (25% in a gum base)	Dog (M, F)	6 months	0, 60, or 600	600	Harrisson, 1953	Reviewed by EFSA, 2012c
Lanolin fatty acids	Rat (M, F)	90 days	100, 300, or 1,000	1,000	Unnamed, 2013 as provided in REACH Registration for Fatty Acids, Lanolin	Detailed report summary available online; https://echa.europa.eu/registration-dossier/-/registered-dossier/13395/7/6/2
Jojoba wax	Rat (not reported)	30 days	2,100 mg/day	2,100 mg/day	Heise et al., 1982	Publication purchased and reviewed; not available online despite journal being indexed in Medline
Jojoba oil	Rat (M, F)	3 months	2.5, 5, or 10% dietary	Not identified[D]	Stalder et al., 1985[C]	Conference abstract purchased and reviewed; not available online
Jojoba oil	Rat	7 days	10,000, 20,000,	10,000[E]	Hamm, 1984	http://onlinelibrary.wiley.com/doi/10.1111/j.1365-

Test Material	Species (Sex[A])	Duration	Doses Tested (mg/kg-bw/day[B])	NOAEL (mg/kg-bw/day[B])	Reference	Publication and Access Information
			40,000, or 60,000			2621.1984.tb12436.x/abstract
Jojoba oil	Rat	4 weeks	2.2, 4.5, or 9% dietary	Not identified[F]	Vershuren, 1989	https://www.ncbi.nlm.nih.gov/pubmed/?term=PMID%3A+2703192
Jojoba oil	Mouse (M, F)	3 weeks	1 or 2% dietary	Not identified[F]	Verbiscar et al., 1980	https://www.ncbi.nlm.nih.gov/pubmed/?term=PMID%3A+7391402
Oleyl palmitate	Rat (M)	10 days or 4 weeks[G]	7,500	7,500[H]	Hansen and Mead, 1965	http://journals.sagepub.com/doi/abs/10.3181/00379727-120-30581

[A]M, male; F, female

[B]Unless otherwise noted, units are mg test material/kg-bw/day; weight-based equivalents for dietary studies reported.

[C]Appears also to be Nestle Product Technical Assistance—Orbe, Switzerland (n.d.), as cited by EPA (1995).

[D]While no pathological abnormalities were found in the liver, increased transaminase and alkaline phosphatase activities were reported in both sexes. Dose levels at which these effects were observed were not specified.

[E]Observed effects in the higher dose groups are described as secondary physiological effects.

[F]The authors suggest that the observed deaths were due to malnutrition, as opposed to a direct toxicological effect.

[G]Other summary documents describe this as 2 weeks; however, according to the publication, rats were giving the standard diet only for the first 4 days of the 2-week period.

[H]EFSA (2007, 2012c) and JECFA (2006) have estimated this intake to be 40 g/diet, equivalent to 2,000 mg/kg-bw-day (EFSA, 2007; 2012c) or 15,000 mg/kg-bw/day (JECFA, 2006).

Reproductive and Developmental Toxicity

A summary of available repeated exposure studies is provided in Table 10.

Carnauba Wax

Parent et al. (1983b) evaluated the potential reproductive effects of carnauba wax (0, 0.1, 0.3, or 1%) given in the diet of male rats (equivalent to 0, 80, 250, and 810 mg/kg-bw/day) and female rats (equivalent to 0, 90, 270, and 670 mg/kg-bw/day). Following four weeks of the carnauba wax diet, rats were paired and diets continued through mating, gestation, and lactation. F_1 generation rats were randomly selected and given the same diet for an additional 13 weeks. All animals were sacrificed after weaning. The number of pups born (dead or alive) was decreased, though not significantly, for treatment groups compared to controls (228-230 pups compared to 269 pups); no differences were noted in fertility, gestation, viability, or lactation indices. Some significant differences in food consumption were mentioned but concluded to be intermittent. In carnauba wax-treated animals, statistically significant effects included: increased hematocrit (females in 0.1% and 1% groups); increased nitrogen urea levels (males in 1% group); increased chloride levels (males in 0.3% and 1% groups); decreased serum glutamatepyruvate transaminase and free fatty acid levels (males in all treatment groups); and decreased free fatty acids (females in 0.3% and 1% groups). The EFSA ANS Panel determined the NOAEL to be 670 mg/kg-bw/day based on the highest dose given to female rats (EFSA, 2012b).

In addition to the study summarized above, the EFSA ANS Panel (EFSA, 2012b[5]; originally reviewed by JECFA, 1993a) also reviewed an unpublished report by FDRL (1977).[6] In this study, the potential for developmental toxicity of carnauba wax was studied in rats. Carnauba wax (0, 0.1, 0.3, or 1%; equivalent to 0, 50, 150, and 500 mg/kg-bw/day) given in the diet of females for 2 weeks prior to mating and for the duration of gestation did not cause any treatment-related adverse developmental effects on maternal weight, reproductive parameters, or skeletal or soft tissue development of fetuses. Maternal body weight, gross pathology, number of corpora lutea, implantation sites, resorption sites, number of live and dead fetuses, weights of live fetuses, visceral pathology, and skeletal changes were evaluated.

Candelilla Wax

A reproductive toxicity study was conducted by Harrisson (1949, as cited in EFSA, 2012a), which was limited to three male and three female rats in each dose group. Following dietary exposure to 0, 340, or 1,710 mg/kg-bw/day candelilla wax (in a 50/50 mixture with styrene-butadiene polymer) for five months prior to mating, two of the three

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[5] Note that the study, as reviewed in EFSA (2012b), was not made available to the Panel for review at that time.

[6] A thorough search was performed; however, unpublished laboratory reports were not located or accessible for this review.

females were reported to have conceived and produced "normal" litters. No additional information was provided.

Table 10. Available reproductive and developmental toxicity studies on rice bran wax, similar waxes, or its constituents

Test Material	Species (Sex[A])	Study Type/ Duration	Doses Tested (mg/kg-bw/day)	NOAEL (mg/kg-bw/day)	Reference	Publication and Access Information
Carnauba wax	Rat (M, F)	2-Generation Reproductive Toxicity	0, 80, 250, or 810 (M); 0, 90, 270, or 670 (F)	670	Parent et al., 1983b	https://www.ncbi.nlm.nih.gov/pubmed/6681798
Carnauba wax	Rat (F)	Reproductive/ 2 weeks prior to mating and duration of gestation	0, 50, 150, or 500	500	FDRL, 1977	Reviewed by EFSA, 2012b; JECFA, 1993a
Candelilla wax (1:1 mixture of candelilla wax and a butadiene-styrene polymer)	Rat (M, F)	5 months prior to mating	0, 340, or 1,710	1,710[A] (reproductive)	Harrisson, 1949	Reviewed by EFSA, 2012c

[A]Small sample size and limited parameters measured (two of three females of each dose group conceived and produced normal litters)

Genotoxicity/Mutagenicity

A summary of available mutagenicity and genotoxicity studies is provided in Table 11.

Rice Bran Wax

In a recent GLP-compliant study, a rice bran wax product (Licocare RBW 106) was found to be non-mutagenic *in vitro* (Unnamed, 2015[7]). The rice bran wax was tested according to OECD Guideline 471 (Bacterial Reverse Mutation Assay) in *S. typhimurium* strains TA1535, TA1537, TA98, and TA100 and *E. coli* WP2uvrA with and without metabolic activation with rat liver S9-mix induced by Aroclor 1254. Following a preliminary test, the doses selected for the main study were 17, 52, 164, 512, or

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[7] As cited in REACH Registration for Polar Modified Rice Bran Wax; full study summary available online at https://echa.europa.eu/registration-dossier/-/registered-dossier/18316/7/7/2. ***Study information from this dossier is publicly available but may be subject to copyright laws; the authors of this GRAS assessment are in the process of attempting to obtain permission for its use.***

1,600 µg/plate[8]; positive control substances included methylmethanesulfonate, 2-nitrofluorene, 4-nitroquinoline-N-oxide, sodium azide, and 2-aminoanthracene. Exposures were conducted in triplicate for 48 hours. Cytotoxicity was observed in all strains, except TA1535, TA1537, and TA98 in the presence of S9-mix and WP2uvrA with and without metabolic activation. Rice bran wax was negative over the entire dose range in *S. typhimurium* and *E. coli* reverse mutation assays. No significant dose-related increases in the number of revertants were observed, and all control values were within laboratory historical control ranges.

Rice bran wax ("Rice Wax") did not show any mutagenic effect up to concentrations of 5,000 µg/mL in a histidine-dependent auxotroph of *Salmonella typhimurium* strain TA100 (Environmental Technical Laboratory, Ltd., 1998, as cited in Andersen, 2006). No increases in revertant colony numbers compared to control counts were observed with or without metabolic activation (S9 mixture); positive and negative controls were used in this study.

Carnauba Wax

Carnauba wax (0.031, 0.063, 0.125 0.25, or 0.5 mg/mL of 10% soybean oil) was evaluated in *in vitro* chromosomal aberration tests using human lymphocytes with and without S-9 metabolic activation (Edwards, 1996; 1997, as cited by EFSA, 2012b). No statistically significant increases in aberrant metaphases were reported in the first chromosomal aberration test (without metabolic activation for 3 hours) with or without gaps; however, there was a statistically significant linear trend for both the untreated control and treatment groups (without gaps). No statistically significant increases in aberrant metaphases or linear trend were observed in the second test, with and without metabolic activation. However, due to a low response elicited by the positive control, cyclophosphamide, in this study (with metabolic activation), a third test was conducted using the same conditions. In this study, statistically significant increases in aberrant metaphases were measured for the positive control while no statistically significant effects were noted for the test article. The Panel concluded that "carnauba wax is not regarded to cause structural chromosomal aberrations *in vitro* under the reported experimental conditions."

EFSA (2012a,b; as well as SCF, 2001; JEFCA, 1993a; and Bassan et al., 2012) reviewed several unpublished laboratory reports in its assessment. The EFSA CONTAM Panel determined there is no concern for genotoxicity for carnauba wax based on the available data and the lack of structural alerts (EFSA, 2012a). In addition, the ANS Panel concluded in its scientific opinion re-evaluating the safety of carnauba wax that "there is no concern for genotoxicity for carnauba wax," although they do note that there are limitations in testing insoluble compounds *in vitro* (EFSA, 2012b). The study summaries provided in EFSA (2012a,b) on carnauba wax, as well as for other waxes, are described below. Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1993a) also

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[8] Testing at 5,000 µg/plate was not feasible due to precipitation of the test article at this concentration.

reviewed studies evaluating the mutagenicity of carnauba wax; while complete study information was not available, the EFSA ANS Panel also considered these as part of its evaluation (EFSA, 2012b). The available information on these studies is summarized in Table 11 below.

Candelilla Wax

Candelilla wax (CAS 8006-44-8) was negative in all *S. typhimurium* strains tested (TA98, TA100, TA1535, TA1537, and TA1538) up to 10 mg/plate using an Ames mutagenicity assay with and without metabolic activation (Prival et al., 1991).

In addition, EFSA (2012c) summarized two studies with candelilla wax also previously summarized by JECFA (1993b); candelilla wax was found to be negative for reverse mutation and gene conversion. The available information on this study is summarized in Table 11 below.

Beeswax

Beeswax (yellow domestic; CAS 8012-89-3) was negative in all *S. typhimurium* strains tested (TA98, TA100, TA1535, TA1537, and TA1538) up to 10 mg/plate using an Ames mutagenicity assay with and without metabolic activation (Prival et al., 1991).

In addition, JECFA (2006) summarized a study with white beeswax reported by the Federation of American Societies for Experimental Biology (1975); beeswax was found to be negative for reverse mutation in *S. typhimurium* and *S. cerevisiae* D4. The available information on this study is summarized in Table 11 below.

Lanolin Wax

Three recent GLP-compliant studies evaluating the mutagenic potential of lanolin fatty acids have been reported as part of the REACH Registration for Fatty Acids, Lanolin.[9]

In the first, lanolin fatty acids were tested according to OECD Guideline 471 (Bacterial Reverse Mutation Assay) in *S. typhimurium* strains TA1535, TA1537, TA98, and TA100 and *E. coli* WP2uvrA with and without metabolic activation with phenobarbitone/ betanaphthoflavone (Unnamed, 2010a). Following a preliminary test, the doses selected for the main study were 50, 150, 500, 1,500, or 5,000 µg/plate; positive control substances included N-ethyl-N-nitro-N-nitrosoguanidine, 9-aminoacridine, 4-nitroquinoline-N-oxide, benzo(a)pyrene, and 2-aminoanthracene. Exposures were conducted in triplicate for 48 hours. Cytotoxicity was observed in all strains, except

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[9] As cited in REACH Registration for Fatty Acids, Lanolin; full study summary available online at https://echa.europa.eu/registration-dossier/-/registered-dossier/13395/7/7/2/?documentUUID=d72c357f-4328-4df0-9809-57d83c1adaae. ***Study information from this dossier is publicly available but may be subject to copyright laws; the authors of this GRAS assessment are in the process of attempting to obtain permission for its use.***

TA1535, TA1537, and TA98 in the presence of S9-mix and WP2uvrA with and without metabolic activation. No significant increases in the number of revertants were observed; lanolin fatty acids were negative over the entire dose range in *S. typhimurium* and *E. coli* reverse mutation assays with and without metabolic activation.

In an *in vitro* mammalian chromosome aberration test, lanolin fatty acids were determined to be non-clastogenic to human lymphocyte (Unnamed, 2010b). This study was carried out according to OECD Guideline 473 with and without metabolic activation with phenobarbitone/betanaphthoflavone. Three treatment conditions were used for the study: (1) 4-hour exposure in the absence of metabolic activation (S9) with a 20-hour expression period; (2) 4-hour exposure in the presence of an induced rat liver homogenate metabolizing system (S9), at a 2% final concentration, with cell harvest after a 20-hour expression period; and (3) a 24-hour continuous exposure in the absence of metabolic activation. Following a preliminary test, the concentrations selected for the chromosome aberration test were 0, 78.13, 156.25, 312.5, 625, 1,250, or 2,500 µg/mL for the 4-hour exposures, and 0, 78.13, 156.25, 312.5, 625, or 1,250 µg/mL for the 24-hour exposure. Positive control substances included mitomycin C and cyclophosphamide and were within historical ranges. No statistically significant increases in frequency of cells with aberrations or polyploid cells were observed with the test material at any concentration, with or without metabolic activation.

In a companion study, lanolin fatty acids were evaluated according to OECD Guideline 476 for gene mutation on the thymidine kinase, TK +/-, locus of the L5178Y mouse lymphoma cell line with and without metabolic activation with phenobarbitone/ betanaphthoflavone (Unnamed, 2010c). Positive control substances included ethylmethanesulphonate and cyclophosphamide and were within historical ranges. As in the study above, three treatment conditions were used for the study: (1) 4-hour exposure in the absence of metabolic activation (concentrations 18.75–600 µg/mL), (2) 4-hour exposure in the presence of metabolic activation (concentrations 75–400 µg/mL), and (3) a 24-hour continuous exposure (concentrations 20–320 µg/mL). In the main experiment, L5178Y TK +/- 3.7.2c mouse lymphoma cells (heterozygous at the thymidine kinase locus) were treated with the test material at eight dose levels; no statistically significant dose-related increases in mutant frequency occurred with the test material at any concentration, with or without metabolic activation.

Jojoba Wax

Jojoba esters were negative for mutagenicity as 30% in a mixture of isopropyl jojobate, jojoba alcohol, jojoba esters, and tocopherol (Celsis Laboratory Group, 1999). This Ames assay was conducted in *S. typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538 and *E. coli* WP2 with and without S9 metabolic activation from rat liver. Positive control substances included 2-aminoanthracine, 2-nitrofluorene, sodium azide, 9-aminoacridene, and methyl methone sulfate. Exposures to 1, 3, 10, 30, or 100 mg/plate were conducted in triplicate for 48–72 hours. The test material was concluded not to be mutagenic by the authors in this study.

Table 11. Available mutagenicity and genotoxicity studies on rice bran wax, similar waxes, or its constituents

Test Material	Endpoint	Test System	Doses Tested	Results	Reference	Publication and Access Information
Licocare RBW 106	Reverse mutation	*S. typhimurium* TA1535, TA1537, TA908, TA100; *E. coli* WP2 uvr A	17, 52, 164, 512 or 1,600 µg/plate	Negative	Unnamed, 2015, as provided in REACH Registration for Polar Modified Rice Bran Wax	Detailed report summary available online; https://echa.europa.eu/registration-dossier/-/registered-dossier/18316/7/7/2
Rice bran wax	Reverse mutation	*S. typhimurium* TA100	Range of concentrations up to 5,000 µg/ml	Negative	Environmental Technical Laboratory, Ltd., 1998	As cited in Andersen, 2006
Carnauba wax	*In vitro* chromosomal aberration	Human lymphocytes	0.031, 0.063, 0.125 0.25, or 0.5 mg/ml	Negative[A]	Edwards, 1996; 1997	Reviewed and summarized cited by EFSA, 2012b
Carnauba wax	Reverse mutation[a]	*S. typhimurium* TA1537, TA1538, TA98	3.3-1000 µg in plate tests	Negative	Mortelmans and Griffin, 1981	Reviewed by JECFA, 1993a, and further summarized by EFSA, 2012b
Carnauba wax	Reverse mutation[a]	*S. typhimurium* TA1537, TA1538, TA98	0.01-0.5% in suspension tests	Negative	Mortelmans and Griffin, 1981	
Carnauba wax	Reverse mutation[a]	*S. typhimurium* TA1537, TA1538, TA98	0.1-2.5% in suspension tests	Negative	Mortelmans and Griffin, 1981	
Carnauba wax	Reverse Mutation[b]	*S. typhimurium* TA1535, TA1537, TA1538	0.01% in plate tests	Negative	Litton Bionetics, Inc., 1975	

Test Material	Endpoint	Test System	Doses Tested	Results	Reference	Publication and Access Information
Carnauba wax	Reverse Mutation[b]	*S. typhimurium* TA1535, TA1537, TA1538	0.00 5or 0.01% in suspension tests	Inconsistent changes[c]	Litton Bionetics, Inc., 1975	
Carnauba wax	Gene Conversion[b]	*S. cerevisiae* D4	0.3 or 1.75% in suspension tests	Negative	Litton Bionetics, Inc., 1975	
Candelilla wax	Reverse mutation[d]	*S. typhimurium* TA1535, TA1537, TA1538	1.25, 2.5, or 5 (units not given)	Negative	Brusick, 1976	Reviewed by JECFA, 1993b and further summarized by EFSA, 2012c
Candelilla wax	Gene conversion[d]	*S. cerevisiae* D4	1.25, 2.5, or 5 (units not given)	Negative		
Candelilla wax	Reverse mutation[e]	*S. typhimurium* TA1535, TA1537, TA1538, TA98, TA100; *E. coli* WP2	10-10,000 µg/plate	Negative	Mortelmans and Eckford, 1979	Reviewed by JECFA, 1993b and further summarized by EFSA, 2012c

Test Material	Endpoint	Test System	Doses Tested	Results	Reference	Publication and Access Information
Candelilla wax	Reverse mutation	*S. typhimurium* TA98, TA100, TA1535, TA1537 and TA1538	Up to 10mg/plate	Negative	Prival et al. 1991	https://www.ncbi.nlm.nih.gov/pubmed/1870621
Beeswax	Reverse mutation	*S. typhimurium* TA98, TA100, TA1535, TA1537 and TA1538	Up to 10mg/plate	Negative		
Beeswax	Reverse mutation[d]	*S. typhimurium* TA1535, TA1537, TA1538; *S. cerevisiae* D4	0.5 or 1 mg/plate	Negative	Federation of American Societies for Experimental Biology, 1975	Reviewed by JECFA, 2006
Lanolin fatty acids	Reverse mutation	*S. typhimurium* TA1535, TA1537, TA98, TA100; *E. coli* WP2	50, 150, 500, 1,500, or 5,000 µg/plate	Negative	Unnamed, 2010a, as provided in REACH Registration for Fatty Acids, Lanolin	Detailed report summary available online; https://echa.europa.eu/registration-dossier/-/registered-dossier/13395/7/7/2/?documentUUID=d72c357f-4328-4df0-9809-57d83c1adaae

Test Material	Endpoint	Test System	Doses Tested	Results	Reference	Publication and Access Information
Lanolin fatty acids	Chromosomal aberration	Human lymphocytes	0, 78.13, 156.25, 312.5, 625, 1,250, or 2,500 µg/mL	Non-clastogenic	Unnamed, 2010b as provided in REACH Registration for Fatty Acids, Lanolin	Detailed report summary available online; https://echa.europa.eu/registration-dossier/-/registered-dossier/13395/7/7/2/?documentUUID=9e9d3f31-321d-4f32-886c-5a3b174ef573
Lanolin fatty acids	Gene mutation	Mouse lymphoma cells	18.75–400 µg/mL	Negative	Unnamed, 2010c, as provided in REACH Registration for Fatty Acids, Lanolin	Detailed report summary available online; https://echa.europa.eu/registration-dossier/-/registered-dossier/13395/7/7/2
Mixture of isopropyl jojobate, jojoba alcohol, jojoba esters, and tocopherol (jojoba esters 30 wt%)	Reverse mutation	*S. typhimurium* TA1538, TA1535, TA1537, TA98, TA100; *E. coli* WP2	1, 3, 10, 30, or 100 mg/plate	Negative	Celsis Laboratory Group, 1999	Obtained from CIR and reviewed[f]

Note: Study information with carnauba wax is adapted from EFSA (2012b).[a] The Ames/Salmonella assays in the presence and absence of an Aroclor 1254-stimulated, rat-liver homogenate metabolic activation system, were used in this study.[b] A series of *in vitro* microbial assays with and without metabolic activation were used. In the activation assays, the tissue homogenate of liver, lung, and testes were prepared from mouse, rat, or monkey.

[c] The results from non-activation suspension tests were negative. The results from activation suspension tests showed scattered increased mutation responses in the presence of rat-liver or testes homogenate with strain TA1537, and in the presence of monkey-lung homogenate with TA1538.

[d] Assays carried out with and without the S9 fraction of rat, mouse, and monkey liver.[e] Assays carried out with and without the S9 fraction of rat liver.

[f] A copy of this study can be provided by submitter, if desired.

Carcinogenicity

In its discussion of carcinogenic potential, EFSA noted that, in the candelilla wax study conducted by Harrisson (1953, as cited in EFSA, 2012c, and described above in the repeated-dose toxicity section), no histological changes were observed up to the highest dose tested (750 mg/kg-bw/day) for 19 months or 2 years.

Allergy

There are some reports in the literature of allergic responses to rice. However, rice bran wax and rice are two different foods given that rice bran wax contains little to no protein (<0.10g/100g as reported) and that waxes, oils, and other lipids are considered to have chemical structures that are nonallergenic. Therefore, rice bran wax is not likely to pose an allergenic risk due to its vanishingly small protein content. In its report, the CIR Panel provides a review of available animal and human data regarding the potential for sensitization and allergic reaction to rice (*Oryza sativa*) and its derived ingredients, including rice bran wax (Andersen, 2006). While tests in guinea pigs and rabbits were negative for dermal sensitization, the Expert Panel noted that some isolated cases of allergy to rice or its derivatives have been reported. Such reports include contact urticaria (raw rice), Quincke's edema (rice cereal), erythema of the hands, edema of the eyelids, and cough (raw rice); it is worth noting that in some cases, sensitivity to grains other than rice were also confirmed. Burlando and Cornara (2014) also reviewed cases including reactions such as rhinitis, asthma, pollinosis, rhinoconjunctivitis, and dermatitis (raw rice, boiled rice, rice pollen, rice flour). Following its review, the CIR Panel concluded that rice and its derivatives were not allergens of concern notwithstanding a few reported instances of hypersensitivity to rice (Andersen, 2006). Similarly, while Chowdury (2002) reports one case of contact dermatitis in reaction to carnauba wax, the EFSA CONTAM Panel (2012a) concluded it is not likely to be a "significant sensitizer." In addition, the EFSA ANS Panel (2012b) reported that no information on allergic potential following exposure via the oral route was identified for carnauba wax.

Other Safety Concerns

Excessive Wax Intake

As with any wax product, general warnings exist indicating that excessive intake of wax, e.g., candles or crayons, could result in GI obstruction (NLM, 2016). An extensive search for available data regarding intake levels that produce GI obstruction or injury did not identify any such information. In fact, personal communication (Brock, 2016) with the Principal Toxicologist for the Art and Creative Materials Institute, Inc. (https://acmiart.org/), which certifies art materials according to ASTM D 4236 and the U.S. Labeling of Hazardous Art Materials Act (LHAMA), confirmed that their safety evaluation of crayons does not consider GI obstruction to be of concern for human exposure as no reliable exposure data have indicated that such concern is warranted. Nevertheless, the potential that an individual may consume multiple rice bran wax-containing bars in a day or over consecutive days was considered in this safety assessment.

Comparable granola, fiber, and cereal-type bars have a typical weight of 37–40 g (e.g., Kashi®, Nutri-Grain®, and Fiber One™ bars); therefore, J.M. Smucker intends for their bar-form product to be similar, weighing 40 g or less. At the 3% inclusion rate, a person would have to consume more than four bars to ingest the same amount of wax in one standard 5-g crayon (the amount of rice bran wax in four bars would be 4.8 g). For a 60-kg adult, consuming four bars would result in an exposure of 80 mg/kg-bw—more than 62-fold lower than the highest dose tested in most of the acute oral toxicity studies identified (5,000 mg/kg-bw). Using a range of 14–20 kg estimated body weight for children, consuming four bars would result in an exposure of 342–240 mg/kg-bw, or more than 14- to 20-fold lower than the highest acute oral dose tested of 5,000 mg/kg-bw.

Available short-term toxicity studies with very high exposures to the monoesters from jojoba oil also provide perspective regarding excess wax intake from the rice bran wax in the bar. The results of Hamm (1984) suggest that there may be a physiological limit for these types of waxes and oils between 10,000 and 20,000 mg/kg-bw/day. In this study, dietary exposure to 20,000, 40,000, or 60,000 mg/kg-bw/day for 4–7 days resulted in clinical changes (e.g., weakness), diarrhea, and 10% mortality; these adverse effects were attributed to metabolic disturbances related to nutrient malabsorption (due to the presence of the wax in the GI system) and not direct toxicity of the jojoba (see Repeated Exposure Toxicity section for additional details). None of the observed effects were seen in the 10,000-mg/kg-bw/day group, and no incidences of GI obstruction were reported for any group. In this and several other higher dose studies with jojoba wax and oleyl palmitate, leakage of oil and/or diarrhea as a consequence of the oil/wax passing through the digestive system and acting as a lubricant were reported. This same effect has also been observed in a human population consuming *Lepidocybium flavobrunneum*, or "butterfish," a fish containing 23% wax esters, according to Berman et al. (1981). In this study, the wax esters in the meat of the fish act as a lubricant, leading to frequent stools in this population; the authors note that high intake of this fish is otherwise "harmless."

Even at very high intake levels of comparable monoesters in animal models, physical obstruction of the GI tract has not been observed. In fact, only at doses above 10,000 mg/kg-bw/day for up to a week were physiological effects observed, such as diarrhea, which were related to the presence of intact wax in the digestive system (Hamm, 1984). In addition, an individual would need to consume more than four bar products containing rice bran wax at 3% to ingest the same amount of wax as contained in a single crayon, which is not sufficient to lead to an obstructive effect. Because the intended use of rice bran wax is solely in peanut butter used in bar products, and results in bar-form products similar to granola and nutritional energy bars, it is not expected to result in consumption amounts that would cause such an obstructive effect.

Minor Components of Rice Bran Wax

As shown in Table 7, the majority (87%–98%) of the rice bran wax components are long-chain aliphatic monoesters. The remaining components of the rice bran wax product consist of free long-chain fatty alcohols, free long-chain fatty acids, triglycerides from rice bran oil. In addition, as previously discussed, when limited hydrolysis of wax esters

occurs, the corresponding long-chain fatty acids and alcohols may be available for cellular uptake. Therefore, consideration has been given to the presence of these constituents with regard to safety.

Rice bran oil has a long history of use in human consumption as a cooking oil in Asian cultures (Andersen, 2006). In addition, Andersen (2006) summarized the available safety data on rice bran oil, which included several acute oral toxicity studies, a genotoxicity study, and a multi-generation reproductive toxicity study in rats, and found it to be safe for consumption. Triglycerides are common components of animal and vegetable fats, and have been determined to be GRAS for human consumption in food (GRN 355, Eicosapentaenoic acid (EPA)-rich triglyceride oil from *Yarrowia lipolytica*; GRN 200, Tailored triglycerides enriched in omega-3 fatty acids from fish oil) and in cooking oils (GRN 217, Tailored triglycerides containing approximately 12 percent medium-chain fatty acids).

In addition to demonstrating the safety of the fatty alcohols and acids by way of their higher concentrations in the other waxes already evaluated here (carnauba wax, candelilla wax, and beeswax) and safety studies on lanolin fatty acids, extensive toxicological testing has been published in recent years on these components isolated from beeswax. D-002 and D-003 correspond to mixtures of very long-chain aliphatic alcohols and acids isolated from beeswax, respectively, and have been evaluated for their therapeutic effect on a number of health issues. Extensive preclinical tests have been performed on these mixtures, all demonstrating a lack of toxic potential. D-002 was reported to have no treatment-related toxicity in a one-year oral study in dogs, a developmental toxicity study in rats and rabbits, and oral subacute, subchronic, and chronic studies in rats (Alemán et al., 2001; Rodríquez et al., 1998; Rodeiro et al., 1998). D-003 lacked treatment-related effects in the following: toxicity in an acute oral study in rats, subchronic studies in rats and dogs, chronic studies in rats and mice, perinatal/postnatal study in rats, and reproductive and developmental studies in rats and rabbits; genotoxicity in rats, carcinogenic potential in rats and mice; and oestrogenic potential in rats (Gámez et al., 2000, 2001, 2002, 2004, 2007; Noa et al., 2007, 2008; Rodríquez et al., 2004, 2006). In addition, D-003 has been evaluated in a number of human clinical trials and found to be well-tolerated at doses up to 20 mg/day (Arruzazabala et al., 2008).

Finally, were a small amount of rice bran wax to be absorbed and metabolized to some degree into ethyl alcohol (ethanol), exposure to ethanol would be low in contrast to exposure from the daily diet. Consumers are routinely exposed to incidental amounts of ethanol from consumption of food items such as orange juice, soft drinks, and breads. GRN 151 (FDA, 2004) received a "no questions letter" for the use of ethyl alcohol as a preservative in the filling used in shelf-stable croissants at a concentration of 3,000 ppm. In addition, GRN 151 reported ethanol levels in ripening fruit and fruit juice ranging from 117 to 1,900 ppm, and Logan and Distefano (1998) reported levels of ethanol in various baked goods ranging from 0 to 1.66 %. It is reasonable to conclude that any absorption of rice bran wax via the oral route of exposure would be negligible and does not present any safety concern related to ethanol exposure.

Basis for the GRAS Determination

Introduction

The regulatory framework for determining whether a substance can be considered GRAS in accordance with section 201(s) (21 U.S.C. § 321(s)) of FD&C Act (21 U.S.C. § 301 et. Seq.) ("the Act"), is set forth at 21 CFR 170.30, which states:

> General recognition of safety may be based only on the view of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food.
>
> General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies, which may be corroborated by unpublished studies and other data and information.

These criteria are applied in the analysis below to determine whether the use of rice bran wax for use in food for human consumption is GRAS based upon scientific procedures. All data used in this GRAS determination are publicly available and generally known, and therefore meet the "general recognition" standard under the FD&C Act.

Safety Determination

The subject of this GRAS determination is the use of rice bran wax as a texturizer in peanut butter used in granola-based bar products that include cereal bars, breakfast bars, cookies and biscuits, nutritional bars, and energy snack bars with similar form and texture. There is common knowledge of a long history of human consumption of rice and rice bran wax.

The safety section describes preclinical safety studies of rice bran wax and other compositionally similar waxes and constituents of these waxes. Rice bran wax consists primarily of high-molecular-weight monoesters ranging from C48 to C64 (87%–98%; Appendix A); the remaining components of the rice bran wax product consist of free long-chain fatty alcohols, free long-chain fatty acids, and triglycerides. While some toxicological data are available for rice bran wax, information on its main constituents and other plant-based waxes with similar chemical structures, and thus similar potential for absorption, was also evaluated as part of the GRAS assessment. Studies conducted on

carnauba wax, candelilla wax, beeswax, lanolin wax, and jojoba wax were identified and deemed suitable for inclusion in the safety assessment of rice bran wax and considered by the Expert Panel in its evaluation.

Taken together, the available data presented here allow for sufficient evaluation of the safety of rice bran wax, based on the following:

1. Up to 98% of rice bran wax consists of long-chain aliphatic monoesters. Jojoba wax also consists almost entirely of long-chain aliphatic monoesters (97%). Therefore, studies evaluating the safety of jojoba wax provide data specific to monoesters and can be bridged to provide insight on the safety of the respective monoester fraction of rice bran wax. In addition, although present to a lesser extent, carnauba wax, candelilla wax, beeswax, and lanolin wax also have a large fraction of these monoesters and so provide additional safety data for this fraction.

2. The monoesters in rice bran and other waxes are generally not absorbed; when absorption does occur, the esters are hydrolyzed into their corresponding fatty acids and fatty alcohols. In addition, the rice bran wax is estimated to contain up to 13% free fatty acids and free fatty alcohols. The safety of these minor components and potential by-products can be demonstrated by extensive preclinical studies conducted on D-002 and D-003, mixtures of very long-chain aliphatic alcohols and acids isolated from beeswax, respectively. Studies conducted with lanolin fatty acids, as presented in this assessment, also support these findings. Finally, free fatty acids and alcohols are present in one or more of the waxes evaluated in this assessment at higher concentrations, thus providing additional safety information on these constituents.

3. The other minor components of the rice bran wax product can include up to 13% triglycerides from rice bran oil. Rice bran oil has a long history of use in human consumption as a cooking oil in Asian cultures (Andersen, 2006). In addition, Andersen (2006) summarized the available safety data on rice bran oil, which included several acute oral toxicity studies, a genotoxicity study, and a multi-generation reproductive toxicity study in rats, and concluded it to be safe for consumption. Triglycerides are common components of animal and vegetable fats, and have been determined to be GRAS for human consumption in food (GRN 355, Eicosapentaenoic acid (EPA)-rich triglyceride oil from Yarrowia lipolytica; GRN 200, Tailored triglycerides enriched in omega-3 fatty acids from fish oil) and in cooking oils (GRN 217, Tailored triglycerides containing approximately 12 percent medium-chain fatty acids).

4. The available data on carnauba wax, candelilla wax, beeswax, lanolin wax, and jojoba wax show a lack of potential for toxicity for any of them. Available studies demonstrate that the potential for toxicity of a wax is inversely associated with its chain length and molecular weight. As demonstrated by Smith et al. (1996), the incidence and severity of adverse effects associated with wax exposure decrease as molecular weight of waxes increase. Of the waxes evaluated in the present GRAS assessment, rice bran wax, with its large monoester fraction, has the

longest chain length distribution, which suggests that it would be the least bioavailable and therefore would have the lowest potential for toxicity. Thus, the lack of toxicity observed in safety studies conducted with carnauba wax, candelilla wax, beeswax, lanolin wax, or jojoba wax can be confidently extended to the more inert rice bran wax.

5. The above approaches relying on information from chemically similar waxes sufficiently address the safety of rice bran wax and its components: monoesters, free long-chain fatty alcohols, free long-chain fatty acids, and triglycerides from rice bran oil. Further supporting the safety of rice bran wax is that the other waxes considered in this assessment contain additional constituents that are not relevant to rice bran wax. These impurities can impart toxicities of their own (or are of unknown toxicity), increasing any potential of toxicity of these more complex waxes relative to rice bran wax or jojoba wax. These waxes provide conservative comparisons to rice bran wax, which is considered purer and consists almost exclusively of esters or their fatty acid and alcohol components, providing further support for the safety of its intended use.

Taken together, the available published and unpublished safety data suggest that rice bran wax has little potential for toxicity when used in foods for human consumption. There is also nothing in the chemical structure of rice bran wax, available genotoxicity data, or regulatory reviews of rice bran wax or related waxes to suggest a carcinogenic potential.

Diarrhea was observed in three studies conducted with very high doses (>10,000 mg/kg-bw/day) of monoesters (Hamm, 1984; Hansen and Mead, 1965; Verschuren, 1989). In addition, as with any wax product, general warnings exist to indicate that excessive intake of wax (e.g., candles or crayons), could result in GI obstruction (NLM, 2016). While this potential risk is a logical concern given the nature of waxes, an extensive search for available data regarding intake levels that produced this outcome did not identify any such information. Nevertheless, the potential that an individual may consume multiple rice bran wax–containing bars in a day or over consecutive days was considered in this safety assessment. Even at very high intake levels of comparable monoesters in animal models, physical obstruction of the GI tract has not been observed. In fact, only at doses above 10,000 mg/kg-bw/day for up to a week were physiological effects observed (diarrhea, nutrient malabsorption, and weakness), which were related to the presence of intact wax in the digestive system. In addition, an individual would need to consume more than four bar products containing rice bran wax at 3% to ingest the same amount of wax as in one crayon, and over eight bars to ingest the same amount of wax as in two crayons. Because the intended use of rice bran wax is solely in peanut butter used in granola-based bar products that include cereal bars, breakfast bars, cookies and biscuits, nutritional bars, and energy snack bars with similar form and texture, it is not expected to result in consumption amounts that would cause such an obstructive effect or lead to diarrhea.

Rice is not listed among the major food allergens by FDA as noted by its absence in the *Food Allergen Labeling and Consumer Protection Act of 2004.* Given that rice bran wax

contains little to no protein, the component responsible for imparting allergic potential, rice bran wax is not likely to pose an allergenic risk.

Subchronic toxicity and/or reproductive/developmental toxicity studies were identified for carnauba wax, candelilla wax, and jojoba oil. In each of the studies, the NOAEL was the highest dose level administered and ranged from 250 to 10,800 mg/kg/day, the highest of which was a concentration of 10% carnauba wax (equivalent to 8,800 and 10,200 mg/kg-bw/day in males and females, respectively) administered in the diet of rats for 90 days. Chronic studies with candelilla wax were also identified, and the NOAELs in these studies were also the highest dose tested, up to 2,400 mg/kg-bw-day. An overview of these studies is presented in Table 12.

The history of use in foods of other vegetable-based waxes, in particular carnauba wax, provides additional information relevant to the safety assessment of rice bran wax. Hargrove et al. (2004) reviewed the intake of wax worldwide and noted that the intake in some populations can average as high as 4 g/day. Rice bran wax has been approved for use in various food applications in the US. It is permitted as a direct human food additive (21 CFR §172.890) when used in candy (maximum 50 ppm as a coating), fresh fruits and fresh vegetables (maximum 50 ppm as a coating), and chewing gum (maximum 2.5% in gum when used as a plasticizing material in chewing gum base, 21CFR §172.615). It is also permitted as an indirect food additive as Type VIII in table 1of 176.170(c), at a maximum level of 1.0 percent by weight of the polymer. Carnauba wax is similarly permitted as a GRAS direct human food ingredient, with no limitation other than cGMP, in baked goods and baking mixes, chewing gum, confections and frostings, fresh fruits and fruit juices, gravies and sauces, processed fruits and fruit juices, and soft candy (21 CFR § 184.1978). The FDA has listed carnauba wax, beeswax, and candelilla wax as GRAS as a direct food substances for human consumption with no specific limitation other than good manufacturing practice (21 CFR § 184.1978; 1973; and 1976, respectively). Candelilla wax is also considered GRAS by the Flavor & Extract Manufacturer's Association (GRAS No. 3479; Oser and Ford, 1977). From the data presented above, it is reasonable to conclude that the use of rice bran wax, which is structurally a much less complex wax compared to the other waxes evaluated here, could be similarly approved.

As described in the Dietary Exposure section, FDA has conducted an intake assessment of rice bran wax using 2-day survey data from NHANES (FDA, 2017). However, because the available information suggested that these 2-day surveys significantly overestimated the intake of rice bran wax, FDA conducted a second assessment using data from a 10- to 14-day survey to more accurately reflect intake frequency. Notably, the analysis by FDA included any and all bars, and as such, is very conservative, and results in an overestimate of the actual consumption. FDA reported an approximately 10-fold lower average daily intake for the population 2+ years using these data; the EDI for the 2- to 5-year-old age group was found to be approximately 5-fold lower than the FDA calculations based on 2-day data. The lower EDIs prepared by FDA using the NET-NID 14-day data reflect a more accurate estimation of the long-term consumption of the bar products intended to contain the rice bran wax product, compared to the 2-day data.

Survey duration has been shown to affect the estimated percent of consumers, as well as the classification of individuals as high or low consumers of a given food (Lambe and

Table 12. Long-term oral toxicity studies, adapted from Tables 9 and 10

Wax	Species (Sex)	Duration	NOAEL and Highest Dose Tested (mg/kg-bw/day)	Reference
Carnauba	Rat (M, F)	13 weeks	8,800 (M); 10,200 (F)	Rowland et al., 1982; https://www.ncbi.nlm.nih.gov/pubmed/6890026
Carnauba	Rat (M, F)	90 days	1,500	Edwards, 1998, as cited in EFSA, 2012b
Carnauba	Dog	28 weeks	250	Parent et al., 1983a; https://www.ncbi.nlm.nih.gov/pubmed/6681797
Candelilla	Rat (M, F)	27 weeks	1,800	Harrisson, 1949, as cited in EFSA, 2012c
Candelilla	Rat (M, F)	180 days	2,400	Hodge, 1973, as cited in EFSA, 2012c
Candelilla	Mouse (M, F)	12-13 months	1,900	Hodge, 1973, as cited in EFSA, 2012c
Candelilla	Rat (M, F)	19 months or 2 years	750	Harrisson, 1953, as cited in EFSA, 2012c
Candelilla	Dog (M, F)	6 months	600	Harrisson, 1953, as cited in EFSA, 2012c
Carnauba	Rat (M, F)	2-Generations	670	Parent et al., 1983b; https://www.ncbi.nlm.nih.gov/pubmed/6681798
Carnauba wax	Rat (F)	2 weeks prior to mating and duration of gestation	500	FDRL, 1977, as cited in EFSA, 2012b
Candelilla wax	Rat (M, F)	5 months prior to mating	1,710	Harrisson, 1949, as cited in EFSA, 2012c

Kearney, 1999; Lambe et al., 2000). As reviewed by Lambe and colleagues (1999, 2000), shorter surveys are associated with misclassification of individuals, inaccurate correlation coefficients, reduced power, and overestimation of percentage of high and low intakes. These effects of survey duration are thought to be due to the within-person and day-to-day variation for a given self-selected diet. The percentage of respondents who consume a food increases as the survey duration increases; the longer duration begins to incorporate days with no consumption, thus decreasing the mean intakes among consumers over time. This phenomenon has been demonstrated in studies, such as in Lambe and Kearney (1999), which showed that 7-day consumer intakes were ~33% of 1-day intakes for the same foods (apples, carbonated beverages). Similarly, in the study by Lambe et al. (2000), mean consumer intakes based on 3- and 14-day survey data were 53% and 32% of the day 1 estimates, respectively. The results of this study also demonstrate that ~50% of the slopes were significantly different from zero, suggesting that intakes were not the same for all survey time periods, with a slight downward trend as survey duration increased.

While no ADI was established, EFSA (2007) estimated the average intake of beeswax for an adult (60 kg) to be ~22 mg/kg-bw/day. The Panel found the margins of exposure (MOEs) of 10–50×, based on animal studies, to be adequate. Similarly, EFSA (2012c) did not establish an ADI for candelilla wax but concluded that the margins of exposure of 74–1,600×, based on their intake assessment and animal studies, was sufficient. Of note, EFSA (2012b) conducted an exposure assessment as part of their evaluation of carnauba wax. Based on the highest exposure estimates, EFSA calculated margins of exposure ranging from 31× to 5,867× and determined these to be adequate. While EFSA did not calculate an ADI for carnauba wax, JECFA (1993) previously determined an ADI of 0–7 mg/kg-bw/day. Importantly, the intakes of carnauba wax, beeswax, and candelilla wax estimated by EFSA were each very similar to that of rice bran wax, and all spanned ranges higher than the JECFA ADI of 0–7 mg/kg bw/day (0.7–8.1, 5.8–22, 0.7–8.1).

MOEs for rice bran wax for its intended use in bars were calculated based on the EDIs determined by FDA. As presented in the Dietary Exposure section, estimated mean and 90th percentile intakes of rice bran wax of 0.003 g/kg-bw/day and 0.005 g/kg-bw/day, respectively, were calculated (assuming a 3% use level) for the U.S. population ages 2 and over. This provides margins of exposure of approximately 223× and 134×, respectively, for mean and 90th percentile intakes when compared to the lowest NOAEL reported from the 2-generation study with carnauba wax (Parent et al., 1983b). When considering the population with the highest EDI, ages 2–5 years, the estimated mean and 90th percentile intakes of rice bran wax were 0.007 g/kg/day and 0.014 g/kg/day, respectively. This provides margins of exposure of approximately 96× and 48×, respectively, for the mean and 90th percentile. Therefore, all calculated MOEs were determined to be at or greater than 100x, with the exception of the 90th percentile in the 2-5-year age group.

More importantly, all EDIs calculated by FDA are at or near the JECFA ADI for carnauba wax of 0-7 mg/kg-bw/day. Only the 90th percentile in the 2-5-year age group had an EDI marginally above the JECFA ADI. As stated by Lambe et al. (2002), the overestimations of shorter-term surveys may be of more significance when comparing to standards, such as ADIs. It is possible that utilization of longer term survey data, e.g., 30 days, would further reduce the within-person variability and result in even lower EDIs relative to the ADI. Regardless, an EDI marginally above the ADI for the 90th percentile of only one age group – 2-5 year olds – is of limited concern given the inherent over-conservatism in both the EDI calculations (i.e., inclusion of any all bar types) and the basis of the ADI determination. An ADI, as determined by JECFA, is "an estimate of the amount of the additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (notionally "zero" risk). JECFA does not make a quantitative estimate of risk at an intake corresponding to the ADI, but concludes that the risk is so small as to be negligible from a public health point of view"[10]. JECFA goes on to state that this evaluation "can be considered to be mainly the hazard characterization step". In other words, the ADI is not a threshold above which the risk of health effects will suddenly be of concern. In addition, the ADI for carnauba wax was developed assuming ingestion over a lifetime. The EDI for the age group in question, 2-5 years, is a transient time period that has limited relevance to a lifetime exposure.

The analysis as presented in this GRAS assessment demonstrates that all EDIs for rice bran wax are at or near the most relevant ADI. Together with the supporting safety data, the available information demonstrates the rice bran wax product to be safe for the intended use described herein.

General Recognition of the Safety of Rice Bran Wax

The intended use of rice bran wax has been determined to be safe through scientific procedures as set forth in 21 CFR § 170.3(b), thus satisfying the so-called "technical" element of the GRAS determination and is based on the following:

- The rice bran wax that is the subject of this notification is a high melting point vegetable wax obtained from rice husks. The rice bran wax product is manufactured consistent with current cGMP for food (21 CFR Part 110). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use as in food.

- Brown rice, and their derivatives have a long history of human consumption with rice cultivation documented back to prehistoric times. Importantly, the known history of use of rice bran wax in food such as candy, chewing gum, and fresh fruit and vegetables (21 CFR § 172.890 and 21 CFR § 172.615) is supportive of its safe use in food.

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[10] http://www.fao.org/docrep/008/ae922e/ae922e05.htm

- Rice bran wax consists primarily of high-molecular-weight monoesters ranging from C48 to C64 (87%–98%; Appendix A); the remaining components of the rice bran wax product consist of free long-chain fatty alcohols, free long-chain fatty acids, or triglycerides from rice bran oil. While some toxicological data are available for rice bran wax, information on its main constituents and other plant-based waxes with similar chemical structures, and thus similar potential for absorption, was also evaluated as part of the GRAS assessment. Studies conducted on carnauba wax, candelilla wax, beeswax, lanolin wax, and jojoba wax were identified and deemed suitable for inclusion in the safety assessment of rice bran wax and its constituents, and were considered by the Expert Panel in its evaluation. Safety studies on these materials have been conducted and are publicly available and/or have been previously reviewed and reported in summary form by an authoritative regulatory body.

- Subchronic toxicity and/or reproductive/developmental toxicity studies were identified for carnauba wax, candelilla wax, and jojoba oil. In each of the published studies on carnauba wax, the NOAEL was the highest dose level administered and ranged from 250 to 10,800 mg/kg/day, the highest of which was a concentration of 10% (equivalent to 8,800 and 10,200 mg/kg-bw/day in males and females, respectively) administered in the diet of rats for 90 days. Chronic studies with candelilla wax were also identified, and the NOAELs in these studies were also the highest dose tested, up to 2,400 mg/kg-bw-day.

- The intake analysis conducted by FDA resulted in EDIs below the JECFA ADI for carnauba wax of 0–7 mg/kg-bw/day, apart from the 90th percentile of the 2- to 5-year-old age group. Regardless, an EDI marginally above the ADI for the 90th percentile of only one age group—2- to 5-year–olds—is of limited concern given the inherent over-conservatism in both the EDI calculations (i.e., incorporates any and all bar types) and the basis of the JECFA ADI determination developed for a lifetime exposure.

- Given that rice bran wax contains little to no protein, the component responsible for imparting allergic potential, rice bran wax is not likely to pose an allergenic risk.

- The intake of total and inorganic arsenic from the intended use of rice bran wax is negligible and would not be expected to contribute to the background dietary intake of arsenic. In addition, inorganic arsenic is water soluble, and thus, the manufacturing process of rice bran wax will remove most of the inorganic arsenic.

- The publicly available scientific literature on the consumption and safety of rice bran wax and similar waxes is sufficient to support the safety and GRAS status of the proposed rice bran wax product.

Because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called "common knowledge" element of a GRAS determination.

Determination of the safety and GRAS status of rice bran wax that is the subject of this self-determination has been made through the deliberations of an Expert Panel convened by Smucker and composed of Michael Carakostas, DVM, Ph.D.; Stanley M. Tarka, Jr., Ph.D.; and Thomas Vollmuth, Ph.D. These individuals are qualified by scientific training and experience to evaluate the safety of substances intended to be added to foods. They have critically reviewed and evaluated the publicly available information summarized in this document and have individually and collectively concluded that rice bran wax, produced in a manner consistent with GMP and meeting the specifications described herein, is safe under its intended conditions of use. The Panel further unanimously concludes that the use of rice bran wax is GRAS based on scientific procedures, and that other experts qualified to assess the safety of foods and food additives would concur with these conclusions. The Panel's GRAS opinion is included as Exhibit 1 to this document.

It is also Smucker's opinion that other qualified scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Smucker has concluded that rice bran wax is GRAS under the intended conditions of use on the basis of scientific procedures, and therefore, it is excluded from the definition of a food additive and may be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21 of the CFR.

Smucker is not aware of any information that would be inconsistent with a finding that the proposed use of rice bran wax in food for human consumption meeting appropriate specifications, and used according to GMP, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concerns.

§ 170.250 Part 7, Supporting Data and Information

The following references are all generally available, unless otherwise noted. Appendix A and Exhibit 1 (analytical COAs for rice bran wax, signed Expert Panel report) are not generally available but are attached for reference.

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APPENDIX A

Gas Chromatographs

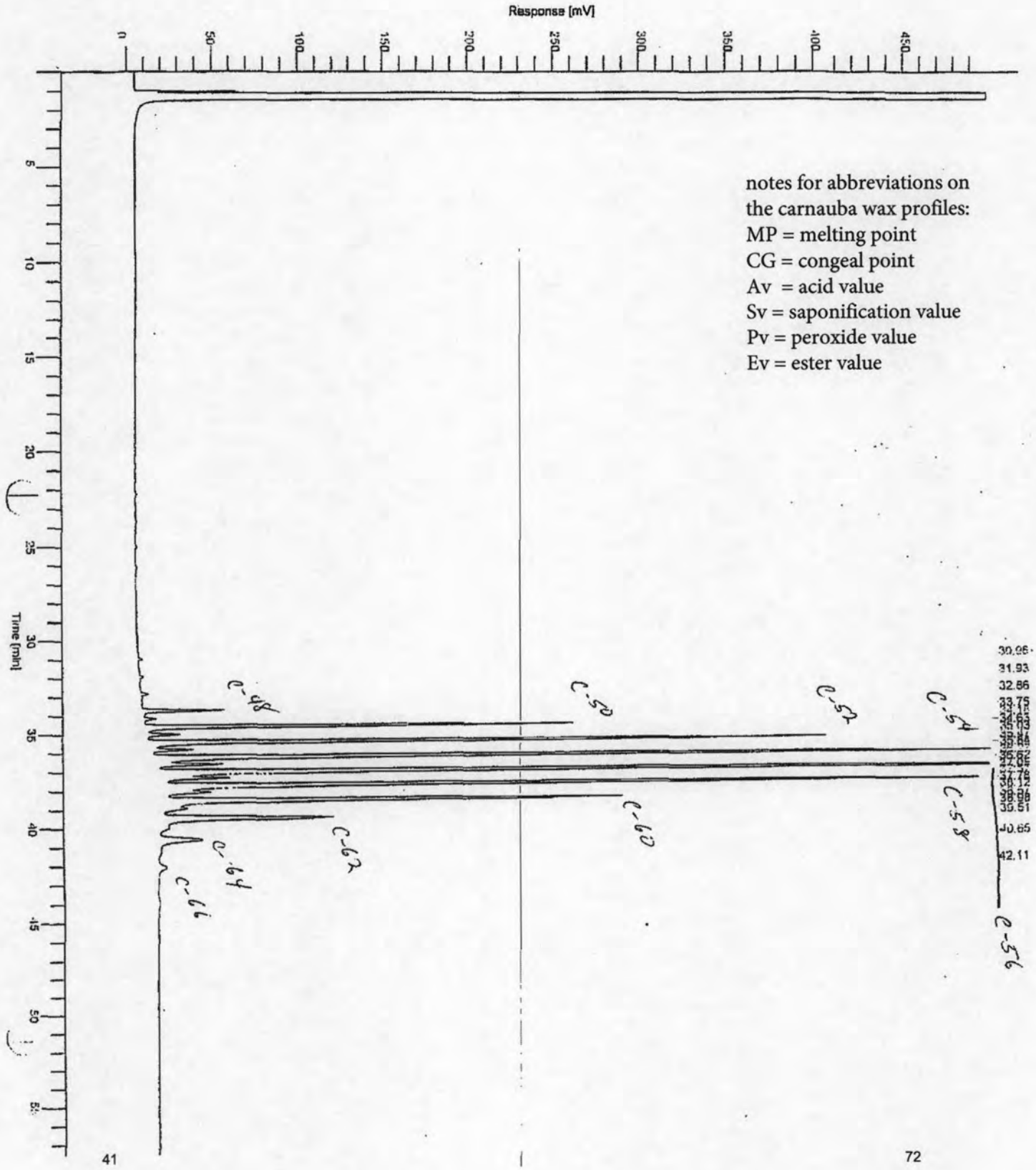
Chromatogram

Sample Name :
FileName : C:\TC Data\Data\Unknown001-20150630-095948.raw
Date : 6/30/2015 10:57:20 AM
Method : unknown.mth
Start Time : 0.00 min
Offset: 0.00 mV

Sample #: 001-
End Time : 57.58 min
Plot Scale: 500.0 mV

Page 1 of 1
Time of Injection: 6/30/2015 9:58:39 AM
Low Point : 0.00 mV
High Point : 500.00 mV

3906 :
Rice Bran Wax
B# 20033



notes for abbreviations on the carnauba wax profiles:
MP = melting point
CG = congeal point
Av = acid value
Sv = saponification value
Pv = peroxide value
Ev = ester value

Software Version	: 6.3.2.0646	Date	: 6/30/2015 10:57:20 AM
Reprocess Number	: test-cb061b7723: 4626		
Sample Name	:		
Instrument Name	: Autosystem	Data Acquisition Time	: 6/30/2015 9:59:39 AM
Rack/Vial	: 0/0	Channel	: A
Sample Amount	: 1.000000	Operator	: GC
Cycle	: 1	Dilution Factor	: 1.000000

Result File : C:\TC Data\Data\Unknown001-20150630-105720.rst
Sequence File : C:\TC Data\Sequence\Unknown.seq

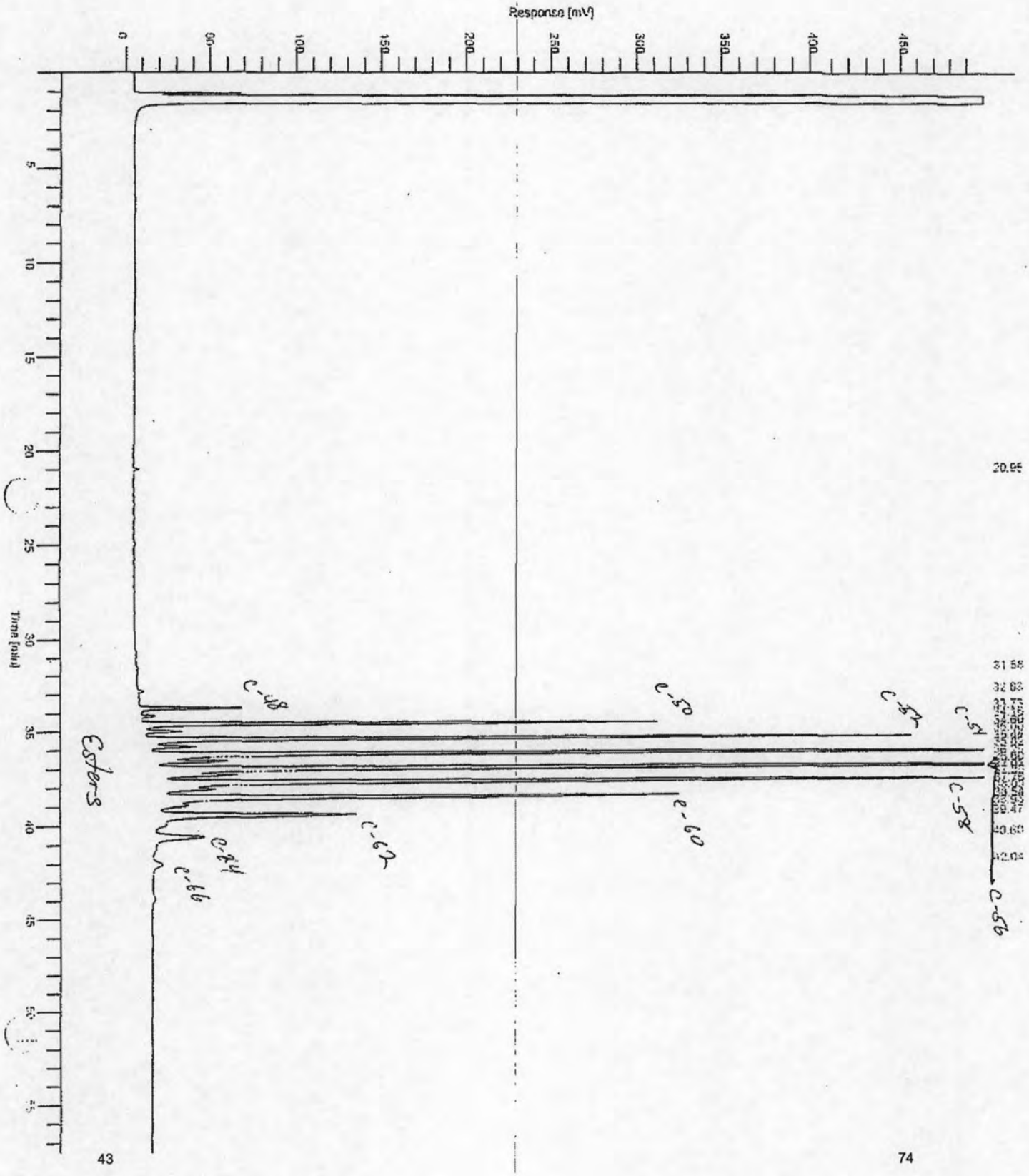
Rice Bran Wax (224P) B#20033

Peak #	Time [min]	Component Name	Area [uV*sec]	Norm. Area [%]
1	30.957		15661.13	0.06
2	31.933		13525.69	0.06
3	32.863		27870.63	0.11
4	33.753		333187.86	1.37
5	34.183		44937.57	0.19
6	34.627		1775411.71	7.32
7	35.028		137374.44	0.57
8	35.466		2876961.59	11.86
9	35.841		199670.29	0.82
10	36.274		4092070.98	16.87
11	36.624		344945.91	1.42
12	37.053		5069358.34	20.89
13	37.373		461433.74	1.90
14	37.780		3921734.22	16.16
15	38.119		381702.73	1.57
16	38.575		2717288.56	11.20
17	38.975		193504.39	0.80
18	39.508		1183497.75	4.88
19	40.652		380932.30	1.57
20	42.113		92469.67	0.38
			24263539.52	100.00

Chromatogram

Sample Name :
Sample #: 001-
Page 1 of 1
FileName : C:\TC Data\Data\Unknown001-20150701-135314.raw
Date : 7/1/2015 2:50:47 PM
Method : unknown.mth
Time of Injection: 7/1/2015 1:53:06 PM
Start Time : 0.00 min
End Time : 57.56 min
Low Point : 0.00 mV
High Point : 500.00 mV
Offset: 0.00 mV
Plot Scale: 500.0 mV

3912
Rice Bran Wax
B# 20048



Software Version	: 6.3.2.0646	Date	: 7/1/2015 2:50:46 PM
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Sample Name	:		
Instrument Name	: Autosystem	Data Acquisition Time	: 7/1/2015 1:53:06 PM
Rack/Vial	: 0/0	Channel	: A
Sample Amount	: 1.000000	Operator	: GC
Cycle	: 1	Dilution Factor	: 1.000000

Result File : C:\TC Data\Data\Unknown001-20150701-145046.rst
Sequence File : C:\TC Data\Sequence\Unknown.seq

Rice Bran Wax (224P) B# 20048

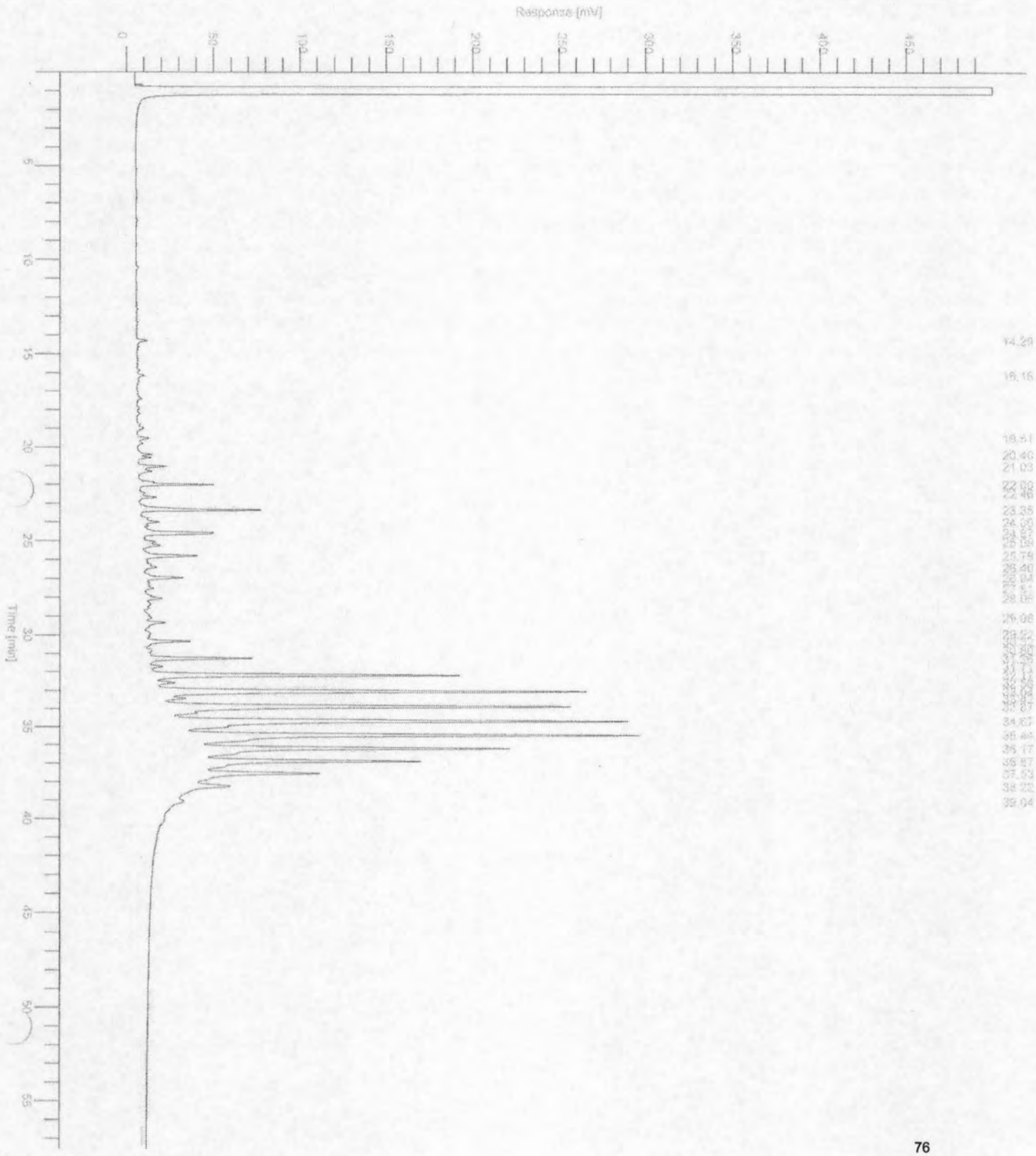
Peak #	Time [min]	Component Name	Area [uV*sec]	Norm. Area [%]
1	20.983		20608.44	0.07
2	31.583		9702.14	0.03
3	32.832		24281.61	0.09
4	33.727		433007.48	1.52
5	34.157		57968.79	0.20
6	34.603		2231083.02	7.84
7	35.003		167512.56	0.59
8	35.444		3454763.34	12.15
9	35.819		238401.81	0.84
10	36.254		4755959.99	16.72
11	36.600		456174.59	1.60
12	37.033		5845335.81	20.55
13	37.347		558600.25	1.96
14	37.755		4507671.36	15.85
15	38.087		448114.81	1.58
16	38.543		3101139.67	10.90
17	38.932		232118.18	0.82
18	39.466		1358306.00	4.78
19	40.601		437570.71	1.54
20	42.040		106016.80	0.37
			28444337.37	100.00

Chromatogram

4681

Rice Bran Wax
847P
B# 1600955

Sample Name :
Sample #: 001-
Page 1 of 1
FileName : C:\TC Data\Data\Unknown001-20160606-134512.raw
Date : 6/6/2016 2:42:45 PM
Method : unknown.mth
Time of Injection: 6/6/2016 1:45:05 PM
Start Time : 0.00 min
End Time : 57.56 min
Low Point : 0.00 mV
High Point : 500.00 mV
Offset: 0.00 mV
Plot Scale: 500.0 mV



Software Version : 6.3.2.0646
Reprocess Number : test-cb061b7723: 5828
Sample Name :
Instrument Name : Autosystem
Rack/Vial : 0/0
Sample Amount : 1.000000
Cycle : 1

Date : 6/6/2016 2:42:45 PM

Data Acquisition Time : 6/6/2016 1:45:05 PM
Channel : A
Operator : GC
Dilution Factor : 1.000000

Result File : C:\TC Data\Data\Unknown001-20160606-144245.rst
Sequence File : C:\TC Data\Sequence\Unknown.seq

Rice Bran Wax (874P) # 1600955

Peak #	Time [min]	Component Name	Area [uV*sec]	Norm. Area [%]
1	14.291		40984.95	0.19
2	16.155		27957.85	0.13
3	19.514		43347.67	0.20
4	20.401		50761.17	0.23
5	20.564		42502.86	0.20
6	21.026		131956.64	0.61
7	21.291		63981.72	0.30
8	22.004		312175.14	1.44
9	22.457		28430.63	0.13
10	22.680		69173.99	0.32
11	23.354		490370.35	2.27
12	23.996		80525.03	0.37
13	24.568		403764.80	1.87
14	25.057		48461.98	0.22
15	25.230		80536.75	0.37
16	25.784		258326.05	1.20
17	26.399		64652.35	0.30
18	26.945		174449.15	0.81
19	27.514		27732.95	0.13
20	28.047		82721.34	0.38
21	29.079		57990.00	0.27
22	29.334		118589.75	0.55
23	29.916		45781.67	0.21
24	30.317		219288.76	1.01
25	30.799		24866.43	0.12
26	31.259		505970.99	2.34
27	31.707		49726.73	0.23
28	32.171		1552468.02	7.19
29	32.583		80607.63	0.37
30	33.041		2449051.98	11.33
31	33.425		83997.00	0.39
32	33.869		2298857.13	10.64
33	34.672		2426200.41	11.23

6/6/2016 2:42:45 PM Result: C:\TC Data\Data\Unknown001-20160606-144245.rst

Peak #	Time [min]	Component Name	Area [uV*sec]	Norm. Area [%]
34	35.444		3152631.29	14.59
35	36.171		2397464.30	11.10
36	36.869		1845492.46	8.54
37	37.535		1218931.29	5.64
38	38.223		502004.58	2.32
39	39.041		54297.45	0.25
			21607031.25	100.00

APPENDIX B

Analytical Results

3344 NW Industrial Street
Portland, Oregon 97210 USA
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OMIC USA Inc.

A Member of OMIC Group of Companies
Independent Analytical Laboratory

Report Date: *April 01, 2015*

Koster Keunen Inc.

1021 Echo Lake Road
Watertown, CT 06795

ANALYTICAL REPORT

Sample ID : B#18940 **Matrix:** ***RICE BRAN WAX 224P***

Date Received: *February 20, 2015*

Lab ID # : *AB78145*

PAH'S Screen

	Analyte	Result	Units	MDL
1	*Acenaphthene	ND	ppb	120
2	*Acenaphthylene	ND	ppb	100
3	*Anthracene	ND	ppb	180
4	*Benz(a)anthracene	ND	ppb	130
5	*Benzo(a)pyrene	ND	ppb	90
6	*Benzo(b)fluoranthene	ND	ppb	100
7	*Benzo(g,h,i)perylene	ND	ppb	100
8	*Benzo(k)fluoranthene	ND	ppb	100
9	*Chrysene	ND	ppb	90
10	*Dibenzo(a,h)anthracene	ND	ppb	150
11	*Flouranthene	ND	ppb	120
12	*Fluorene	ND	ppb	190
13	*Indeno((1,2,3-cd)pyrene	ND	ppb	130
14	*Napthalene	ND	ppb	120
15	*Phenanthrene	ND	ppb	100
16	*Pyrene	ND	ppb	90

Solvent Screen

	Analyte	Result	Units	MDL
1	Hexane	ND	ppb	10

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
*MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted*

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OMIC USA Inc.

A Member of OMIC Group of Companies
Independent Analytical Laboratory

Koster Keunen Inc.

1021 Echo Lake Road
Watertown, CT 06795

Report Date: *April 16, 2015*

ANALYTICAL REPORT

Sample ID : B#18940 **Matrix:** ***RICE BRAN WAX 224P***

Date Received: *April 06, 2015*

Lab ID # : *AB79475*

Arsenic Speciation

	Analyte	Result	Units	MDL
1	Arsenate {As(V)}	N/A	ppb	5
2	Arsenite {As(III)}	N/A	ppb	5
3	Inorganic Arsenic	N/A	ppb	
4	Dimethylarsenic acid	N/A	ppb	5
5	Monomethylarsonic acid	N/A	ppb	5
6	Organic Arsenic	N/A	ppb	

Chemical Residue

	Analyte	Result	Units	MDL
1	2,6-Diisopropylnaphthalene	ND	ppm	0.02
2	Abamectin	ND	ppm	0.05
3	Acephate	ND	ppm	0.25
4	Acetamiprid	ND	ppm	0.05
5	Acetochlor	ND	ppm	0.02
6	Acibenzolar-S-Methyl	ND	ppm	0.25
7	Acrinathrin	ND	ppm	0.02
8	Alachlor	ND	ppm	0.02
9	Aldicarb	ND	ppm	0.05
10	Aldicarb Sulfone	ND	ppm	0.1
11	Aldicarb Sulfoxide	ND	ppm	0.25
12	Aldrin	ND	ppm	0.01
13	Allethrin	ND	ppm	0.02
14	Ametryn	ND	ppm	0.05
15	Amitraz	ND	ppm	0.05
16	Anilofos	ND	ppm	0.02
17	Atrazine	ND	ppm	0.02

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AB79475

18	Azaconazole	ND	ppm	0.02
19	Azamethiphos	ND	ppm	0.05
20	Azinphos-Ethyl	ND	ppm	0.1
21	Azinphos-Methyl	ND	ppm	0.1
22	Azoxystrobin	ND	ppm	0.1
23	Benalaxyl	ND	ppm	0.02
24	Bendiocarb	ND	ppm	0.05
25	Benfluralin	ND	ppm	0.02
26	Benfuresate	ND	ppm	0.02
27	Benomyl (as Carbendazim)	ND	ppm	0.1
28	Benoxacor	ND	ppm	0.02
29	Bensulide	ND	ppm	0.1
30	Bentazone	ND	ppm	0.02
31	Benzobicyclon	ND	ppm	0.1
32	Benzofenap	ND	ppm	0.05
33	Benzyladenine	ND	ppm	0.05
34	BHC's	ND	ppm	0.02
35	Bifenazate	ND	ppm	0.25
36	Bifenox	ND	ppm	0.02
37	Bifenthrin	ND	ppm	0.02
38	Bioresmethrin	ND	ppm	0.1
39	Bitertanol	ND	ppm	0.05
40	Boscalid	ND	ppm	0.02
41	Bromobutide	ND	ppm	0.02
42	Bromophos Methyl	ND	ppm	0.02
43	Bromophos-Ethyl	ND	ppm	0.02
44	Bromopropylate	ND	ppm	0.02
45	Bupirimate	ND	ppm	0.02
46	Buprofezin	ND	ppm	0.02
47	Butachlor	ND	ppm	0.02
48	Butafenacil	ND	ppm	0.02
49	Butamifos	ND	ppm	0.02
50	Butralin	ND	ppm	0.02
51	Butylate	ND	ppm	0.02
52	Cadusafos	ND	ppm	0.02
53	Cafenstrole	ND	ppm	0.05
54	Captan	ND	ppm	0.1
55	Carbaryl	ND	ppm	0.05
56	Carbendazim	ND	ppm	0.1
57	Carbofuran	ND	ppm	0.05
58	Carbophenothion	ND	ppm	0.02
59	Carboxin	N/A	ppm	0.02
60	Carfentrazone-Ethyl	ND	ppm	0.02
61	Carpropamid	ND	ppm	0.02
62	Chlorantraniliprole	ND	ppm	0.05
63	Chlorbenside	ND	ppm	0.02
64	Chlorbufam	ND	ppm	0.02
65	Chlordane	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
*MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted*

AB79475

66	Chlorethoxyfos	ND	ppm	0.02
67	Chlorfenapyr	ND	ppm	0.02
68	Chlorfenson	ND	ppm	0.02
69	Chlorfenvinphos	ND	ppm	0.02
70	Chloridazon	ND	ppm	0.5
71	Chlornitrofen	ND	ppm	0.1
72	Chlorobenzilate	ND	ppm	0.02
73	Chloroneb	ND	ppm	0.06
74	Chloroxuron	ND	ppm	0.25
75	Chlorpropham	ND	ppm	0.02
76	Chlorpyrifos	ND	ppm	0.02
77	Chlorpyrifos Methyl	ND	ppm	0.02
78	Chlorthal-Dimethyl	ND	ppm	0.08
79	Chlorthiofos	ND	ppm	0.1
80	Chlozolinate	ND	ppm	0.1
81	Chromafenozide	ND	ppm	0.05
82	Cinidon-Ethyl	ND	ppm	0.05
83	Cinmethylin	ND	ppm	0.02
84	Clethodim	N/A	ppm	0.02
85	Clodinafop-Propargyl	ND	ppm	0.05
86	Clofentezine	ND	ppm	0.05
87	Clomazone	ND	ppm	0.04
88	Clomeprop	ND	ppm	0.1
89	Cloquintocet-Mexyl	ND	ppm	0.05
90	Clothianidin	ND	ppm	0.05
91	CPMC (Etrofol)	ND	ppm	0.1
92	Cumyluron	ND	ppm	0.1
93	Cyanazine	ND	ppm	0.05
94	Cyanophenphos	ND	ppm	0.04
95	Cyanophos	ND	ppm	0.02
96	Cyazofamid	ND	ppm	0.05
97	Cycloate	ND	ppm	0.02
98	Cyflufenamid	ND	ppm	0.02
99	Cyfluthrin	ND	ppm	0.1
100	Cyhalofop-Butyl	ND	ppm	0.06
101	Cyhalothrin	ND	ppm	0.02
102	Cymoxanil	ND	ppm	0.1
103	Cypermethrin	ND	ppm	0.1
104	Cyproconazole	ND	ppm	0.02
105	Cyprodinil	ND	ppm	0.05
106	Daimuron	ND	ppm	0.05
107	DDD	ND	ppm	0.02
108	DDE	ND	ppm	0.02
109	DDT	ND	ppm	0.02
110	Deltamethrin	ND	ppm	0.04
111	Demeton O & S	N/A	ppm	0.04
112	Demeton-S-Methyl	N/A	ppm	0.02
113	Desmedipham	ND	ppm	1

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AB79475

114	Diafenthiuron	N/A	ppm	0.1
115	Dialifos	ND	ppm	0.1
116	Di-allate	ND	ppm	0.04
117	Diazinon	ND	ppm	0.02
118	Dichlobenil	ND	ppm	0.1
119	Dichlofenthion (ECP)	ND	ppm	0.02
120	Dichlofluanid	ND	ppm	0.1
121	Dichlormid	ND	ppm	0.02
122	Dichlorvos	ND	ppm	0.02
123	Diclobutrazol	ND	ppm	0.05
124	Diclocymet	ND	ppm	0.02
125	Diclofop-Methyl	ND	ppm	0.02
126	Diclomezine	ND	ppm	0.1
127	Dicloran	ND	ppm	0.04
128	Dicofol	ND	ppm	0.02
129	Dicrotophos	ND	ppm	0.02
130	Dieldrin	ND	ppm	0.01
131	Diethofencarb	ND	ppm	0.06
132	Difenoconazole	ND	ppm	0.06
133	Difenzoquat	ND	ppm	0.5
134	Diflubenzuron	ND	ppm	0.05
135	Diflufenican	ND	ppm	0.02
136	Dimepiperate	ND	ppm	0.02
137	Dimethametryn	ND	ppm	0.05
138	Dimethenamid	ND	ppm	0.02
139	Dimethoate	ND	ppm	0.02
140	Dimethylvinphos	ND	ppm	0.02
141	Diniconazole	ND	ppm	0.05
142	Dinotefuran	ND	ppm	0.05
143	Dioxathion	ND	ppm	0.1
144	Diphenamid	ND	ppm	0.02
145	Diphenylamine	ND	ppm	0.04
146	Disulfoton	N/A	ppm	0.02
147	Disulfoton Sulfone	ND	ppm	0.02
148	Dithiopyr	ND	ppm	0.02
149	Diuron	ND	ppm	0.05
150	Edifenphos	ND	ppm	0.02
151	Emamectin Benzoate	ND	ppm	0.05
152	Endosulfan	ND	ppm	0.02
153	Endosulfan Sulfate	ND	ppm	0.04
154	Endrin	ND	ppm	0.01
155	EPN	ND	ppm	0.02
156	Epoxiconazole	ND	ppm	0.02
157	EPTC	ND	ppm	0.02
158	Esfenvalerate	ND	ppm	0.04
159	Esprocarb	ND	ppm	0.02
160	Ethalfluralin	ND	ppm	0.02
161	Ethion	ND	ppm	0.02

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AB79475

162	Ethiprole	ND	ppm	0.05
163	Ethofumesate	ND	ppm	0.02
164	Ethoprophos	ND	ppm	0.025
165	Ethoxyquin	N/A	ppm	0.1
166	Ethychlozate	ND	ppm	0.05
167	Etobenzanid	ND	ppm	0.02
168	Etofenprox	ND	ppm	0.02
169	Etoxazole	ND	ppm	0.1
170	Etridiazole	ND	ppm	0.1
171	Etrimfos	ND	ppm	0.02
172	Famphur	ND	ppm	0.04
173	Fenamidone	ND	ppm	0.02
174	Fenamiphos	ND	ppm	0.1
175	Fenamiphos Sulfone	ND	ppm	0.02
176	Fenarimol	ND	ppm	0.02
177	Fenbuconazole	ND	ppm	0.05
178	Fenchlorphos	ND	ppm	0.02
179	Fenhexamid	ND	ppm	0.05
180	Fenitrothion	ND	ppm	0.02
181	Fenobucarb	ND	ppm	0.05
182	Fenothiocarb	ND	ppm	0.05
183	Fenoxanil	ND	ppm	0.05
184	Fenoxaprop-Ethyl	ND	ppm	0.02
185	Fenoxycarb	ND	ppm	0.1
186	Fenpropathrin	ND	ppm	0.02
187	Fenpropimorph	ND	ppm	0.02
188	Fenpyroximate	ND	ppm	0.1
189	Fensulfothion	ND	ppm	0.1
190	Fenthion	ND	ppm	0.02
191	Fentrazamide	ND	ppm	0.05
192	Fenvalerate	ND	ppm	0.04
193	Ferimzone	ND	ppm	0.05
194	Fipronil	ND	ppm	0.01
195	Flamprop-Methyl	ND	ppm	0.02
196	Fluacrypyrim	ND	ppm	0.1
197	Fluazifop-Butyl	ND	ppm	0.02
198	Fluazinam	ND	ppm	0.25
199	Flucythrinate	ND	ppm	0.04
200	Fludioxonil	ND	ppm	0.05
201	Flufenacet	ND	ppm	0.02
202	Fluometuron	ND	ppm	0.1
203	Fluquinconazole	ND	ppm	0.02
204	Fluridone	ND	ppm	0.05
205	Flusilazole	ND	ppm	0.02
206	Flusulfamide	ND	ppm	0.1
207	Fluthiacet Methyl	ND	ppm	0.15
208	Flutolanil	ND	ppm	0.02
209	Flutriafol	ND	ppm	0.1

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AB79475

210	Fluvalinate	ND	ppm	0.06
211	Fonofos	ND	ppm	0.02
212	Forchlorfenuron	ND	ppm	0.05
213	Fosthiazate	ND	ppm	0.1
214	Fthalide	ND	ppm	0.02
215	Furametpyr	ND	ppm	0.02
216	Furathiocarb	ND	ppm	0.05
217	Furilazole	ND	ppm	0.02
218	Halfenprox	ND	ppm	0.1
219	Haloxyfop	ND	ppm	0.01
220	Haloxyfop Methyl	ND	ppm	0.02
221	Heptachlor	ND	ppm	0.02
222	Heptachlor Epoxide	ND	ppm	0.02
223	Hexachlorobenzene	ND	ppm	0.02
224	Hexaconazole	ND	ppm	0.05
225	Hexazinone	ND	ppm	0.02
226	Hexythiazox	ND	ppm	0.1
227	Imazalil	ND	ppm	0.02
228	Imazamethabenz Methyl Ester	ND	ppm	0.2
229	Imibenconazole	ND	ppm	0.1
230	Imidacloprid	ND	ppm	0.1
231	Inabenfide	ND	ppm	0.05
232	Indoxacarb	ND	ppm	0.1
233	Iprobenfos	ND	ppm	0.02
234	Iprodione	ND	ppm	0.25
235	Iprovalicarb	ND	ppm	0.1
236	Isazophos	ND	ppm	0.02
237	Isocarbophos	ND	ppm	0.02
238	Isofenphos	ND	ppm	0.02
239	Isofenphos-Methyl	ND	ppm	0.02
240	Isoprocarb	ND	ppm	0.05
241	Isoprothiolane	ND	ppm	0.06
242	Isotianil	ND	ppm	0.02
243	Isouron	ND	ppm	0.1
244	Isoxadifen-Ethyl	ND	ppm	0.02
245	Isoxaflutole	ND	ppm	0.05
246	Isoxathion	ND	ppm	0.05
247	Kresoxim-Methyl	ND	ppm	0.02
248	Lenacil	ND	ppm	0.25
249	Lindane (gamma-BHC)	ND	ppm	0.02
250	Linuron	ND	ppm	0.1
251	Malathion	ND	ppm	0.02
252	Mandipropamid	ND	ppm	0.05
253	Mecarbam	ND	ppm	0.02
254	Mefenacet	ND	ppm	0.05
255	Mefenpyr-Diethyl	ND	ppm	0.05
256	Mepanipyrim	ND	ppm	0.02
257	Mephosfolan	ND	ppm	0.1

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AB79475

258	Mepronil	ND	ppm	0.02
259	Metalaxyl / Mefenoxam	ND	ppm	0.02
260	Metconazole	ND	ppm	0.04
261	Methabenzthiazuron	N/A	ppm	0.02
262	Methacrifos	ND	ppm	0.02
263	Methamidophos	ND	ppm	0.05
264	Methidathion	ND	ppm	0.05
265	Methiocarb	ND	ppm	0.05
266	Methomyl	ND	ppm	0.05
267	Methoprene	ND	ppm	0.02
268	Methoxychlor	ND	ppm	0.02
269	Methoxyfenozide	ND	ppm	0.05
270	Metolachlor	ND	ppm	0.02
271	Metominostrobin	ND	ppm	0.02
272	Metribuzin	ND	ppm	0.02
273	Mevinphos	ND	ppm	0.02
274	Mirex	ND	ppm	0.2
275	Molinate	ND	ppm	0.02
276	Monocrotophos	ND	ppm	0.02
277	Monolinuron	ND	ppm	0.05
278	Myclobutanil	ND	ppm	0.02
279	Naled	ND	ppm	0.02
280	Naproanilide	ND	ppm	0.02
281	Napropamide	ND	ppm	0.02
282	Nitenpyram	ND	ppm	0.25
283	Nitrofen	ND	ppm	0.06
284	Nitrothal-Isopropyl	ND	ppm	0.02
285	Norflurazon	ND	ppm	0.06
286	Novaluron	ND	ppm	0.05
287	Ofurace	ND	ppm	0.05
288	Omethoate	ND	ppm	0.1
289	o-Phenyl Phenol	ND	ppm	0.1
290	Orysastrobin	ND	ppm	0.02
291	Oryzalin	ND	ppm	0.05
292	Oxadiazon	ND	ppm	0.02
293	Oxadixyl	ND	ppm	0.5
294	Oxamyl	ND	ppm	0.05
295	Oxaziclomefone	ND	ppm	0.05
296	Oxpoconazole-Fumarate	ND	ppm	0.15
297	Oxycarboxin	ND	ppm	0.25
298	Oxydemeton-Methyl	ND	ppm	0.05
299	Oxyfluorfen	ND	ppm	0.02
300	Paclobutrazol	ND	ppm	0.02
301	Parathion	ND	ppm	0.02
302	Parathion-Methyl	ND	ppm	0.02
303	Pebulate	ND	ppm	0.02
304	Penconazole	ND	ppm	0.02
305	Pencycuron	ND	ppm	0.05

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
*MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted*

AB79475

306	Pendimethalin	ND	ppm	0.04
307	Pentoxazone	ND	ppm	0.02
308	Permethrin	ND	ppm	0.04
309	Perthane	ND	ppm	0.06
310	Phenmedipham	ND	ppm	0.25
311	Phenothiol	ND	ppm	0.1
312	Phenothrin	ND	ppm	0.04
313	Phenthoate	ND	ppm	0.02
314	Phorate	ND	ppm	0.02
315	Phorate Sulfone	ND	ppm	0.02
316	Phosalone	ND	ppm	0.02
317	Phosmet	ND	ppm	0.02
318	Phosphamidon	ND	ppm	0.02
319	Phoxim	ND	ppm	0.1
320	Picolinafen	ND	ppm	0.05
321	Piperonyl Butoxide	ND	ppm	0.04
322	Piperophos	ND	ppm	0.02
323	Pirimicarb	ND	ppm	0.02
324	Pirimioxyphos	ND	ppm	0.02
325	Pirimiphos Ethyl	ND	ppm	0.04
326	Pirimiphos-Methyl	ND	ppm	0.02
327	Pretilachlor	ND	ppm	0.02
328	Prochloraz	ND	ppm	0.02
329	Procymidone	ND	ppm	0.04
330	Profenofos	ND	ppm	0.02
331	Prohydrojasmon	ND	ppm	0.25
332	Prometryn	ND	ppm	0.04
333	Propachlor	ND	ppm	0.02
334	Propanil	ND	ppm	0.02
335	Propaphos	ND	ppm	0.02
336	Propargite	ND	ppm	0.02
337	Propazine	ND	ppm	0.02
338	Propetamphos	ND	ppm	0.02
339	Propiconazole	ND	ppm	0.06
340	Propoxur	ND	ppm	0.05
341	Propyzamide	ND	ppm	0.05
342	Prothiofos	ND	ppm	0.02
343	Pyraclofos	ND	ppm	0.04
344	Pyraclonil	ND	ppm	0.02
345	Pyraclostrobin	ND	ppm	0.05
346	Pyraflufen Ethyl	ND	ppm	0.02
347	Pyrazolynate	ND	ppm	0.05
348	Pyrazophos	ND	ppm	0.02
349	Pyrazoxyfen	ND	ppm	0.25
350	Pyrethrins	ND	ppm	0.2
351	Pyributicarb	ND	ppm	0.02
352	Pyridaben	ND	ppm	0.02
353	Pyridafenthion	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
*MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted*

AB79475

354	Pyrifenox	ND	ppm	0.02
355	Pyriftalid	ND	ppm	0.05
356	Pyrimethanil	ND	ppm	0.02
357	Pyrimidifen	ND	ppm	0.02
358	Pyriminobac-Methyl	ND	ppm	0.02
359	Pyriproxyfen	ND	ppm	0.02
360	Pyroquilon	ND	ppm	0.02
361	Quinalphos	ND	ppm	0.02
362	Quinoclamine	ND	ppm	0.05
363	Quinoxyfen	ND	ppm	0.02
364	Quintozene	ND	ppm	0.02
365	Quizalofop-Ethyl	ND	ppm	0.02
366	Salithion (Dioxabenzofos)	ND	ppm	0.02
367	Sethoxydim	ND	ppm	0.25
368	Silafluofen	ND	ppm	0.02
369	Simazine	ND	ppm	0.1
370	Simeconazole	ND	ppm	0.05
371	Simetryn	ND	ppm	0.04
372	Spinosad	ND	ppm	0.05
373	Spiromesifen	ND	ppm	0.05
374	Sulfotep	ND	ppm	0.02
375	Sulprofos	ND	ppm	0.02
376	TCMTB (Benthiazole)	ND	ppm	0.04
377	Tebuconazole	ND	ppm	0.06
378	Tebufenozide	ND	ppm	0.25
379	Tebufenpyrad	ND	ppm	0.02
380	Tebupirimfos	ND	ppm	0.04
381	Tebuthiuron	ND	ppm	0.1
382	Tecnazene	ND	ppm	0.02
383	Tefluthrin	ND	ppm	0.04
384	Terbacil	ND	ppm	0.25
385	Terbufos	ND	ppm	0.01
386	Terbutryn	ND	ppm	0.04
387	Tetrachlorvinphos	ND	ppm	0.02
388	Tetraconazole	ND	ppm	0.02
389	Tetradifon	ND	ppm	0.02
390	Tetramethrin	ND	ppm	0.02
391	Thenylchlor	ND	ppm	0.02
392	Thiabendazole	ND	ppm	0.25
393	Thiacloprid	ND	ppm	0.1
394	Thiamethoxam	ND	ppm	0.05
395	Thiazopyr	ND	ppm	0.02
396	Thidiazuron	ND	ppm	0.15
397	Thifluzamide	ND	ppm	0.04
398	Thiobencarb	ND	ppm	0.02
399	Thiometon	ND	ppm	0.02
400	Tiadinil	ND	ppm	0.05
401	Tolclofos-Methyl	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
*MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted*

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402	Tralomethrin	ND	ppm	0.04
403	Triadimefon	ND	ppm	0.02
404	Triadimenol	ND	ppm	0.05
405	Tri-allate	ND	ppm	0.02
406	Triazophos	ND	ppm	0.02
407	Tribuphos	ND	ppm	0.02
408	Trichlamide	ND	ppm	0.1
409	Trichlorfon	ND	ppm	0.05
410	Tricyclazole	ND	ppm	0.1
411	Tridiphane	ND	ppm	0.04
412	Trifloxystrobin	ND	ppm	0.1
413	Triflumizole	ND	ppm	0.02
414	Triflumuron	ND	ppm	0.1
415	Trifluralin	ND	ppm	0.02
416	Triforine	ND	ppm	0.05
417	Triticonazole	ND	ppm	0.05
418	Uniconazole P	ND	ppm	0.1
419	Vinclozolin	ND	ppm	0.02
420	XMC	ND	ppm	0.05
421	Xylylcarb	ND	ppm	0.05
422	Zoxamide	ND	ppm	0.1

Minerals / Metals Screen

	Analyte	Result	Units	MDL
1	Arsenic	ND	ppb	10
2	Cadmium	ND	ppb	10
3	Lead	21	ppb	10
4	Mercury	ND	ppb	5

Note:

1. The compounds reported as N/A did not recover from the matrix or had instrument interferences
2. The Lead analysis result is qualified as qualitative due the variation in quality control data
3. Unable to report the Arsenic Speciation results, however the total Arsenic determined by a different test method is not present.

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
*MDL=Minimum Detection Limit; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < MDL; * = Analysis subcontracted*

AB79475

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OMIC USA Inc.

A Member of OMIC Group of Companies
Independent Analytical Laboratory

Report Date: *July 22, 2015*

Koster Keunen Inc.

1021 Echo Lake Road
Watertown, CT 06795

ANALYTICAL REPORT

Sample ID : B#18940 **Matrix:** ***RICE BRAN WAX 224P***

Date Received: *May 06, 2015*

Lab ID # : *AB80320*

Persistent Organic Pollutants

	Analyte	Result
1	*Dioxins/Furans/WHO-12 PCBs	Completed – see attached ALS Analysis Report

Microbiological Tests

	Analyte	Result	Units
1	Aerobic Plate Count (APC)	10	CFU/g
2	Coliform, Plate Count	<10	CFU/g
3	E Coli, Plate Count	<10	CFU/g
4	Listeria Genus (by PCR)	Negative	
5	Mold	<10	CFU/g
6	Salmonella (by PCR)	Negative	
7	Yeast	<10	CFU/g

Mycotoxins Screen

	Analyte	Result	Units	LOQ
1	Aflatoxin B1	ND	ppb	5
2	Aflatoxin B2	ND	ppb	5
3	Aflatoxin G1	ND	ppb	5
4	Aflatoxin G2	ND	ppb	5

*This analysis is outside the scope of OMIC USA operations and has been subcontracted to ALS laboratory. Their report analysis is attached in its entirety. OMIC USA assumes no responsibility for its interpretations or use.

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
*LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted*

ALS Life Sciences
1435 Norjohn Court, Unit 1, Burlington, ON, Canada L7L 0E6
Phone: 905-331-3111, FAX: 905-331-4567

Certificate of Analysis

ALS Project Contact:	Ron McLeod	**Client Name:**	ALS Environmental
ALS Project ID:	ALS800	**Client Address:**	10450 Stancliff Road, Suite 210
ALS WO#:	L1623923		Houston, Texas 77099-4338
Date of Report	17-Jul-15		
Date of Sample Receipt	9-Jun-15	**Client Contact:**	Nicole Brown
		Client Project ID:	E1500506

COMMENTS: **PCDD/F by EPA 1613B**

Percent recovery for 13C12 TCDD was below method acceptance criteria in Method blank. However, there was no native TCDD in the sample and therefore there is no compromise to the batch based upon this QC exceedance.

(b) (6)

Ron McLeod, PhD
Director, Air Toxics & Special Chemistries

ALS Life Sciences

Sample Analysis summary Report

Sample Name	**AB80320**
ALS Sample ID	L1623923-1
Sample Size	1.00
Sample size units	g
Percent Moisture	n/a
Sample Matrix	Wax pellets
Sampling Date	6-May-15
Extraction Date	16-Jun-15
Target Analytes	**pg/g**
2,3,7,8-TCDD	<1.3
1,2,3,7,8-PeCDD	<1.0
1,2,3,4,7,8-HxCDD	<0.95
1,2,3,6,7,8-HxCDD	<1.0
1,2,3,7,8,9-HxCDD	<0.90
1,2,3,4,6,7,8-HpCDD	<0.91
OCDD	<0.87
2,3,7,8-TCDF	<0.79
1,2,3,7,8-PeCDF	<0.74
2,3,4,7,8-PeCDF	<0.62
1,2,3,4,7,8-HxCDF	<0.67
1,2,3,6,7,8-HxCDF	<0.65
2,3,4,6,7,8-HxCDF	<0.68
1,2,3,7,8,9-HxCDF	1.05
1,2,3,4,6,7,8-HpCDF	<0.55
1,2,3,4,7,8,9-HpCDF	<0.75
OCDF	1.24
Extraction Standards	**% Rec**
13C12-2,3,7,8-TCDD	54
13C12-1,2,3,7,8-PeCDD	84
13C12-1,2,3,4,7,8-HxCDD	85
13C12-1,2,3,6,7,8-HxCDD	107
13C12-1,2,3,4,6,7,8-HpCDD	68
13C12-OCDD	56
13C12-2,3,7,8-TCDF	83
13C12-1,2,3,7,8-PeCDF	89
13C12-2,3,4,7,8-PeCDF	95
13C12-1,2,3,4,7,8-HxCDF	93
13C12-1,2,3,6,7,8-HxCDF	108
13C12-2,3,4,6,7,8-HxCDF	97
13C12-1,2,3,7,8,9-HxCDF	92
13C12-1,2,3,4,6,7,8-HpCDF	85
13C12-1,2,3,4,7,8,9-HpCDF	73
Cleanup Standard	
37Cl4-2,3,7,8-TCDD (Cleanup)	52
Homologue Group Totals	**pg/g**
Total-TCDD	<1.3
Total-PeCDD	<0.59
Total-HxCDD	<0.95
Total-HpCDD	<0.68
Total-TCDF	<0.79
Total-PeCDF	<0.74
Total-HxCDF	1.97
Total-HpCDF	<0.75
Toxic Equivalency - (WHO 2005)	
Lower Bound PCDD/F TEQ (WHO 2005)	0.105
Mid Point PCDD/F TEQ (WHO 2005)	2.24
Upper Bound PCDD/F TEQ (WHO 2005)	3.20

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Quality Control Summary Report

Sample Name	Method Blank	Laboratory Control Sample
ALS Sample ID	WG2108486-1	WG2108486-2
Sample Size	1.00	1.00
Sample size units	g	n/a
Percent Moisture	n/a	n/a
Sample Matrix	QC	QC
Sampling Date	n/a	n/a
Extraction Date	16-Jun-15	16-Jun-15
Target Analytes	**pg/g**	**% Rec**
2,3,7,8-TCDD	<8.6	93
1,2,3,7,8-PeCDD	<1.9	98
1,2,3,4,7,8-HxCDD	<2.2	101
1,2,3,6,7,8-HxCDD	<2.0	90
1,2,3,7,8,9-HxCDD	<2.1	97
1,2,3,4,6,7,8-HpCDD	<2.7	98
OCDD	<6.4	90
2,3,7,8-TCDF	<1.3	89
1,2,3,7,8-PeCDF	<1.7	96
2,3,4,7,8-PeCDF	<2.3	89
1,2,3,4,7,8-HxCDF	<0.88	97
1,2,3,6,7,8-HxCDF	<1.4	96
2,3,4,6,7,8-HxCDF	<1.9	100
1,2,3,7,8,9-HxCDF	2.73	97
1,2,3,4,6,7,8-HpCDF	<1.2	93
1,2,3,4,7,8,9-HpCDF	<1.7	94
OCDF	<4.1	98
Extraction Standards	**% Rec**	**% Rec**
13C12-2,3,7,8-TCDD	17	31
13C12-1,2,3,7,8-PeCDD	74	79
13C12-1,2,3,4,7,8-HxCDD	80	87
13C12-1,2,3,6,7,8-HxCDD	115	107
13C12-1,2,3,4,6,7,8-HpCDD	73	75
13C12-OCDD	76	65
13C12-2,3,7,8-TCDF	76	80
13C12-1,2,3,7,8-PeCDF	84	87
13C12-2,3,4,7,8-PeCDF	86	89
13C12-1,2,3,4,7,8-HxCDF	94	89
13C12-1,2,3,6,7,8-HxCDF	108	111
13C12-2,3,4,6,7,8-HxCDF	96	95
13C12-1,2,3,7,8,9-HxCDF	88	91
13C12-1,2,3,4,6,7,8-HpCDF	87	91
13C12-1,2,3,4,7,8,9-HpCDF	82	78
Cleanup Standard		
37Cl4-2,3,7,8-TCDD (Cleanup)	16	29
Homologue Group Totals	**pg/g**	
Total-TCDD	<8.6	
Total-PeCDD	<1.5	
Total-HxCDD	<2.2	
Total-HpCDD	<1.8	
Total-TCDF	1.31	
Total-PeCDF	2.26	
Total-HxCDF	2.73	
Total-HpCDF	<1.7	
Toxic Equivalency - (WHO 2005)		
Lower Bound PCDD/F TEQ (WHO 2005)	0.273	
Mid Point PCDD/F TEQ (WHO 2005)	8.01	
Upper Bound PCDD/F TEQ (WHO 2005)	12.8	

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Sample Analysis Report

Sample Name	**AB80320**	Sampling Date	6-May-15		Approved:
ALS Sample ID	L1623923-1	Extraction Date	16-Jun-15		*A.Ali*
Analysis Method	EPA 1613B	Sample Size	1	g	--e-signature--
Analysis Type	Sample	Percent Moisture	n/a		17-Jul-2015
Sample Matrix	Wax pellets	Split Ratio	1		

Run Information	**Run 1**
Filename	1-150715A S:5
Run Date	15-Jul-15 15:39
Final Volume	25 uL
Dilution Factor	1
Analysis Units	pg/g
Instrument - Column	HRMS-1 DB5MS60USE364727H

Target Analytes	**TEF (WHO 2005)**	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**
2,3,7,8-TCDD	1	NotFnd	<1.3	1.3	U		13
1,2,3,7,8-PeCDD	1	31:29	<1.0	0.59	M,J,R	1.0	63
1,2,3,4,7,8-HxCDD	0.1	NotFnd	<0.95	0.95	M,U		63
1,2,3,6,7,8-HxCDD	0.1	33:40	<1.0	0.88	J,R	1.0	63
1,2,3,7,8,9-HxCDD	0.1	NotFnd	<0.90	0.90	U		63
1,2,3,4,6,7,8-HpCDD	0.01	35:12	<0.91	0.68	J,R	0.91	63
OCDD	0.0003	36:21	<0.87	0.87	U	0.62	130
2,3,7,8-TCDF	0.1	NotFnd	<0.79	0.79	U		13
1,2,3,7,8-PeCDF	0.03	NotFnd	<0.74	0.74	U		63
2,3,4,7,8-PeCDF	0.3	NotFnd	<0.62	0.62	U		63
1,2,3,4,7,8-HxCDF	0.1	33:07	<0.67	0.67	U		63
1,2,3,6,7,8-HxCDF	0.1	NotFnd	<0.65	0.65	U		63
2,3,4,6,7,8-HxCDF	0.1	33:31	<0.68	0.67	M,J,R	0.68	63
1,2,3,7,8,9-HxCDF	0.1	33:56	1.05	0.94	J,B		63
1,2,3,4,6,7,8-HpCDF	0.01	34:42	<0.55	0.49	J,R	0.55	63
1,2,3,4,7,8,9-HpCDF	0.01	NotFnd	<0.75	0.75	U		63
OCDF	0.0003	36:26	1.24	0.75	M,J		130

Extraction Standards	**pg**		**% Rec**	**Limits**	
13C12-2,3,7,8-TCDD	2000	26:46	54	25-164	
13C12-1,2,3,7,8-PeCDD	2000	31:28	84	25-181	
13C12-1,2,3,4,7,8-HxCDD	2000	33:37	85	32-141	R
13C12-1,2,3,6,7,8-HxCDD	2000	33:40	107	28-130	
13C12-1,2,3,4,6,7,8-HpCDD	2000	35:12	68	23-140	
13C12-OCDD	4000	36:22	56	17-157	
13C12-2,3,7,8-TCDF	2000	25:51	83	24-169	
13C12-1,2,3,7,8-PeCDF	2000	30:27	89	24-185	
13C12-2,3,4,7,8-PeCDF	2000	31:15	95	21-178	
13C12-1,2,3,4,7,8-HxCDF	2000	33:06	93	26-152	
13C12-1,2,3,6,7,8-HxCDF	2000	33:11	108	26-123	
13C12-2,3,4,6,7,8-HxCDF	2000	33:31	97	29-147	
13C12-1,2,3,7,8,9-HxCDF	2000	33:56	92	28-136	
13C12-1,2,3,4,6,7,8-HpCDF	2000	34:42	85	28-143	
13C12-1,2,3,4,7,8,9-HpCDF	2000	35:24	73	26-138	

Cleanup Standard	**pg**				
37Cl4-2,3,7,8-TCDD (Cleanup)	40	26:48	52	35-197	

Homologue Group Totals	**# peaks**	**Conc. pg/g**	**EDL pg/g**		
Total-TCDD	0	<1.3	1.3	U	13
Total-PeCDD	0	<0.59	0.59	U	63
Total-HxCDD	0	<0.95	0.95	U	63
Total-HpCDD	0	<0.68	0.68	U	63
Total-TCDF	0	<0.79	0.79	U	13
Total-PeCDF	0	<0.74	0.74	U	63
Total-HxCDF	3	1.97	0.94		63
Total-HpCDF	0	<0.75	0.75	U	63

Toxic Equivalency - (WHO 2005)	**pg/g**
Lower Bound PCDD/F TEQ (WHO 2005)	0.105
Mid Point PCDD/F TEQ (WHO 2005)	2.24
Upper Bound PCDD/F TEQ (WHO 2005)	3.20

EDL	Indicates the Estimated Detection Limit, based on the measured background noise for this target in this sample.
TEF	Indicates the Toxic Equivalency Factor TEQ Indicates the Toxic Equivalenc
M	Indicates that a peak has been manually integrated.
U	Indicates that this compound was not detected above the MDL.
J	indicates that a target analyte was detected below the calibrated range.
R	Indicates that the ion abundance ratio for this compound did not meet the acceptance criterion.
B	Indicates that this target was detected in the blank at greater than 10% of the sample concentration.

ALS Life Sciences

Laboratory Method Blank Analysis Report

Sample Name	**Method Blank**	Sampling Date	n/a		Approved:
ALS Sample ID	WG2108486-1	Extraction Date	16-Jun-15		*A.Ali*
Analysis Method	EPA 1613B	Sample Size	1	g	--e-signature--
Analysis Type	Blank	Percent Moisture	n/a		17-Jul-2015
Sample Matrix	QC	Split Ratio	1		

Run Information	**Run 1**
Filename	1-150715A S:4
Run Date	15-Jul-15 14:58
Final Volume	25 uL
Dilution Factor	1
Analysis Units	pg/g
Instrument - Column	HRMS-1 DB5MS60USE364727H

Target Analytes	**TEF (WHO 2005)**	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**
2,3,7,8-TCDD	1	NotFnd	<8.6	8.6	U		13
1,2,3,7,8-PeCDD	1	31:29	<1.9	1.5	M,J,R	1.9	63
1,2,3,4,7,8-HxCDD	0.1	NotFnd	<2.2	2.2	U		63
1,2,3,6,7,8-HxCDD	0.1	NotFnd	<2.0	2.0	U		63
1,2,3,7,8,9-HxCDD	0.1	NotFnd	<2.1	2.1	U		63
1,2,3,4,6,7,8-HpCDD	0.01	35:11	<2.7	1.8	M,J,R	2.7	63
OCDD	0.0003	36:22	<6.4	3.3	M,J,R	6.4	130
2,3,7,8-TCDF	0.1	25:52	<1.3	1.3	U	0.11	13
1,2,3,7,8-PeCDF	0.03	30:27	<1.7	1.1	M,J,R	1.7	63
2,3,4,7,8-PeCDF	0.3	31:15	<2.3	0.98	M,J,R	2.3	63
1,2,3,4,7,8-HxCDF	0.1	NotFnd	<0.88	0.88	U		63
1,2,3,6,7,8-HxCDF	0.1	33:10	<1.4	0.84	J,R	1.4	63
2,3,4,6,7,8-HxCDF	0.1	33:31	<1.9	0.88	M,J,R	1.9	63
1,2,3,7,8,9-HxCDF	0.1	33:56	2.73	1.2	M,J		63
1,2,3,4,6,7,8-HpCDF	0.01	NotFnd	<1.2	1.2	U		63
1,2,3,4,7,8,9-HpCDF	0.01	NotFnd	<1.7	1.7	U		63
OCDF	0.0003	36:27	<4.1	3.6	J,R	4.1	130

Extraction Standards	**pg**		**% Rec**	**Limits**
13C12-2,3,7,8-TCDD	2000	26:45	17	25-164
13C12-1,2,3,7,8-PeCDD	2000	31:27	74	25-181
13C12-1,2,3,4,7,8-HxCDD	2000	33:36	80	32-141
13C12-1,2,3,6,7,8-HxCDD	2000	33:39	115	28-130
13C12-1,2,3,4,6,7,8-HpCDD	2000	35:11	73	23-140
13C12-OCDD	4000	36:22	76	17-157
13C12-2,3,7,8-TCDF	2000	25:50	76	24-169
13C12-1,2,3,7,8-PeCDF	2000	30:26	84	24-185
13C12-2,3,4,7,8-PeCDF	2000	31:13	86	21-178
13C12-1,2,3,4,7,8-HxCDF	2000	33:05	94	26-152
13C12-1,2,3,6,7,8-HxCDF	2000	33:10	108	26-123
13C12-2,3,4,6,7,8-HxCDF	2000	33:30	96	29-147
13C12-1,2,3,7,8,9-HxCDF	2000	33:56	88	28-136
13C12-1,2,3,4,6,7,8-HpCDF	2000	34:41	87	28-143
13C12-1,2,3,4,7,8,9-HpCDF	2000	35:23	82	26-138

Cleanup Standard	**pg**			
37Cl4-2,3,7,8-TCDD (Cleanup)	40	26:46	16	35-197

Homologue Group Totals	**# peaks**	**Conc. pg/g**	**EDL pg/g**		
Total-TCDD	0	<8.6	8.6	U	13
Total-PeCDD	0	<1.5	1.5	U	63
Total-HxCDD	0	<2.2	2.2	U	63
Total-HpCDD	0	<1.8	1.8	U	63
Total-TCDF	5	1.31	1.3		13
Total-PeCDF	2	2.26	1.1		63
Total-HxCDF	1	2.73	1.2		63
Total-HpCDF	0	<1.7	1.7	U	63

Toxic Equivalency - (WHO 2005)	**pg/g**
Lower Bound PCDD/F TEQ (WHO 2005)	0.273
Mid Point PCDD/F TEQ (WHO 2005)	8.01
Upper Bound PCDD/F TEQ (WHO 2005)	12.8

EDL	Indicates the Estimated Detection Limit, based on the measured background noise for this target in this sample.
TEF	Indicates the Toxic Equivalency Factor TEQ Indicates the Toxic Equivalenc
M	Indicates that a peak has been manually integrated.
U	Indicates that this compound was not detected above the MDL.
J	indicates that a target analyte was detected below the calibrated range.
R	Indicates that the ion abundance ratio for this compound did not meet the acceptance criterion.

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Laboratory Control Sample Analysis Report

Sample Name	**Laboratory Control Sample**	Sampling Date	n/a		Approved:
ALS Sample ID	WG2108486-2	Extraction Date	16-Jun-15		*A.All*
Analysis Method	EPA 1613B	Sample Size	1	n/a	--e-signature--
Analysis Type	LCS	Percent Moisture	n/a		17-Jul-2015
Sample Matrix	QC	Split Ratio	1		

Run Information	**Run 1**
Filename	1-150715A S:2
Run Date	15-Jul-15 13:34
Final Volume	25 uL
Dilution Factor	1
Analysis Units	%
Instrument - Column	HRMS-1 DB5MS60USE364727H

Target Analytes	**pg**	**Ret. Time**	**% Rec**	**Limits**	**Flags**
2,3,7,8-TCDD	200	26:48	93	67-158	
1,2,3,7,8-PeCDD	1000	31:29	98	70-142	
1,2,3,4,7,8-HxCDD	1000	33:38	101	70-164	
1,2,3,6,7,8-HxCDD	1000	33:40	90	76-134	
1,2,3,7,8,9-HxCDD	1000	33:48	97	64-162	
1,2,3,4,6,7,8-HpCDD	1000	35:12	98	70-140	
OCDD	2000	36:23	90	78-144	
2,3,7,8-TCDF	200	25:52	89	75-158	
1,2,3,7,8-PeCDF	1000	30:28	96	80-134	
2,3,4,7,8-PeCDF	1000	31:15	89	68-160	
1,2,3,4,7,8-HxCDF	1000	33:07	97	72-134	
1,2,3,6,7,8-HxCDF	1000	33:11	96	84-130	
2,3,4,6,7,8-HxCDF	1000	33:32	100	78-130	
1,2,3,7,8,9-HxCDF	1000	33:57	97	70-156	
1,2,3,4,6,7,8-HpCDF	1000	34:42	93	82-122	
1,2,3,4,7,8,9-HpCDF	1000	35:24	94	78-138	
OCDF	2000	36:26	98	63-170	
Extraction Standards	**pg**		**% Rec**	**Limits**	
13C12-2,3,7,8-TCDD	2000	26:47	31	20-175	
13C12-1,2,3,7,8-PeCDD	2000	31:28	79	21-227	
13C12-1,2,3,4,7,8-HxCDD	2000	33:37	87	21-193	
13C12-1,2,3,6,7,8-HxCDD	2000	33:40	107	25-163	
13C12-1,2,3,4,6,7,8-HpCDD	2000	35:12	75	26-166	
13C12-OCDD	4000	36:22	65	13-138	
13C12-2,3,7,8-TCDF	2000	25:51	80	22-152	
13C12-1,2,3,7,8-PeCDF	2000	30:27	87	21-192	
13C12-2,3,4,7,8-PeCDF	2000	31:15	89	13-328	
13C12-1,2,3,4,7,8-HxCDF	2000	33:07	89	19-202	
13C12-1,2,3,6,7,8-HxCDF	2000	33:11	111	21-159	
13C12-2,3,4,6,7,8-HxCDF	2000	33:31	95	17-205	
13C12-1,2,3,7,8,9-HxCDF	2000	33:57	91	22-176	
13C12-1,2,3,4,6,7,8-HpCDF	2000	34:42	91	21-158	
13C12-1,2,3,4,7,8,9-HpCDF	2000	35:24	78	20-186	
Cleanup Standard	**pg**				
37Cl4-2,3,7,8-TCDD (Cleanup)	40	26:48	29	31-191	

ALS Life Sciences
1435 Norjohn Court, Unit 1, Burlington, ON, Canada L7L 0E6
Phone: 905-331-3111, FAX: 905-331-4567

Certificate of Analysis

ALS Project Contact:	Ron McLeod	**Client Name:**	ALS Environmental
ALS Project ID:	ALS800	**Client Address:**	10450 Stancliff Road, Suite 210
ALS WO#:	L1623923		Houston, Texas 77099-4338
Date of Report	17-Jul-15		
Date of Sample Receipt	9-Jun-15	**Client Contact:**	Nicole Brown
		Client Project ID:	E1500506

COMMENTS: **PCB Congeners by EPA 1668A**

PCB Congener Group Totals and Total PCB are a sum of detected values, including EMPC values, consistent with USEPA CLP SOW CBC1.2

The 13C12-PCB-3 (in L1623923-1) and 13C12-PCB-1 (in the method blank) extraction standard recoveries were below the 1668A control limits but were well above the 1668C control limits. Due to isotope dilution technique there is no significant impact to data quality from these lower recoveries.

Ron McLeod, PhD
Director Special Chemistries & Air Toxics, Eastern Canada

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Sample Analysis summary Report

Sample Name	**AB80320**
ALS Sample ID	L1623923-1
Sample Size	1.01
Sample size units	g
Percent Moisture	n/a
Sample Matrix	Wax pellets
Sampling Date	6-May-15
Extraction Date	n/a

Target Analytes	**pg/g**
PCB-001	7.49
PCB-002	7.48
PCB-003	<10
PCB-004	10.4
PCB-010	<0.44
PCB-009	<9.5
PCB-007	0.874
PCB-006	3.22
PCB-005	<0.45
PCB-008	19.0
PCB-014	<0.57
PCB-011	76.9
PCB-012/013	<0.67
PCB-015	<5.5
PCB-019	4.25
PCB-018/030	33.3
PCB-017	14.0
PCB-027	1.78
PCB-024	<0.22
PCB-016	14.8
PCB-032	9.92
PCB-034	<0.42
PCB-023	<0.38
PCB-026/029	6.01
PCB-025	1.89
PCB-031	41.0
PCB-020/028	42.0
PCB-021/033	22.6
PCB-022	13.8
PCB-036	<0.40
PCB-039	<0.45
PCB-038	<0.39
PCB-035	0.911
PCB-037	3.87
PCB-054	<0.39
PCB-050/053	7.46
PCB-045/051	10.4
PCB-046	3.30
PCB-052	50.7
PCB-073	<0.37
PCB-043	<1.8
PCB-049/069	23.1
PCB-048	10.6
PCB-044/047/065	43.2
PCB-059/062/075	3.26
PCB-042	10.1
PCB-040/041/071	23.1
PCB-064	16.5
PCB-072	<0.89
PCB-068	<0.74
PCB-057	<0.88
PCB-058	<0.91
PCB-067	<0.74
PCB-063	<0.85
PCB-061/070/074/076	45.2
PCB-066	24.9
PCB-055	<0.84
PCB-056	10.8
PCB-060	7.27
PCB-080	<0.83
PCB-079	<0.82
PCB-078	<0.88
PCB-081	<0.92
PCB-077	<0.98
PCB-104	0.240
PCB-096	<0.22
PCB-103	<0.17
PCB-094	<0.19
PCB-095	15.8
PCB-093/098/100/102	1.55

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Sample Analysis summary Report

Sample Name	**AB80320**
ALS Sample ID	L1623923-1
PCB-088/091	<3.2
PCB-084	5.97
PCB-089	<0.71
PCB-121	<0.12
PCB-092	<2.1
PCB-090/101/113	13.9
PCB-083/099	9.21
PCB-112	<0.13
PCB-086/087/097/108/119/125	11.1
PCB-085/110/115/116/117	17.2
PCB-082	2.72
PCB-111	<0.13
PCB-120	<0.13
PCB-107/124	<4.3
PCB-109	<4.3
PCB-123	<4.3
PCB-106	<4.1
PCB-118	11.4
PCB-122	<4.3
PCB-114	<4.3
PCB-105	<4.9
PCB-127	<4.1
PCB-126	<6.2
PCB-155	<1.0
PCB-152	<0.19
PCB-150	<0.17
PCB-136	1.35
PCB-145	<0.19
PCB-148	<0.25
PCB-135/151	1.38
PCB-154	<0.22
PCB-144	0.471
PCB-147/149	5.77
PCB-134/143	<0.41
PCB-139/140	<0.36
PCB-131	<0.40
PCB-142	<0.42
PCB-132	2.82
PCB-133	<0.40
PCB-165	<0.30
PCB-146	0.831
PCB-161	<0.28
PCB-153/168	5.56
PCB-141	<1.3
PCB-130	<0.47
PCB-137/164	1.02
PCB-129/138/163	7.55
PCB-160	<0.27
PCB-158	<0.57
PCB-128/166	<0.49
PCB-159	<0.26
PCB-162	<0.24
PCB-167	0.517
PCB-156/157	1.01
PCB-169	<0.26
PCB-188	<3.0
PCB-179	<4.0
PCB-184	<3.4
PCB-176	<3.8
PCB-186	<3.9
PCB-178	<5.1
PCB-175	<4.8
PCB-187	<4.0
PCB-182	<4.5
PCB-183	<4.5
PCB-185	<4.6
PCB-174	<4.9
PCB-177	<5.0
PCB-181	<4.5
PCB-171/173	<5.0
PCB-172	<4.8
PCB-192	<3.6
PCB-180/193	<3.7
PCB-191	<3.3
PCB-170	<4.5
PCB-190	<2.8
PCB-189	<5.9
PCB-202	<0.21
PCB-201	<0.21

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Sample Analysis summary Report

Sample Name	**AB80320**
ALS Sample ID	L1623923-1
PCB-204	<0.20
PCB-197	<0.19
PCB-200	<0.22
PCB-198/199	<0.50
PCB-196	<0.29
PCB-203	<0.28
PCB-195	<0.39
PCB-194	<0.37
PCB-205	<0.34
PCB-208	<0.82
PCB-207	<0.92
PCB-206	<1.7
PCB-209	<4.4
Extraction Standards	**%**
13C12-PCB-001	28
13C12-PCB-003	11
13C12-PCB-004	53
13C12-PCB-015	66
13C12-PCB-019	62
13C12-PCB-037	73
13C12-PCB-054	60
13C12-PCB-081	78
13C12-PCB-077	78
13C12-PCB-104	74
13C12-PCB-123	81
13C12-PCB-118	82
13C12-PCB-114	80
13C12-PCB-105	80
13C12-PCB-126	64
13C12-PCB-155	62
13C12-PCB-167	64
13C12-PCB-156/157	69
13C12-PCB-169	79
13C12-PCB-188	71
13C12-PCB-189	64
13C12-PCB-202	55
13C12-PCB-205	93
13C12-PCB-208	96
13C12-PCB-206	74
13C12-PCB-209	67
Cleanup Standards	**%**
13C12-PCB-028	71
13C12-PCB-111	81
13C12-PCB-178	73
Homologue Group Totals	**pg/g**
Total MonoCB	25.0
Total DiCB	125
Total TriCB	210
Total TetraCB	292
Total PentaCB	100
Total HexaCB	32.1
Total HeptaCB	0
Total OctaCB	0.780
Total NonaCB	0
DecaCB	0
Total PCB	785
Toxic Equivalency - (WHO 2005)	**pg/g**
Lower Bound PCB TEQ (WHO 2005)	0.000388
Mid Point PCB TEQ (WHO 2005)	0.315
Upper Bound PCB TEQ (WHO 2005)	0.629

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Quality Control Summary Report

Sample Name	Method Blank	Laboratory Control Sample
ALS Sample ID	WG2108486-1	WG2108486-2
Sample Size	1	1
Sample size units	g	n/a
Percent Solids	n/a	n/a
Sample Matrix	QC	QC
Sampling Date	n/a	n/a
Extraction Date	n/a	n/a
Target Analytes	**pg/g**	**%**
PCB-001	<5.3	113
PCB-002	2.99	
PCB-003	<4.1	111
PCB-004	9.82	115
PCB-010	<0.45	
PCB-009	<8.4	
PCB-007	<1.4	
PCB-006	<0.39	
PCB-005	<0.44	
PCB-008	10.5	
PCB-014	<0.35	
PCB-011	<34	
PCB-012/013	0.973	
PCB-015	<2.3	113
PCB-019	<0.87	115
PCB-018/030	6.24	
PCB-017	2.92	
PCB-027	0.336	
PCB-024	<0.13	
PCB-016	<2.9	
PCB-032	<1.4	
PCB-034	<0.20	
PCB-023	<0.19	
PCB-026/029	<0.88	
PCB-025	<0.34	
PCB-031	3.99	
PCB-020/028	4.59	
PCB-021/033	2.76	
PCB-022	1.59	
PCB-036	<0.19	
PCB-039	<0.22	
PCB-038	<0.19	
PCB-035	<0.25	
PCB-037	1.12	99
PCB-054	<0.15	114
PCB-050/053	<0.36	
PCB-045/051	<1.3	
PCB-046	<0.27	
PCB-052	2.79	
PCB-073	<0.16	
PCB-043	<0.24	
PCB-049/069	1.07	
PCB-048	<0.31	
PCB-044/047/065	3.96	
PCB-059/062/075	<0.16	
PCB-042	<0.47	
PCB-040/041/071	<0.51	
PCB-064	<0.60	
PCB-072	<0.37	
PCB-068	<0.31	
PCB-057	<0.36	
PCB-058	<0.38	
PCB-067	<0.31	
PCB-063	<0.35	
PCB-061/070/074/076	<0.43	
PCB-066	<0.44	
PCB-055	<0.35	
PCB-056	<0.37	
PCB-060	<0.36	
PCB-080	<0.34	
PCB-079	<0.34	
PCB-078	<0.36	
PCB-081	<0.45	107
PCB-077	<0.35	106
PCB-104	<0.11	107
PCB-096	<0.11	
PCB-103	<0.11	
PCB-094	<0.12	
PCB-095	<0.75	
PCB-093/098/100/102	<0.11	

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Quality Control Summary Report

Sample Name	Method Blank	Laboratory Control Sample
ALS Sample ID	WG2108486-1	WG2108486-2
PCB-088/091	0.189	
PCB-084	0.430	
PCB-089	<0.13	
PCB-121	<0.080	
PCB-092	<0.12	
PCB-090/101/113	0.970	
PCB-083/099	<0.13	
PCB-112	<0.081	
PCB-086/087/097/108/119/125	<0.43	
PCB-085/110/115/116/117	<0.67	
PCB-082	<0.14	
PCB-111	<0.082	
PCB-120	<0.082	
PCB-107/124	<0.13	
PCB-109	<0.12	
PCB-123	<0.12	113
PCB-106	<0.13	
PCB-118	0.711	110
PCB-122	<0.14	
PCB-114	<0.15	113
PCB-105	<0.11	110
PCB-127	<0.13	
PCB-126	0.278	112
PCB-155	<0.11	109
PCB-152	<0.075	
PCB-150	<0.068	
PCB-136	<0.077	
PCB-145	<0.077	
PCB-148	<0.099	
PCB-135/151	0.184	
PCB-154	<0.087	
PCB-144	<0.098	
PCB-147/149	0.490	
PCB-134/143	<0.13	
PCB-139/140	<0.11	
PCB-131	<0.12	
PCB-142	<0.13	
PCB-132	<0.18	
PCB-133	<0.12	
PCB-165	<0.093	
PCB-146	<0.10	
PCB-161	<0.087	
PCB-153/168	<0.25	
PCB-141	<0.12	
PCB-130	<0.14	
PCB-137/164	<0.10	
PCB-129/138/163	0.699	
PCB-160	<0.082	
PCB-158	<0.080	
PCB-128/166	<0.10	
PCB-159	<0.080	
PCB-162	<0.075	
PCB-167	<0.080	109
PCB-156/157	<0.26	109
PCB-169	0.288	108
PCB-188	<0.081	108
PCB-179	<0.10	
PCB-184	<0.086	
PCB-176	<0.097	
PCB-186	<0.10	
PCB-178	<0.13	
PCB-175	<0.13	
PCB-187	0.225	
PCB-182	<0.12	
PCB-183	<0.12	
PCB-185	<0.12	
PCB-174	<0.24	
PCB-177	<0.13	
PCB-181	<0.12	
PCB-171/173	<0.13	
PCB-172	<0.13	
PCB-192	<0.11	
PCB-180/193	<0.27	
PCB-191	<0.096	
PCB-170	<0.19	
PCB-190	0.0971	
PCB-189	<0.42	114
PCB-202	<0.078	111
PCB-201	<0.11	

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Quality Control Summary Report

Sample Name	Method Blank	Laboratory Control Sample
ALS Sample ID	WG2108486-1	WG2108486-2
PCB-204	<0.10	
PCB-197	<0.10	
PCB-200	<0.12	
PCB-198/199	<0.15	
PCB-196	<0.16	
PCB-203	<0.14	
PCB-195	<0.32	
PCB-194	<0.30	
PCB-205	<0.44	108
PCB-208	<1.2	108
PCB-207	<1.2	
PCB-206	<1.9	118
PCB-209	1.18	115
Extraction Standards	**%**	**%**
13C12-PCB-001	15	30
13C12-PCB-003	42	30
13C12-PCB-004	46	35
13C12-PCB-015	49	45
13C12-PCB-019	49	42
13C12-PCB-037	58	55
13C12-PCB-054	50	38
13C12-PCB-081	64	64
13C12-PCB-077	67	68
13C12-PCB-104	58	47
13C12-PCB-123	66	67
13C12-PCB-118	39	69
13C12-PCB-114	67	68
13C12-PCB-105	70	73
13C12-PCB-126	84	78
13C12-PCB-155	60	50
13C12-PCB-167	93	82
13C12-PCB-156/157	88	81
13C12-PCB-169	79	89
13C12-PCB-188	67	65
13C12-PCB-189	50	81
13C12-PCB-202	86	73
13C12-PCB-205	84	91
13C12-PCB-208	109	82
13C12-PCB-206	110	90
13C12-PCB-209	116	78
Cleanup Standard	**%**	**%**
13C12-PCB-028	63	58
13C12-PCB-111	79	74
13C12-PCB-178	82	76
Homologue Group Totals	**pg/g**	
Total MonoCB	12.4	
Total DiCB	67.8	
Total TriCB	30.2	
Total TetraCB	12.2	
Total PentaCB	4.71	
Total HexaCB	2.54	
Total HeptaCB	1.02	
Total OctaCB	0	
Total NonaCB	0	
DecaCB	1.18	
Total PCB	132	
Toxic Equivalency - (WHO 2005)	**pg/g**	
Lower Bound PCB TEQ (WHO 2005)	0.0365	
Mid Point PCB TEQ (WHO 2005)	0.0366	
Upper Bound PCB TEQ (WHO 2005)	0.0367	

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Sample Analysis Report

Sample Name	**AB80320**	Associated Method Blank	WG2108486-1		
ALS Sample ID	L1623923-1	Sampling Date	6-May-15		
		Extraction Date	n/a	Approved:	
Analysis Method	EPA 1668C	Sample Size	1.01 g	*E. Sabljic*	
Analysis Type	Sample	Percent Moisture	n/a	--e-signature--	
Sample Matrix	Wax pellets	Split Ratio	1	17-Jul-2015	

Run Information	**Run 1**	**Run 2**
Filename	5-150710A06	5-150713A09
Run Date	10-Jul-15 16:27	13-Jul-15 16:40
Final Volume	45 ul	45 uL
Dilution Factor	1	10
Analysis Units	pg/g	pg/g
Instrument - Column	HRMS-5 SPBOCTYL55800-02B	HRMS-5 SPBOCTYL55800-02B

Target Analytes	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**
PCB-001	8:50	7.49	0.51	J		45						
PCB-002	10:16	7.48	0.70	J,B		45						
PCB-003	10:22	<10	1.5	J,R	10	45						
PCB-004	10:32	10.4	0.68	J,B		45						
PCB-010	10:39	<0.44	0.44	U	0.32	45						
PCB-009	11:49	<9.5	0.44	J,R	9.5	45						
PCB-007	11:55	0.874	0.41	J		45						
PCB-006	12:04	3.22	0.39	J		45						
PCB-005	NotFnd	<0.45	0.45	U		45						
PCB-008	12:21	19.0	0.38	J,B		45						
PCB-014	NotFnd	<0.57	0.57	U		45						
PCB-011	13:52	76.9	0.68			45						
PCB-012/013	NotFnd	<0.67	0.67	U		45						
PCB-015	14:14	<5.5	0.90	J,R	5.5	45						
PCB-019	12:32	4.25	0.30	J		45						
PCB-018/030	13:39	33.3	0.25	J,B		45						
PCB-017	13:54	14.0	0.31	J,B		45						
PCB-027	14:01	1.78	0.22	J,B		45						
PCB-024	14:07	<0.22	0.22	U	0.092	45						
PCB-016	14:11	14.8	0.36	J		45						
PCB-032	14:29	9.92	0.20	J		45						
PCB-034	NotFnd	<0.42	0.42	U		45						
PCB-023	NotFnd	<0.38	0.38	U		45						
PCB-026/029	15:28	6.01	0.46	J		45						
PCB-025	15:36	1.89	0.36	J		45						
PCB-031	15:47	41.0	0.41	J		45						
PCB-020/028	15:57	42.0	0.42	J,B		45						
PCB-021/033	16:05	22.6	0.39	J,B		45						
PCB-022	16:19	13.8	0.43	J,B		45						
PCB-036	NotFnd	<0.40	0.40	U		45						
PCB-039	NotFnd	<0.45	0.45	U		45						
PCB-038	NotFnd	<0.39	0.39	U		45						
PCB-035	17:58	0.911	0.45	J		45						
PCB-037	18:11	3.87	0.59	J,B		45						
PCB-054	NotFnd	<0.39	0.39	U		45						
PCB-050/053	15:37	7.46	0.50	J		45						
PCB-045/051	16:01	10.4	0.52	J		45						
PCB-046	16:11	3.30	0.61	J		45						
PCB-052	16:56	50.7	0.53			45						
PCB-073	NotFnd	<0.37	0.37	U		45						
PCB-043	17:04	<1.8	0.56	J,R	1.8	45						
PCB-049/069	17:13	23.1	0.42	J		45						
PCB-048	17:22	10.6	0.51	J		45						
PCB-044/047/065	17:30	43.2	0.47	J		45						
PCB-059/062/075	17:40	3.26	0.37	J		45						
PCB-042	17:48	10.1	0.52	J		45						
PCB-040/041/071	18:03	23.1	0.51	J		45						
PCB-064	18:11	16.5	0.37	J		45						
PCB-072	NotFnd	<0.89	0.89	U		45						
PCB-068	NotFnd	<0.74	0.74	U		45						
PCB-057	NotFnd	<0.88	0.88	U		45						
PCB-058	NotFnd	<0.91	0.91	U		45						
PCB-067	19:14	<0.74	0.74	U	0.41	45						
PCB-063	19:22	<0.85	0.85	U	0.81	45						
PCB-061/070/074/076	19:34	45.2	0.86			45						
PCB-066	19:44	24.9	0.88	J		45						
PCB-055	19:53	<0.84	0.84	U	0.086	45						
PCB-056	20:06	10.8	0.89	J		45						
PCB-060	20:13	7.27	0.86	J		45						
PCB-080	NotFnd	<0.83	0.83	U		45						
PCB-079	NotFnd	<0.82	0.82	U		45						
PCB-078	NotFnd	<0.88	0.88	U		45						
PCB-081	NotFnd	<0.92	0.92	U		45						
PCB-077	NotFnd	<0.98	0.98	U		45						
PCB-104	17:28	0.240	0.077	J		45						
PCB-096	17:41	<0.22	0.068	J,R	0.22	45						

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Sample Analysis Report

Sample Name	**AB80320**	Associated Method Blank	WG2108486-1		
ALS Sample ID	L1623923-1	Sampling Date	6-May-15		
		Extraction Date	n/a	Approved:	
Analysis Method	EPA 1668C	Sample Size	1.01 g	*E. Sabljic*	
Analysis Type	Sample	Percent Moisture	n/a	--e-signature--	
Sample Matrix	Wax pellets	Split Ratio	1	17-Jul-2015	

Run Information	**Run 1**	**Run 2**
Filename	5-150710A06	5-150713A09
Run Date	10-Jul-15 16:27	13-Jul-15 16:40
Final Volume	45 ul	45 uL
Dilution Factor	1	10
Analysis Units	pg/g	pg/g
Instrument - Column	HRMS-5 SPBOCTYL55800-02B	HRMS-5 SPBOCTYL55800-02B

Target Analytes	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**
PCB-103	18:41	<0.17	0.17	U	0.11	45						
PCB-094	NotFnd	<0.19	0.19	U		45						
PCB-095	19:04	15.8	0.20	J		45						
PCB-093/098/100/102	19:14	1.55	0.17	M,J		45						
PCB-088/091	19:32	<3.2	0.18	J,R	3.2	45						
PCB-084	19:40	5.97	0.21	J		45						
PCB-089	19:56	<0.71	0.20	J,R	0.71	45						
PCB-121	20:03	<0.12	0.12	U	0.036	45						
PCB-092	20:18	<2.1	0.19	J,R	2.1	45						
PCB-090/101/113	20:37	13.9	0.17	J		45						
PCB-083/099	20:55	9.21	0.19	J		45						
PCB-112	NotFnd	<0.13	0.13	U		45						
PCB-086/087/097/108/119/125	21:14	11.1	0.16	M,J		45						
PCB-085/110/115/116/117	21:39	17.2	0.14	M,J		45						
PCB-082	21:52	2.72	0.21	J		45						
PCB-111	NotFnd	<0.13	0.13	U		45						
PCB-120	NotFnd	<0.13	0.13	U		45						
PCB-107/124							NotFnd	<4.3	4.3	U		450
PCB-109							NotFnd	<4.3	4.3	U		450
PCB-123							NotFnd	<4.3	4.3	U		450
PCB-106							NotFnd	<4.1	4.1	U		450
PCB-118							23:17	11.4	4.2	J		450
PCB-122							NotFnd	<4.3	4.3	U		450
PCB-114							NotFnd	<4.3	4.3	U		450
PCB-105							23:55	<4.9	4.6	J,R	4.9	450
PCB-127							NotFnd	<4.1	4.1	U		450
PCB-126							NotFnd	<6.2	6.2	U		450
PCB-155	20:30	<1.0	0.19	J,R	1.0	45						
PCB-152	NotFnd	<0.19	0.19	U		45						
PCB-150	NotFnd	<0.17	0.17	U		45						
PCB-136	20:55	1.35	0.19	J		45						
PCB-145	NotFnd	<0.19	0.19	U		45						
PCB-148	21:46	<0.25	0.25	U	0.077	45						
PCB-135/151	22:10	1.38	0.25	J,B		45						
PCB-154	NotFnd	<0.22	0.22	U		45						
PCB-144	22:26	0.471	0.24	J		45						
PCB-147/149	22:37	5.77	0.36	M,J		45						
PCB-134/143	22:45	<0.41	0.41	U	0.35	45						
PCB-139/140	22:54	<0.36	0.36	U	0.21	45						
PCB-131	NotFnd	<0.40	0.40	U		45						
PCB-142	NotFnd	<0.42	0.42	U		45						
PCB-132	23:18	2.82	0.40	J		45						
PCB-133	23:32	<0.40	0.40	U	0.10	45						
PCB-165	NotFnd	<0.30	0.30	U		45						
PCB-146	23:51	0.831	0.33	J		45						
PCB-161	NotFnd	<0.28	0.28	U		45						
PCB-153/168	24:10	5.56	0.30	J		45						
PCB-141	24:17	<1.3	0.40	J,R	1.3	45						
PCB-130	24:31	<0.47	0.44	J,R	0.47	45						
PCB-137/164	24:39	1.02	0.33	J		45						
PCB-129/138/163	24:50	7.55	0.36	J		45						
PCB-160	NotFnd	<0.27	0.27	U		45						
PCB-158	25:02	<0.57	0.26	J,R	0.57	45						
PCB-128/166	25:31	<0.49	0.33	J,R	0.49	45						
PCB-159	NotFnd	<0.26	0.26	U		45						
PCB-162	NotFnd	<0.24	0.24	U		45						
PCB-167	26:23	0.517	0.30	J		45						
PCB-156/157	26:59	1.01	0.32	J		45						
PCB-169	NotFnd	<0.26	0.26	U		45						
PCB-188							NotFnd	<3.0	3.0	U		450
PCB-179							NotFnd	<4.0	4.0	U		450
PCB-184							NotFnd	<3.4	3.4	U		450
PCB-176							NotFnd	<3.8	3.8	U		450
PCB-186							NotFnd	<3.9	3.9	U		450
PCB-178							NotFnd	<5.1	5.1	U		450
PCB-175							NotFnd	<4.8	4.8	U		450
PCB-187							25:32	<4.0	4.0	U		450

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Sample Analysis Report

Sample Name	**AB80320**	Associated Method Blank	WG2108486-1		
ALS Sample ID	L1623923-1	Sampling Date	6-May-15		
		Extraction Date	n/a	Approved:	
Analysis Method	EPA 1668C	Sample Size	1.01 g	*E. Sabljic*	
Analysis Type	Sample	Percent Moisture	n/a	--e-signature--	
Sample Matrix	Wax pellets	Split Ratio	1	17-Jul-2015	

Run Information	**Run 1**	**Run 2**
Filename	5-150710A06	5-150713A09
Run Date	10-Jul-15 16:27	13-Jul-15 16:40
Final Volume	45 ul	45 uL
Dilution Factor	1	10
Analysis Units	pg/g	pg/g
Instrument - Column	HRMS-5 SPBOCTYL55800-02B	HRMS-5 SPBOCTYL55800-02B

Target Analytes	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**
PCB-182							25:37	<4.5	4.5	U	2.3	450
PCB-183							NotFnd	<4.5	4.5	U		450
PCB-185							NotFnd	<4.6	4.6	U		450
PCB-174							NotFnd	<4.9	4.9	U		450
PCB-177							NotFnd	<5.0	5.0	U		450
PCB-181							26:27	<4.5	4.5	U	0.45	450
PCB-171/173							NotFnd	<5.0	5.0	U		450
PCB-172							27:20	<4.8	4.8	U	2.2	450
PCB-192							NotFnd	<3.6	3.6	U		450
PCB-180/193							NotFnd	<3.7	3.7	U		450
PCB-191							NotFnd	<3.3	3.3	U		450
PCB-170							NotFnd	<4.5	4.5	U		450
PCB-190							NotFnd	<2.8	2.8	U		450
PCB-189							NotFnd	<5.9	5.9	U		450
PCB-202	NotFnd	<0.21	0.21	U		45						
PCB-201	NotFnd	<0.21	0.21	U		45						
PCB-204	NotFnd	<0.20	0.20	U		45						
PCB-197	NotFnd	<0.19	0.19	U		45						
PCB-200	NotFnd	<0.22	0.22	U		45						
PCB-198/199	28:39	<0.50	0.29	J,R	0.50	45						
PCB-196	29:00	<0.29	0.29	U	0.21	45						
PCB-203	29:06	<0.28	0.27	J,R	0.28	45						
PCB-195	NotFnd	<0.39	0.39	U		45						
PCB-194	31:02	<0.37	0.37	U	0.25	45						
PCB-205	NotFnd	<0.34	0.34	U		45						
PCB-208	NotFnd	<0.82	0.82	U		45						
PCB-207	NotFnd	<0.92	0.92	U		45						
PCB-206	NotFnd	<1.7	1.7	U		45						
PCB-209							NotFnd	<4.4	4.4	U		450

Extraction Standards	**pg**		**%**	**Limits**		**%**
13C12-PCB-001	2000	8:50	28	25-150		
13C12-PCB-003	2000	10:23	11	25-150		
13C12-PCB-004	2000	10:31	53	25-150		
13C12-PCB-015	2000	14:14	66	25-150		
13C12-PCB-019	2000	12:31	62	25-150		
13C12-PCB-037	2000	18:11	73	25-150		
13C12-PCB-054	2000	14:22	60	25-150		
13C12-PCB-081	2000	21:46	78	25-150		
13C12-PCB-077	2000	22:04	78	25-150		
13C12-PCB-104	2000	17:27	74	25-150		
13C12-PCB-123	2000	23:03	81	25-150		
13C12-PCB-118	2000	23:14	82	25-150		
13C12-PCB-114	2000	23:31	80	25-150		
13C12-PCB-105	2000	23:52	80	25-150		
13C12-PCB-126	2000			25-150	25:31	64
13C12-PCB-155	2000	20:28	62	25-150		
13C12-PCB-167	2000	26:22	64	25-150		
13C12-PCB-156/157	4000	26:59	69	25-150		
13C12-PCB-169	2000	28:39	79	25-150		
13C12-PCB-188	2000	23:28	71	25-150		
13C12-PCB-189	2000			25-150	29:57	64
13C12-PCB-202	2000	26:14	55	25-150		
13C12-PCB-205	2000	31:18	93	25-150		
13C12-PCB-208	2000	29:39	96	25-150		
13C12-PCB-206	2000	32:22	74	25-150		
13C12-PCB-209	2000			25-150	33:32	67

Cleanup Standards	**pg**		**%**	
13C12-PCB-028	2000	15:56	71	30-135
13C12-PCB-111	2000	22:00	81	30-135
13C12-PCB-178	2000	25:02	73	30-135

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Sample Analysis Report

Sample Name	**AB80320**	Associated Method Blank	WG2108486-1	
ALS Sample ID	L1623923-1	Sampling Date	6-May-15	
		Extraction Date	n/a	Approved:
Analysis Method	EPA 1668C	Sample Size	1.01 g	*E. Sabljic*
Analysis Type	Sample	Percent Moisture	n/a	--e-signature--
Sample Matrix	Wax pellets	Split Ratio	1	17-Jul-2015

Run Information	**Run 1**	**Run 2**
Filename	5-150710A06	5-150713A09
Run Date	10-Jul-15 16:27	13-Jul-15 16:40
Final Volume	45 ul	45 uL
Dilution Factor	1	10
Analysis Units	pg/g	pg/g
Instrument - Column	HRMS-5 SPBOCTYL55800-02B	HRMS-5 SPBOCTYL55800-02B

Target Analytes	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**
Homologue Group Totals												
Total MonoCB		25.0	0.51	J		45						
Total DiCB		125	0.38	J		45						
Total TriCB		210	0.2	J		45						
Total TetraCB		292	0.37	J		45						
Total PentaCB		100	0.068	J		45						
Total HexaCB		32.1	0.17	J		45						
Total HeptaCB		0	2.8	U		45						
Total OctaCB		0.780	0.19	J		45						
Total NonaCB		0	0.82	U		45						
DecaCB		0	4.4	U		45						
Total PCB		785		J								

Toxic Equivalency - (WHO 2005)	**pg/g**
Lower Bound PCB TEQ (WHO 2005)	0.000388
Mid Point PCB TEQ (WHO 2005)	0.315
Upper Bound PCB TEQ (WHO 2005)	0.629

EDL	Indicates the Estimated Detection Limit, based on the measured background noise for this target in this sample.
TEF	Indicates the Toxic Equivalency Factor TEQ Indicates the Toxic Equivalency
M	Indicates that a peak has been manually integrated.
U	Indicates that the analyte was not detcted at or above the reported estimated detection limit.
J	indicates that the analyte was positively identifed. The associated numerical result is an estimate.
R	Indicates that the ion abundance ratio for this analyte did not meet the control limit. The reported value represents an estimated concentration.
B	Indicates that this target was detected in the blank at greater than 10% of the sample concentration.

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Laboratory Method Blank Analysis Report

Sample Name	**Method Blank**				
ALS Sample ID	WG2108486-1	Sampling Date	n/a		
		Extraction Date	n/a		Approved:
Analysis Method	EPA 1668C	Sample Size	1	g	*E. Sabljic*
Analysis Type	Blank	Percent Moisture	n/a		--e-signature--
Sample Matrix	QC	Split Ratio	1		17-Jul-2015

Run Information	**Run 1**
Filename	5-150710A05
Run Date	10-Jul-15 15:48
Final Volume	45 ul
Dilution Factor	1
Analysis Units	pg/g
Instrument - Column	HRMS-5 SPBOCTYL55800-02B

Target Analytes	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**
PCB-001	9:12	<5.3	1.0	J,R	5.3	45
PCB-002	10:19	2.99	0.54	J		45
PCB-003	10:26	<4.1	0.43	J,R	4.1	45
PCB-004	10:36	9.82	0.61	J		45
PCB-010	10:43	<0.45	0.43	J,R	0.45	45
PCB-009	11:51	<8.4	0.43	J,R	8.4	45
PCB-007	11:57	<1.4	0.40	J,R	1.4	45
PCB-006	NotFnd	<0.39	0.39	U		45
PCB-005	12:18	<0.44	0.44	U		45
PCB-008	12:23	10.5	0.37	J		45
PCB-014	NotFnd	<0.35	0.35	U		45
PCB-011	13:53	<34	0.42	J,R	34	45
PCB-012/013	14:05	0.973	0.41	J		45
PCB-015	14:15	<2.3	0.57	J,R	2.3	45
PCB-019	12:34	<0.87	0.25	J,R	0.87	45
PCB-018/030	13:41	6.24	0.15	J		45
PCB-017	13:56	2.92	0.18	J		45
PCB-027	14:03	0.336	0.13	J		45
PCB-024	14:08	<0.13	0.13	U	0.024	45
PCB-016	14:12	<2.9	0.21	J,R	2.9	45
PCB-032	14:30	<1.4	0.12	J,R	1.4	45
PCB-034	NotFnd	<0.20	0.20	U		45
PCB-023	NotFnd	<0.19	0.19	U		45
PCB-026/029	15:28	<0.88	0.22	J,R	0.88	45
PCB-025	15:36	<0.34	0.17	J,R	0.34	45
PCB-031	15:47	3.99	0.20	J		45
PCB-020/028	15:57	4.59	0.20	J		45
PCB-021/033	16:06	2.76	0.19	J		45
PCB-022	16:19	1.59	0.21	J		45
PCB-036	NotFnd	<0.19	0.19	U		45
PCB-039	NotFnd	<0.22	0.22	U		45
PCB-038	NotFnd	<0.19	0.19	U		45
PCB-035	17:58	<0.25	0.22	J,R	0.25	45
PCB-037	18:12	1.12	0.28	J		45
PCB-054	14:25	<0.15	0.15	U	0.077	45
PCB-050/053	15:38	<0.36	0.22	J,R	0.36	45
PCB-045/051	16:02	<1.3	0.23	J,R	1.3	45
PCB-046	NotFnd	<0.27	0.27	U		45
PCB-052	16:57	2.79	0.23	J		45
PCB-073	NotFnd	<0.16	0.16	U		45
PCB-043	NotFnd	<0.24	0.24	U		45
PCB-049/069	17:13	1.07	0.18	J		45
PCB-048	17:22	<0.31	0.22	J,R	0.31	45
PCB-044/047/065	17:31	3.96	0.20	J		45
PCB-059/062/075	17:41	<0.16	0.16	U	0.074	45
PCB-042	17:48	<0.47	0.23	J,R	0.47	45
PCB-040/041/071	18:03	<0.51	0.23	J,R	0.51	45
PCB-064	18:11	<0.60	0.16	J,R	0.60	45
PCB-072	NotFnd	<0.37	0.37	U		45
PCB-068	18:46	<0.31	0.31	U	0.29	45
PCB-057	NotFnd	<0.36	0.36	U		45
PCB-058	NotFnd	<0.38	0.38	U		45
PCB-067	NotFnd	<0.31	0.31	U		45
PCB-063	NotFnd	<0.35	0.35	U		45
PCB-061/070/074/076	19:34	<0.43	0.36	J,R	0.43	45
PCB-066	19:44	<0.44	0.36	J,R	0.44	45
PCB-055	19:48	<0.35	0.35	U	0.11	45
PCB-056	20:06	<0.37	0.37	U	0.14	45
PCB-060	NotFnd	<0.36	0.36	U		45
PCB-080	NotFnd	<0.34	0.34	U		45
PCB-079	NotFnd	<0.34	0.34	U		45
PCB-078	NotFnd	<0.36	0.36	U		45
PCB-081	NotFnd	<0.45	0.45	U		45
PCB-077	NotFnd	<0.35	0.35	U		45
PCB-104	NotFnd	<0.11	0.11	U		45
PCB-096	NotFnd	<0.11	0.11	U		45

ALS Life Sciences

Laboratory Method Blank Analysis Report

Sample Name	**Method Blank**				
ALS Sample ID	WG2108486-1	Sampling Date	n/a		Approved:
		Extraction Date	n/a		*E. Sabljic*
Analysis Method	EPA 1668C	Sample Size	1	g	--e-signature--
Analysis Type	Blank	Percent Moisture	n/a		17-Jul-2015
Sample Matrix	QC	Split Ratio	1		

Run Information	**Run 1**
Filename	5-150710A05
Run Date	10-Jul-15 15:48
Final Volume	45 ul
Dilution Factor	1
Analysis Units	pg/g
Instrument - Column	HRMS-5 SPBOCTYL55800-02B

Target Analytes	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**
PCB-103	18:43	<0.11	0.11	U		45
PCB-094	NotFnd	<0.12	0.12	U		45
PCB-095	19:05	<0.75	0.12	J,R	0.75	45
PCB-093/098/100/102	NotFnd	<0.11	0.11	U		45
PCB-088/091	19:32	0.189	0.12	J		45
PCB-084	19:40	0.430	0.13	J		45
PCB-089	NotFnd	<0.13	0.13	U		45
PCB-121	20:07	<0.080	0.080	U		45
PCB-092	20:18	<0.12	0.12	U	0.063	45
PCB-090/101/113	20:37	0.970	0.11	J		45
PCB-083/099	20:57	<0.13	0.12	J,R	0.13	45
PCB-112	NotFnd	<0.081	0.081	U		45
PCB-086/087/097/108/119/125	21:17	<0.43	0.10	J,R	0.43	45
PCB-085/110/115/116/117	21:41	<0.67	0.092	J,R	0.67	45
PCB-082	NotFnd	<0.14	0.14	U		45
PCB-111	21:58	<0.082	0.082	U	0.0025	45
PCB-120	22:16	<0.082	0.082	U	0.043	45
PCB-107/124	NotFnd	<0.13	0.13	U		45
PCB-109	NotFnd	<0.12	0.12	U		45
PCB-123	23:04	<0.12	0.12	J,R	0.12	45
PCB-106	NotFnd	<0.13	0.13	U		45
PCB-118	23:16	0.711	0.21	J		45
PCB-122	NotFnd	<0.14	0.14	U		45
PCB-114	23:33	<0.15	0.11	J,R	0.15	45
PCB-105	23:55	<0.11	0.11	U	0.093	45
PCB-127	NotFnd	<0.13	0.13	U		45
PCB-126	25:28	0.278	0.11	J		45
PCB-155	20:29	<0.11	0.099	J,R	0.11	45
PCB-152	NotFnd	<0.075	0.075	U		45
PCB-150	20:43	<0.068	0.068	U	0.016	45
PCB-136	NotFnd	<0.077	0.077	U		45
PCB-145	21:01	<0.077	0.077	U	0.011	45
PCB-148	21:47	<0.099	0.099	U		45
PCB-135/151	22:11	0.184	0.099	J		45
PCB-154	NotFnd	<0.087	0.087	U		45
PCB-144	NotFnd	<0.098	0.098	U		45
PCB-147/149	22:39	0.490	0.11	J		45
PCB-134/143	22:49	<0.13	0.13	U	0.033	45
PCB-139/140	NotFnd	<0.11	0.11	U		45
PCB-131	NotFnd	<0.12	0.12	U		45
PCB-142	NotFnd	<0.13	0.13	U		45
PCB-132	23:20	<0.18	0.12	J,R	0.18	45
PCB-133	NotFnd	<0.12	0.12	U		45
PCB-165	23:46	<0.093	0.093	U	0.015	45
PCB-146	23:52	<0.10	0.10	J,R	0.10	45
PCB-161	NotFnd	<0.087	0.087	U		45
PCB-153/168	24:12	<0.25	0.092	J,R	0.25	45
PCB-141	24:18	<0.12	0.12	U	0.073	45
PCB-130	NotFnd	<0.14	0.14	U		45
PCB-137/164	NotFnd	<0.10	0.10	U		45
PCB-129/138/163	24:52	0.699	0.11	J		45
PCB-160	24:58	<0.082	0.082	U	0.017	45
PCB-158	25:03	<0.080	0.080	U	0.050	45
PCB-128/166	25:31	<0.10	0.10	U	0.019	45
PCB-159	26:00	<0.080	0.080	U	0.040	45
PCB-162	26:11	<0.075	0.075	U	0.047	45
PCB-167	26:24	<0.080	0.071	J,R	0.080	45
PCB-156/157	27:00	<0.26	0.090	J,R	0.26	45
PCB-169	28:41	0.288	0.093	J		45
PCB-188	23:31	<0.081	0.081	U	0.050	45
PCB-179	23:42	<0.10	0.10	U	0.054	45
PCB-184	NotFnd	<0.086	0.086	U		45
PCB-176	NotFnd	<0.097	0.097	U		45
PCB-186	NotFnd	<0.10	0.10	U		45
PCB-178	25:06	<0.13	0.13	U	0.054	45
PCB-175	25:24	<0.13	0.13	U	0.046	45
PCB-187	25:32	0.225	0.11	J		45

ALS Life Sciences

Laboratory Method Blank Analysis Report

Sample Name	**Method Blank**				
ALS Sample ID	WG2108486-1	Sampling Date	n/a		Approved:
		Extraction Date	n/a		*E. Sabljic*
Analysis Method	EPA 1668C	Sample Size	1	g	--e-signature--
Analysis Type	Blank	Percent Moisture	n/a		17-Jul-2015
Sample Matrix	QC	Split Ratio	1		

Run Information	**Run 1**
Filename	5-150710A05
Run Date	10-Jul-15 15:48
Final Volume	45 ul
Dilution Factor	1
Analysis Units	pg/g
Instrument - Column	HRMS-5 SPBOCTYL55800-02B

Target Analytes	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**
PCB-182	25:37	<0.12	0.12	U	0.069	45
PCB-183	25:53	<0.12	0.12	U	0.099	45
PCB-185	25:56	<0.12	0.12	U	0.064	45
PCB-174	26:00	<0.24	0.12	J,R	0.24	45
PCB-177	26:13	<0.13	0.13	U	0.071	45
PCB-181	26:23	<0.12	0.12	U	0.040	45
PCB-171/173	NotFnd	<0.13	0.13	U		45
PCB-172	27:19	<0.13	0.13	U	0.087	45
PCB-192	NotFnd	<0.11	0.11	U		45
PCB-180/193	27:42	<0.27	0.11	J,R	0.27	45
PCB-191	NotFnd	<0.096	0.096	U		45
PCB-170	28:22	<0.19	0.14	J,R	0.19	45
PCB-190	28:39	0.0971	0.091	J		45
PCB-189	NotFnd	<0.42	0.42	U		45
PCB-202	26:16	<0.078	0.078	U	0.036	45
PCB-201	26:44	<0.11	0.11	U	0.10	45
PCB-204	NotFnd	<0.10	0.10	U		45
PCB-197	NotFnd	<0.10	0.10	U		45
PCB-200	NotFnd	<0.12	0.12	U		45
PCB-198/199	28:39	<0.15	0.15	U	0.072	45
PCB-196	29:03	<0.16	0.16	U	0.041	45
PCB-203	29:07	<0.14	0.14	U	0.035	45
PCB-195	NotFnd	<0.32	0.32	U		45
PCB-194	NotFnd	<0.30	0.30	U		45
PCB-205	NotFnd	<0.44	0.44	U		45
PCB-208	NotFnd	<1.2	1.2	U		45
PCB-207	NotFnd	<1.2	1.2	U		45
PCB-206	NotFnd	<1.9	1.9	U		45
PCB-209	33:31	1.18	0.35	J		45

Extraction Standards	**ng**		**%**	**Limits**
13C12-PCB-001	2000	9:11	15	25-150 R
13C12-PCB-003	2000	10:26	42	25-150
13C12-PCB-004	2000	10:35	46	25-150
13C12-PCB-015	2000	14:15	49	25-150
13C12-PCB-019	2000	12:33	49	25-150
13C12-PCB-037	2000	18:11	58	25-150
13C12-PCB-054	2000	14:24	50	25-150
13C12-PCB-081	2000	21:47	64	25-150
13C12-PCB-077	2000	22:05	67	25-150
13C12-PCB-104	2000	17:28	58	25-150
13C12-PCB-123	2000	23:05	66	25-150
13C12-PCB-118	2000	23:15	39	25-150
13C12-PCB-114	2000	23:33	67	25-150
13C12-PCB-105	2000	23:53	70	25-150
13C12-PCB-126	2000	25:29	84	25-150
13C12-PCB-155	2000	20:29	60	25-150
13C12-PCB-167	2000	26:23	93	25-150
13C12-PCB-156/157	4000	27:00	88	25-150
13C12-PCB-169	2000	28:39	79	25-150
13C12-PCB-188	2000	23:29	67	25-150
13C12-PCB-189	2000	29:55	50	25-150
13C12-PCB-202	2000	26:14	86	25-150
13C12-PCB-205	2000	31:21	84	25-150
13C12-PCB-208	2000	29:39	109	25-150
13C12-PCB-206	2000	32:23	110	25-150
13C12-PCB-209	2000	33:31	116	25-150

Cleanup Standards	**ng**		**%**	
13C12-PCB-028	2000	15:57	63	30-135
13C12-PCB-111	2000	22:02	79	30-135
13C12-PCB-178	2000	25:03	82	30-135

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Laboratory Method Blank Analysis Report

Sample Name	**Method Blank**				
ALS Sample ID	WG2108486-1	Sampling Date	n/a		Approved:
		Extraction Date	n/a		*E. Sabljic*
Analysis Method	EPA 1668C	Sample Size	1	g	---e-signature--
Analysis Type	Blank	Percent Moisture	n/a		17-Jul-2015
Sample Matrix	QC	Split Ratio	1		

Run Information	**Run 1**
Filename	5-150710A05
Run Date	10-Jul-15 15:48
Final Volume	45 ul
Dilution Factor	1
Analysis Units	pg/g
Instrument - Column	HRMS-5 SPBOCTYL5S800-02B

Target Analytes	**Ret. Time**	**Conc. pg/g**	**EDL pg/g**	**Flags**	**EMPC pg/g**	**LQL**
Homologue Group Totals						
Total MonoCB		12.4	0.43	J		45
Total DiCB		67.8	0.35	J		45
Total TriCB		30.2	0.12	J		45
Total TetraCB		12.2	0.15	J		45
Total PentaCB		4.71	0.08	J		45
Total HexaCB		2.54	0.068	J		45
Total HeptaCB		1.02	0.081	J		45
Total OctaCB		0	0.078	U		45
Total NonaCB		0	1.2	U		45
DecaCB		1.18	0.35	J		45
Total PCB		132		J		

Toxic Equivalency - (WHO 2005)	**pg/g**
Lower Bound PCB TEQ (WHO 2005)	0.0365
Mid Point PCB TEQ (WHO 2005)	0.0366
Upper Bound PCB TEQ (WHO 2005)	0.0367

EDL	Indicates the Estimated Detection Limit, based on the measured background noise for this target in this sample.
TEF	Indicates the Toxic Equivalency Factor TEQ Indicates the Toxic Equivalency
U	Indicates that the analyte was not detcted at or above the reported estimated detection limit.
J	indicates that the analyte was positively identifed. The associated numerical result is an estimate.
R	Indicates that the ion abundance ratio for this analyte did not meet the control limit. The reported value represents an estimated concentration.

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Laboratory Control Sample Analysis Report

Sample Name	**Laboratory Control Sample**				
ALS Sample ID	WG2108486-2	Sampling Date	n/a		
		Extraction Date	n/a		Approved:
Analysis Method	EPA 1668C	Sample Size	1	n/a	*E. Sabljic*
Analysis Type	LCS	Percent Moisture	n/a		--e-signature--
Sample Matrix	QC	Split Ratio	1		17-Jul-2015

Run Information	**Run 1**	
Filename	5-150710A03	
Run Date	10-Jul-15 14:29	
Final Volume	45 ul	
Dilution Factor	1	
Analysis Units	%	
Instrument - Column	0	0

Target Analytes	**ng**	**Ret. Time**	**%**	**Limits**	**Flags**
PCB-001	1000	8:51	113	50-150	
PCB-002	1000				
PCB-003	1000	10:23	111	50-150	
PCB-004	1000	10:32	115	50-150	
PCB-010	1000				
PCB-009	1000				
PCB-007	1000				
PCB-006	1000				
PCB-005	1000				
PCB-008	1000				
PCB-014	1000				
PCB-011	1000				
PCB-012/013	1000				
PCB-015	1000	14:14	113	50-150	
PCB-019	1000	12:32	115	50-150	
PCB-018/030	1000				
PCB-017	1000				
PCB-027	1000				
PCB-024	1000				
PCB-016	1000				
PCB-032	1000				
PCB-034	1000				
PCB-023	1000				
PCB-026/029	1000				
PCB-025	1000				
PCB-031	1000				
PCB-020/028	1000				
PCB-021/033	1000				
PCB-022	1000				
PCB-036	1000				
PCB-039	1000				
PCB-038	1000				
PCB-035	1000				
PCB-037	1000	18:11	99	50-150	
PCB-054	1000	14:23	114	50-150	
PCB-050/053	1000				
PCB-045/051	1000				
PCB-046	1000				
PCB-052	1000				
PCB-073	1000				
PCB-043	1000				
PCB-049/069	1000				
PCB-048	1000				
PCB-044/047/065	1000				
PCB-059/062/075	1000				
PCB-042	1000				
PCB-040/041/071	1000				
PCB-064	1000				
PCB-072	1000				
PCB-068	1000				
PCB-057	1000				
PCB-058	1000				
PCB-067	1000				
PCB-063	1000				
PCB-061/070/074/076	1000				
PCB-066	1000				
PCB-055	1000				
PCB-056	1000				
PCB-060	1000				
PCB-080	1000				
PCB-079	1000				
PCB-078	1000				
PCB-081	1000	21:46	107	50-150	
PCB-077	1000	22:04	106	50-150	
PCB-104	1000	17:28	107	50-150	
PCB-096	1000				

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Laboratory Control Sample Analysis Report

Sample Name	**Laboratory Control Sample**				
ALS Sample ID	WG2108486-2	Sampling Date	n/a		
		Extraction Date	n/a		Approved:
Analysis Method	EPA 1668C	Sample Size	1	n/a	*E. Sabljic*
Analysis Type	LCS	Percent Moisture	n/a		--e-signature--
Sample Matrix	QC	Split Ratio	1		17-Jul-2015

Run Information	**Run 1**	
Filename	5-150710A03	
Run Date	10-Jul-15 14:29	
Final Volume	45 ul	
Dilution Factor	1	
Analysis Units	%	
Instrument - Column	0	0

Target Analytes	**ng**	**Ret. Time**	**%**	**Limits**	**Flags**
PCB-103	1000				
PCB-094	1000				
PCB-095	1000				
PCB-093/098/100/102	1000				
PCB-088/091	1000				
PCB-084	1000				
PCB-089	1000				
PCB-121	1000				
PCB-092	1000				
PCB-090/101/113	1000				
PCB-083/099	1000				
PCB-112	1000				
PCB-086/087/097/108/119/125	1000				
PCB-085/110/115/116/117	1000				
PCB-082	1000				
PCB-111	1000				
PCB-120	1000				
PCB-107/124	1000				
PCB-109	1000				
PCB-123	1000	23:03	113	50-150	
PCB-106	1000				
PCB-118	1000	23:14	110	50-150	
PCB-122	1000				
PCB-114	1000	23:31	113	50-150	
PCB-105	1000	23:52	110	50-150	
PCB-127	1000				
PCB-126	1000	25:28	112	50-150	
PCB-155	1000	20:29	109	50-150	
PCB-152	1000				
PCB-150	1000				
PCB-136	1000				
PCB-145	1000				
PCB-148	1000				
PCB-135/151	1000				
PCB-154	1000				
PCB-144	1000				
PCB-147/149	1000				
PCB-134/143	1000				
PCB-139/140	1000				
PCB-131	1000				
PCB-142	1000				
PCB-132	1000				
PCB-133	1000				
PCB-165	1000				
PCB-146	1000				
PCB-161	1000				
PCB-153/168	1000				
PCB-141	1000				
PCB-130	1000				
PCB-137/164	1000				
PCB-129/138/163	1000				
PCB-160	1000				
PCB-158	1000				
PCB-128/166	1000				
PCB-159	1000				
PCB-162	1000				
PCB-167	1000	26:22	109	50-150	
PCB-156/157	2000	26:59	109	50-150	
PCB-169	1000	28:39	108	50-150	
PCB-188	1000	23:28	108	50-150	
PCB-179	1000				
PCB-184	1000				
PCB-176	1000				
PCB-186	1000				
PCB-178	1000				
PCB-175	1000				
PCB-187	1000				

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Laboratory Control Sample Analysis Report

Sample Name	**Laboratory Control Sample**				
ALS Sample ID	WG2108486-2	Sampling Date	n/a		
		Extraction Date	n/a		Approved:
Analysis Method	EPA 1668C	Sample Size	1	n/a	*E. Sabljic*
Analysis Type	LCS	Percent Moisture	n/a		--e-signature--
Sample Matrix	QC	Split Ratio	1		17-Jul-2015

Run Information	**Run 1**	
Filename	5-150710A03	
Run Date	10-Jul-15 14:29	
Final Volume	45 ul	
Dilution Factor	1	
Analysis Units	%	
Instrument - Column	0	0

Target Analytes	**ng**	**Ret. Time**	**%**	**Limits**	**Flags**
PCB-182	1000				
PCB-183	1000				
PCB-185	1000				
PCB-174	1000				
PCB-177	1000				
PCB-181	1000				
PCB-171/173	1000				
PCB-172	1000				
PCB-192	1000				
PCB-180/193	1000				
PCB-191	1000				
PCB-170	1000				
PCB-190	1000				
PCB-189	1000	29:55	114	50-150	
PCB-202	1000	26:14	111	50-150	
PCB-201	1000				
PCB-204	1000				
PCB-197	1000				
PCB-200	1000				
PCB-198/199	1000				
PCB-196	1000				
PCB-203	1000				
PCB-195	1000				
PCB-194	1000				
PCB-205	1000	31:18	108	50-150	
PCB-208	1000	29:39	108	50-150	
PCB-207	1000				
PCB-206	1000	32:22	118	50-150	
PCB-209	1000	33:30	115	50-150	

Extraction Standards	**ng**		**%**	**Limits**
13C12-PCB-001	2000	8:50	30	30-140
13C12-PCB-003	2000	10:23	30	30-140
13C12-PCB-004	2000	10:31	35	30-140
13C12-PCB-015	2000	14:13	45	30-140
13C12-PCB-019	2000	12:31	42	30-140
13C12-PCB-037	2000	18:10	55	30-140
13C12-PCB-054	2000	14:22	38	30-140
13C12-PCB-081	2000	21:45	64	30-140
13C12-PCB-077	2000	22:03	68	30-140
13C12-PCB-104	2000	17:27	47	30-140
13C12-PCB-123	2000	23:03	67	30-140
13C12-PCB-118	2000	23:13	69	30-140
13C12-PCB-114	2000	23:30	68	30-140
13C12-PCB-105	2000	23:51	73	30-140
13C12-PCB-126	2000	25:27	78	30-140
13C12-PCB-155	2000	20:28	50	30-140
13C12-PCB-167	2000	26:21	82	30-140
13C12-PCB-156/157	4000	26:58	81	30-140
13C12-PCB-169	2000	28:38	89	30-140
13C12-PCB-188	2000	23:27	65	30-140
13C12-PCB-189	2000	29:54	81	30-140
13C12-PCB-202	2000	26:13	73	30-140
13C12-PCB-205	2000	31:17	91	30-140
13C12-PCB-208	2000	29:38	82	30-140
13C12-PCB-206	2000	32:22	90	30-140
13C12-PCB-209	2000	33:29	78	30-140

Cleanup Standards	**ng**		**%**
13C12-PCB-028	2000	15:56	58	40-125
13C12-PCB-111	2000	21:59	74	40-125
13C12-PCB-178	2000	25:01	76	40-125

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OMIC USA Inc.

A Member of OMIC Group of Companies
Independent Analytical Laboratory

Report Date: *July 30, 2015*

Koster Keunen Inc.

1021 Echo Lake Road
Watertown, CT 06795

ANALYTICAL REPORT

Sample ID : B#20033 **Matrix:** ***RICE BRAN WAX 224P***

Date Received: *July 15, 2015*

Lab ID # : *AB82050*

Chemical Residue

	Analyte	Result	Units	LOQ
1	2,4-Dichlorobenzophenone	ND	ppm	0.02
2	2,6-Diisopropylnaphthalene	ND	ppm	0.04
3	4,4-Dichlorobenzophenone	ND	ppm	0.02
4	Abamectin	ND	ppm	0.05
5	Acephate	ND	ppm	0.1
6	Acetamiprid	ND	ppm	0.05
7	Acetochlor	ND	ppm	0.02
8	Acibenzolar-S-methyl	ND	ppm	0.05
9	Acrinathrin	ND	ppm	0.02
10	Alachlor	ND	ppm	0.02
11	Aldicarb	ND	ppm	0.05
12	Aldicarb-sulfone	ND	ppm	0.05
13	Aldicarb-sulfoxide	ND	ppm	0.1
14	Aldrin	ND	ppm	0.02
15	Allethrin	ND	ppm	0.2
16	Ametryn	ND	ppm	0.05
17	Amitraz	ND	ppm	0.05
18	Anilofos	ND	ppm	0.05
19	Atrazine	ND	ppm	0.02
20	Azaconazole	ND	ppm	0.02
21	Azamethiphos	ND	ppm	0.05
22	Azinphos-ethyl	ND	ppm	0.05
23	Azinphos-methyl	ND	ppm	0.05
24	Azoxystrobin	ND	ppm	0.05
25	Benalaxyl	ND	ppm	0.02
26	Bendiocarb	ND	ppm	0.05
27	Benfluralin	ND	ppm	0.02
28	Benfuresate	ND	ppm	0.02
29	Benomyl (as Carbendazim)	ND	ppm	0.05
30	Benoxacor	ND	ppm	0.02
31	Bensulide	ND	ppm	0.05
32	Bentazone	ND	ppm	0.02

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33	Benzobicyclon	ND	ppm	0.05
34	Benzofenap	ND	ppm	0.05
35	Benzyladenine	ND	ppm	0.05
36	BHC (alpha)	ND	ppm	0.02
37	BHC (beta)	ND	ppm	0.02
38	BHC (delta)	ND	ppm	0.02
39	Bifenazate	ND	ppm	0.05
40	Bifenox	ND	ppm	0.02
41	Bifenthrin	ND	ppm	0.02
42	Bioresmethrin (as Resmethrin)	ND	ppm	0.1
43	Bitertanol	ND	ppm	0.05
44	Boscalid	ND	ppm	0.02
45	Bromobutide	ND	ppm	0.02
46	Bromophos-ethyl	ND	ppm	0.05
47	Bromophos-methyl	ND	ppm	0.05
48	Bromopropylate	ND	ppm	0.02
49	Bupirimate	ND	ppm	0.02
50	Buprofezin	ND	ppm	0.02
51	Butachlor	ND	ppm	0.02
52	Butafenacil	ND	ppm	0.02
53	Butamifos	ND	ppm	0.05
54	Butralin	ND	ppm	0.02
55	Butylate	ND	ppm	0.02
56	Cadusafos	ND	ppm	0.05
57	Cafenstrole	ND	ppm	0.05
58	Captan	ND	ppm	0.1
59	Carbaryl	ND	ppm	0.05
60	Carbendazim	ND	ppm	0.05
61	Carbofuran	ND	ppm	0.05
62	Carbophenothion	ND	ppm	0.05
63	Carboxin	ND	ppm	0.02
64	Carfentrazone-ethyl	ND	ppm	0.02
65	Carpropamid	ND	ppm	0.02
66	Chlorantraniliprole	ND	ppm	0.05
67	Chlorbenside	ND	ppm	0.02
68	Chlorbufam	ND	ppm	0.02
69	Chlordane (cis)	ND	ppm	0.02
70	Chlordane (trans)	ND	ppm	0.02
71	Chlorethoxyfos	ND	ppm	0.02
72	Chlorfenapyr	ND	ppm	0.02
73	Chlorfenson	ND	ppm	0.02
74	Chlorfenvinphos	ND	ppm	0.05
75	Chloridazon	ND	ppm	0.05
76	Chlornitrofen	ND	ppm	0.02
77	Chlorobenzilate	ND	ppm	0.02
78	Chloroneb	ND	ppm	0.02
79	Chloroxuron	ND	ppm	0.05
80	Chlorpropham	ND	ppm	0.02
81	Chlorpyrifos	ND	ppm	0.05
82	Chlorpyrifos-methyl	ND	ppm	0.05
83	Chlorthal-dimethyl	ND	ppm	0.02
84	Chlorthiofos	ND	ppm	0.05
85	Chlozolinate	ND	ppm	0.02
86	Chromafenozide	ND	ppm	0.05

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87	Cinidon-ethyl	ND	ppm	0.05
88	Cinmethylin	ND	ppm	0.02
89	Clethodim	ND	ppm	0.02
90	Clodinafop-propargyl	ND	ppm	0.05
91	Clofentezine	ND	ppm	0.05
92	Clomazone	ND	ppm	0.02
93	Clomeprop	ND	ppm	0.05
94	Cloquintocet-mexyl	ND	ppm	0.05
95	Clothianidin	ND	ppm	0.05
96	CPMC (Etrofol)	ND	ppm	0.05
97	Cumyluron	ND	ppm	0.05
98	Cyanazine	ND	ppm	0.05
99	Cyanophenphos	ND	ppm	0.05
100	Cyanophos	ND	ppm	0.05
101	Cyazofamid	ND	ppm	0.05
102	Cycloate	ND	ppm	0.02
103	Cyflufenamid	ND	ppm	0.02
104	Cyfluthrin	ND	ppm	0.02
105	Cyhalofop-butyl	ND	ppm	0.02
106	Cyhalothrin (gamma)	ND	ppm	0.02
107	Cyhalothrin (lambda)	ND	ppm	0.02
108	Cymoxanil	ND	ppm	0.05
109	Cypermethrin	ND	ppm	0.02
110	Cyproconazole	ND	ppm	0.02
111	Cyprodinil	ND	ppm	0.05
112	Daimuron	ND	ppm	0.05
113	DDD	ND	ppm	0.02
114	DDE	ND	ppm	0.02
115	DDT	ND	ppm	0.02
116	Deltamethrin	ND	ppm	0.02
117	Demeton O & S	ND	ppm	0.05
118	Demeton-S-methyl	ND	ppm	0.05
119	Desmedipham	ND	ppm	0.1
120	Diafenthiuron	N/A	ppm	0.1
121	Dialifos	ND	ppm	0.05
122	Di-allate	ND	ppm	0.02
123	Diazinon	ND	ppm	0.05
124	Dichlobenil	ND	ppm	0.02
125	Dichlofenthion (ECP)	ND	ppm	0.05
126	Dichlofluanid	ND	ppm	0.02
127	Dichlormid	ND	ppm	0.02
128	Dichlorvos	ND	ppm	0.05
129	Diclobutrazol	ND	ppm	0.05
130	Diclocymet	ND	ppm	0.02
131	Diclofop-methyl	ND	ppm	0.02
132	Diclomezine	ND	ppm	0.05
133	Dicloran	ND	ppm	0.02
134	Dicrotophos	ND	ppm	0.05
135	Dieldrin	ND	ppm	0.02
136	Diethofencarb	ND	ppm	0.02
137	Difenoconazole	ND	ppm	0.02
138	Difenzoquat	ND	ppm	0.05
139	Diflubenzuron	ND	ppm	0.05
140	Diflufenican	ND	ppm	0.02

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141	Dimepiperate	ND	ppm	0.02
142	Dimethametryn	ND	ppm	0.05
143	Dimethenamid	ND	ppm	0.02
144	Dimethoate	ND	ppm	0.05
145	Dimethylvinphos	ND	ppm	0.05
146	Diniconazole	ND	ppm	0.05
147	Dinotefuran	ND	ppm	0.05
148	Dioxathion	ND	ppm	0.05
149	Diphenamid	ND	ppm	0.02
150	Diphenylamine	ND	ppm	0.02
151	Disulfoton	ND	ppm	0.02
152	Disulfoton-sulfone	ND	ppm	0.02
153	Dithiopyr	ND	ppm	0.02
154	Diuron	ND	ppm	0.05
155	Edifenphos	ND	ppm	0.05
156	Emamectin-benzoate	ND	ppm	0.05
157	Endosulfan (alpha)	ND	ppm	0.02
158	Endosulfan (beta)	ND	ppm	0.02
159	Endosulfan-sulfate	ND	ppm	0.04
160	Endrin	ND	ppm	0.02
161	EPN	ND	ppm	0.05
162	Epoxiconazole	ND	ppm	0.02
163	EPTC	ND	ppm	0.02
164	Esfenvalerate	ND	ppm	0.04
165	Esprocarb	ND	ppm	0.02
166	Ethalfluralin	ND	ppm	0.02
167	Ethion	ND	ppm	0.05
168	Ethiprole	ND	ppm	0.05
169	Ethofumesate	ND	ppm	0.02
170	Ethoprophos	ND	ppm	0.025
171	Ethoxyquin	N/A	ppm	0.1
172	Ethychlozate	ND	ppm	0.05
173	Etobenzanid	ND	ppm	0.02
174	Etofenprox	ND	ppm	0.02
175	Etoxazole	ND	ppm	0.02
176	Etridiazole	ND	ppm	0.02
177	Etrimfos	ND	ppm	0.05
178	Famphur	ND	ppm	0.02
179	Fenamidone	ND	ppm	0.02
180	Fenamiphos	ND	ppm	0.05
181	Fenamiphos-sulfone	ND	ppm	0.05
182	Fenarimol	ND	ppm	0.02
183	Fenbuconazole	ND	ppm	0.05
184	Fenchlorphos	ND	ppm	0.05
185	Fenhexamid	ND	ppm	0.05
186	Fenitrothion	ND	ppm	0.05
187	Fenobucarb	ND	ppm	0.05
188	Fenothiocarb	ND	ppm	0.05
189	Fenoxanil	ND	ppm	0.05
190	Fenoxaprop-ethyl	ND	ppm	0.02
191	Fenoxycarb	ND	ppm	0.05
192	Fenpropathrin	ND	ppm	0.02
193	Fenpropimorph	ND	ppm	0.02
194	Fenpyroximate	ND	ppm	0.05

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195	Fensulfothion	ND	ppm	0.05
196	Fenthion	ND	ppm	0.05
197	Fentrazamide	ND	ppm	0.05
198	Fenvalerate	ND	ppm	0.04
199	Ferimzone E	ND	ppm	0.05
200	Ferimzone Z	ND	ppm	0.05
201	Fipronil	ND	ppm	0.01
202	Flamprop-methyl	ND	ppm	0.02
203	Fluacrypyrim	ND	ppm	0.05
204	Fluazifop-butyl	ND	ppm	0.02
205	Fluazinam	ND	ppm	0.05
206	Flucythrinate	ND	ppm	0.02
207	Fludioxonil	ND	ppm	0.05
208	Flufenacet	ND	ppm	0.02
209	Fluometuron	ND	ppm	0.05
210	Fluquinconazole	ND	ppm	0.02
211	Fluridone	ND	ppm	0.05
212	Flusilazole	ND	ppm	0.02
213	Flusulfamide	ND	ppm	0.05
214	Fluthiacet-methyl	ND	ppm	0.05
215	Flutolanil	ND	ppm	0.02
216	Flutriafol	ND	ppm	0.05
217	Fluvalinate	0.03	ppm	0.02
218	Fonofos	ND	ppm	0.05
219	Forchlorfenuron	ND	ppm	0.05
220	Fosthiazate	ND	ppm	0.05
221	Fthalide	ND	ppm	0.02
222	Furametpyr	ND	ppm	0.02
223	Furathiocarb	ND	ppm	0.05
224	Furilazole	ND	ppm	0.02
225	Halfenprox	ND	ppm	0.02
226	Haloxyfop	ND	ppm	0.01
227	Haloxyfop-methyl	ND	ppm	0.02
228	Heptachlor	ND	ppm	0.02
229	Heptachlor-epoxide	ND	ppm	0.02
230	Hexachlorobenzene	ND	ppm	0.02
231	Hexaconazole	ND	ppm	0.05
232	Hexazinone	ND	ppm	0.02
233	Hexythiazox	ND	ppm	0.05
234	Imazalil	ND	ppm	0.05
235	Imazamethabenz-methyl-ester	ND	ppm	0.05
236	Imibenconazole	ND	ppm	0.05
237	Imidacloprid	ND	ppm	0.05
238	Inabenfide	ND	ppm	0.05
239	Indoxacarb	ND	ppm	0.05
240	Iprobenfos	ND	ppm	0.05
241	Iprodione	ND	ppm	0.05
242	Iprovalicarb	ND	ppm	0.05
243	Isazophos	ND	ppm	0.05
244	Isocarbophos	ND	ppm	0.05
245	Isofenphos	ND	ppm	0.05
246	Isofenphos-methyl	ND	ppm	0.05
247	Isoprocarb	ND	ppm	0.05
248	Isoprothiolane	ND	ppm	0.02

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249	Isotianil	ND	ppm	0.02
250	Isouron	ND	ppm	0.05
251	Isoxadifen-ethyl	ND	ppm	0.02
252	Isoxaflutole	ND	ppm	0.05
253	Isoxathion	ND	ppm	0.05
254	Kresoxim-methyl	ND	ppm	0.02
255	Lenacil	ND	ppm	0.05
256	Lindane	ND	ppm	0.02
257	Linuron	ND	ppm	0.05
258	Malathion	ND	ppm	0.05
259	Mandipropamid	ND	ppm	0.05
260	Mecarbam	ND	ppm	0.05
261	Mefenacet	ND	ppm	0.05
262	Mefenpyr-Diethyl	ND	ppm	0.05
263	Mepanipyrim	ND	ppm	0.02
264	Mephosfolan	ND	ppm	0.05
265	Mepronil	ND	ppm	0.02
266	Metalaxyl	ND	ppm	0.02
267	Metconazole	ND	ppm	0.02
268	Methabenzthiazuron	ND	ppm	0.05
269	Methacrifos	ND	ppm	0.05
270	Methamidophos	ND	ppm	0.05
271	Methidathion	ND	ppm	0.05
272	Methiocarb	ND	ppm	0.05
273	Methomyl	ND	ppm	0.05
274	Methoprene	ND	ppm	0.02
275	Methoxychlor	ND	ppm	0.02
276	Methoxyfenozide	ND	ppm	0.05
277	Metolachlor	ND	ppm	0.02
278	Metominostrobin	ND	ppm	0.02
279	Metribuzin	ND	ppm	0.02
280	Mevinphos	ND	ppm	0.05
281	Mirex	ND	ppm	0.02
282	Molinate	ND	ppm	0.02
283	Monocrotophos	ND	ppm	0.05
284	Monolinuron	ND	ppm	0.05
285	Myclobutanil	ND	ppm	0.02
286	Naled (screened as Dichlorvos)	ND	ppm	0.05
287	Naproanilide	ND	ppm	0.02
288	Napropamide	ND	ppm	0.02
289	Nitenpyram	ND	ppm	0.05
290	Nitrofen	ND	ppm	0.02
291	Nitrothal-isopropyl	ND	ppm	0.02
292	Norflurazon	ND	ppm	0.02
293	Novaluron	ND	ppm	0.05
294	Ofurace	ND	ppm	0.05
295	Omethoate	ND	ppm	0.05
296	o-Phenylphenol	ND	ppm	0.1
297	Orysastrobin	ND	ppm	0.02
298	Oryzalin	ND	ppm	0.05
299	Oxadiazon	ND	ppm	0.02
300	Oxadixyl	ND	ppm	0.1
301	Oxamyl	ND	ppm	0.05
302	Oxaziclomefone	ND	ppm	0.05

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303	Oxpoconazole-fumarate	ND	ppm	0.1
304	Oxycarboxin	ND	ppm	0.05
305	Oxydemeton-methyl	ND	ppm	0.05
306	Oxyfluorfen	ND	ppm	0.02
307	Paclobutrazol	ND	ppm	0.02
308	Parathion	ND	ppm	0.05
309	Parathion-methyl	ND	ppm	0.05
310	Pebulate	ND	ppm	0.02
311	Penconazole	ND	ppm	0.02
312	Pencycuron	ND	ppm	0.05
313	Pendimethalin	ND	ppm	0.02
314	Pentoxazone	ND	ppm	0.02
315	Permethrin	ND	ppm	0.02
316	Perthane	ND	ppm	0.02
317	Phenmedipham	ND	ppm	0.05
318	Phenothiol	ND	ppm	0.02
319	Phenothrin	ND	ppm	0.02
320	Phenthoate	ND	ppm	0.05
321	Phorate	ND	ppm	0.05
322	Phorate-sulfone	ND	ppm	0.05
323	Phosalone	ND	ppm	0.05
324	Phosmet	ND	ppm	0.05
325	Phosphamidon	ND	ppm	0.05
326	Phoxim	ND	ppm	0.05
327	Picolinafen	ND	ppm	0.05
328	Piperonyl-butoxide	ND	ppm	0.02
329	Piperophos	ND	ppm	0.05
330	Pirimicarb	ND	ppm	0.02
331	Pirimioxyphos	ND	ppm	0.05
332	Pirimiphos-ethyl	ND	ppm	0.05
333	Pirimiphos-methyl	ND	ppm	0.05
334	Pretilachlor	ND	ppm	0.02
335	Prochloraz	ND	ppm	0.02
336	Procymidone	ND	ppm	0.02
337	Profenofos	ND	ppm	0.05
338	Prohydrojasmon	ND	ppm	0.1
339	Prometryn	ND	ppm	0.02
340	Propachlor	ND	ppm	0.02
341	Propanil	ND	ppm	0.02
342	Propaphos	ND	ppm	0.05
343	Propargite	ND	ppm	0.05
344	Propazine	ND	ppm	0.02
345	Propetamphos	ND	ppm	0.05
346	Propiconazole	ND	ppm	0.02
347	Propoxur	ND	ppm	0.05
348	Propyzamide	ND	ppm	0.05
349	Prothiofos	ND	ppm	0.05
350	Pyraclofos	ND	ppm	0.05
351	Pyraclonil	ND	ppm	0.02
352	Pyraclostrobin	ND	ppm	0.05
353	Pyraflufen-ethyl	ND	ppm	0.02
354	Pyrazolynate	ND	ppm	0.05
355	Pyrazophos	ND	ppm	0.05
356	Pyrazoxyfen	ND	ppm	0.05

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357	Pyrethrins	ND	ppm	0.25
358	Pyributicarb	ND	ppm	0.02
359	Pyridaben	ND	ppm	0.02
360	Pyridafenthion	ND	ppm	0.05
361	Pyrifenox	ND	ppm	0.02
362	Pyriftalid	ND	ppm	0.05
363	Pyrimethanil	ND	ppm	0.02
364	Pyrimidifen	ND	ppm	0.02
365	Pyriminobac-methyl	ND	ppm	0.02
366	Pyriproxyfen	ND	ppm	0.02
367	Pyroquilon	ND	ppm	0.02
368	Quinalphos	ND	ppm	0.05
369	Quinoclamine	ND	ppm	0.05
370	Quinoxyfen	ND	ppm	0.05
371	Quintozene	ND	ppm	0.02
372	Quizalofop-ethyl	ND	ppm	0.02
373	Salithion	ND	ppm	0.05
374	Sethoxydim	ND	ppm	0.05
375	Silafluofen	ND	ppm	0.02
376	Simazine	ND	ppm	0.02
377	Simeconazole	ND	ppm	0.05
378	Simetryn	ND	ppm	0.02
379	Spinosad	ND	ppm	0.05
380	Spiromesifen	ND	ppm	0.1
381	Sulfotep	ND	ppm	0.05
382	Sulprofos	ND	ppm	0.05
383	TCMTB	ND	ppm	0.05
384	Tebuconazole	ND	ppm	0.02
385	Tebufenozide	ND	ppm	0.1
386	Tebufenpyrad	ND	ppm	0.02
387	Tebupirimfos	ND	ppm	0.05
388	Tebuthiuron	ND	ppm	0.05
389	Tecnazene	ND	ppm	0.02
390	Tefluthrin	ND	ppm	0.02
391	Terbacil	ND	ppm	0.05
392	Terbufos	ND	ppm	0.05
393	Terbutryn	ND	ppm	0.02
394	Tetrachlorvinphos	ND	ppm	0.05
395	Tetraconazole	ND	ppm	0.02
396	Tetradifon	ND	ppm	0.02
397	Tetrahydrophthalimide	ND	ppm	0.1
398	Tetramethrin	ND	ppm	0.02
399	Thenylchlor	ND	ppm	0.02
400	Thiabendazole	ND	ppm	0.05
401	Thiacloprid	ND	ppm	0.05
402	Thiamethoxam	ND	ppm	0.05
403	Thiazopyr	ND	ppm	0.02
404	Thidiazuron	ND	ppm	0.05
405	Thifluzamide	ND	ppm	0.02
406	Thiobencarb	ND	ppm	0.02
407	Thiometon	ND	ppm	0.02
408	Tiadinil	ND	ppm	0.05
409	Tolclofos-methyl	ND	ppm	0.05
410	Tralomethrin	ND	ppm	0.02

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411	Triadimefon	ND	ppm	0.02
412	Triadimenol	ND	ppm	0.05
413	Tri-allate	ND	ppm	0.02
414	Triazophos	ND	ppm	0.05
415	Tribuphos	ND	ppm	0.05
416	Trichlamide	ND	ppm	0.02
417	Trichlorfon	ND	ppm	0.05
418	Tricyclazole	ND	ppm	0.05
419	Tridiphane	ND	ppm	0.02
420	Trifloxystrobin	ND	ppm	0.05
421	Triflumizole	ND	ppm	0.02
422	Triflumuron	ND	ppm	0.05
423	Trifluralin	ND	ppm	0.02
424	Triforine	ND	ppm	0.05
425	Triticonazole	ND	ppm	0.05
426	Uniconazole-P	ND	ppm	0.05
427	Vinclozolin	ND	ppm	0.02
428	XMC	ND	ppm	0.05
429	Xylylcarb	ND	ppm	0.05
430	Zoxamide	ND	ppm	0.05

Persistent Organic Pollutants

	Analyte	Result
1	**Dioxins / Furans / WHO-12 PCBs	Complete - see attached eurofins Analysis Report

Microbiological Tests

	Analyte	Result	Units
1	Aerobic Plate Count (APC)	< 10	CFU/g
2	Coliform, Plate Count	<10	CFU/g
3	E Coli, Plate Count	<10	CFU/g
4	Listeria Genus (by PCR)	Negative	
5	Mold	<10	CFU/g
6	Salmonella (by PCR)	Negative	
7	Yeast	<10	CFU/g

Minerals / Metals Screen

	Analyte	Result	Units	LOQ
1	Arsenic	ND	ppb	10
2	Cadmium	ND	ppb	10
3	Lead	ND	ppb	10
4	Mercury	ND	ppb	5

Mycotoxins Screen

	Analyte	Result	Units	LOQ
1	Aflatoxin B1	ND	ppb	5
2	Aflatoxin B2	ND	ppb	5
3	Aflatoxin G1	ND	ppb	5
4	Aflatoxin G2	ND	ppb	5

**This analysis is outside the scope of OMIC USA operations and has been subcontracted to eurofins laboratory. Their report analysis is attached in its entirety. OMIC USA assumes no responsibility for its interpretations or use.

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
*LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted*

PAH'S Screen

	Analyte	Result	Units	LOQ
1	*Acenaphthene	ND	ppm	43
2	*Acenaphthylene	ND	ppm	38
3	*Anthracene	ND	ppm	65
4	*Benz(a)anthracene	ND	ppm	49
5	*Benzo(a)pyrene	ND	ppm	32
6	*Benzo(b)fluoranthene	ND	ppm	38
7	*Benzo(g,h,i)perylene	ND	ppm	38
8	*Benzo(k)fluoranthene	ND	ppm	38
9	*Chrysene	ND	ppm	32
10	*Dibenzo(a,h)anthracene	ND	ppm	54
11	*Flouranthene	ND	ppm	43
12	*Fluorene	ND	ppm	70
13	*Indeno((1,2,3-cd)pyrene	ND	ppm	49
14	*Napthalene	ND	ppm	43
15	*Phenanthrene	ND	ppm	38
16	*Pyrene	ND	ppm	32

Solvent Screen

	Analyte	Result	Units	LOQ
1	Hexane	ND	ppb	10

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Analysis Report

Sample Description: AB82050 RICE BRAN WAX Composite Solid
Rice Bran Wax

LL Sample # G5 7968745
LL Group # 1577323
Account # 30091

Project Name: Rice Bran Wax

Collected: 07/15/2015 13:45 by DF

Submitted: 07/16/2015 09:45
Reported: 07/28/2015 15:28

OMIC USA Inc.
3344 NW Industrial St
Portland OR

CAT No.	Analysis Name	CAS Number	As Received Result	As Received EDL	Dilution Factor
Dioxins/Furans	**EPA 1613B modified**		**ng/kg**	**ng/kg**	
12963	2378-TCDD	1746-01-6	< 0.155	0.155	1
12963	2378-TCDF	51207-31-9	< 0.102	0.102	1
12963	12378-PeCDD	40321-76-4	< 0.117	0.117	1
12963	12378-PeCDF	57117-41-6	< 0.0701	0.0701	1
12963	23478-PeCDF	57117-31-4	< 0.0638	0.0638	1
12963	123478-HxCDD	39227-28-6	< 0.0605	0.0605	1
12963	123678-HxCDD	57653-85-7	< 0.0652	0.0652	1
12963	123789-HxCDD	19408-74-3	< 0.0729	0.0729	1
12963	123478-HxCDF	70648-26-9	< 0.0547	0.0547	1
12963	123678-HxCDF	57117-44-9	< 0.0565	0.0565	1
12963	123789-HxCDF	72918-21-9	< 0.0653	0.0653	1
12963	234678-HxCDF	60851-34-5	< 0.0554	0.0554	1
12963	1234678-HpCDD	35822-46-9	< 0.0776	0.0776	1
12963	1234678-HpCDF	67562-39-4	< 0.0368	0.0368	1
12963	1234789-HpCDF	55673-89-7	< 0.0494	0.0494	1
12963	OCDD	3268-87-9	0.377	0.108	1
12963	OCDF	39001-02-0	< 0.172	0.172	1
D/F Toxic Equivalents	**EPA 1613B modified**		**ng/kg**	**ng/kg**	
12963	WHO2005 PCDD/F TEQ Lower Bound	n.a.	0.000113		1
12963	WHO2005 PCDD/F TEQ Upper Bound	n.a.	0.349		1
WHO 12 PCBs	**EPA 1668 modified**		**ng/kg**	**ng/kg**	
12942	PCB77	32598-13-3	< 0.165	0.165	1
12942	PCB81	70362-50-4	0.395	0.179	1
12942	PCB105	32598-14-4	3.28	0.169	1
12942	PCB114	74472-37-0	0.449	0.204	1
12942	PCB118	31508-00-6	10.3	0.167	1
12942	PCB123	65510-44-3	< 0.167	0.167	1
12942	PCB126	57465-28-8	< 0.171	0.171	1
12942	PCB156	38380-08-4	< 0.144	0.144	1
12942	PCB157	69782-90-7	< 0.126	0.126	1
12942	PCB167	52663-72-6	< 0.170	0.170	1
12942	PCB169	32774-16-6	< 0.120	0.120	1
12942	PCB189	39635-31-9	< 0.0855	0.0855	1
PCB Toxic Equivalents	**EPA 1668 modified**		**ng/kg**	**ng/kg**	
12942	TEQ PCB WHO 2005 -EDLx0.0	n.a.	0.000538		1
12942	TEQ PCB WHO 2005 -EDLx1.0	n.a.	0.0212		1

General Sample Comments

WHO(2005)-PCDD/F + DLPCB TEQ (lower-bound) = 0.000654 pg/g
WHO(2005)-PCDD/F + DLPCB TEQ (upper-bound) = 0.370 pg/g

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Analysis Report

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Sample Description: AB82050 RICE BRAN WAX Composite Solid
Rice Bran Wax

LL Sample # G5 7968745
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Project Name: Rice Bran Wax

Collected: 07/15/2015 13:45 by DF

Submitted: 07/16/2015 09:45
Reported: 07/28/2015 15:28

OMIC USA Inc.
3344 NW Industrial St
Portland OR

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
12963	Solid Dioxins and Furans	EPA 1613B modified	1	15204005	07/23/2015 21:56	Michael A Ziegler	1
12942	Solid WHO12 + 6 Indicators	EPA 1668 modified	1	15204005	07/23/2015 20:32	Michael A Ziegler	1
12961	Dioxins/Furans/PCBs in Oil	EPA 1613B modified	2	15204005	07/23/2015 08:10	Deborah M Zimmerman	1

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Explanation of Symbols and Abbreviations

The following defines common symbols and abbreviations used in reporting technical data:

RL	Reporting Limit	**BMQL**	Below Minimum Quantitation Level
N.D.	none detected	**MPN**	Most Probable Number
TNTC	Too Numerous To Count	**CP Units**	cobalt-chloroplatinate units
IU	International Units	**NTU**	nephelometric turbidity units
umhos/cm	micromhos/cm	**ng**	nanogram(s)
C	degrees Celsius	**F**	degrees Fahrenheit
meq	milliequivalents	**lb.**	pound(s)
g	gram(s)	**kg**	kilogram(s)
µg	microgram(s)	**mg**	milligram(s)
mL	milliliter(s)	**L**	liter(s)
m3	cubic meter(s)	**µL**	microliter(s)
		pg/L	picogram/liter

<	less than
>	greater than
ppm	parts per million - One ppm is equivalent to one milligram per kilogram (mg/kg) or one gram per million grams. For aqueous liquids, ppm is usually taken to be equivalent to milligrams per liter (mg/l), because one liter of water has a weight very close to a kilogram. For gases or vapors, one ppm is equivalent to one microliter per liter of gas.
ppb	parts per billion
Dry weight basis	Results printed under this heading have been adjusted for moisture content. This increases the analyte weight concentration to approximate the value present in a similar sample without moisture. All other results are reported on an as-received basis.

Laboratory Data Qualifiers:

B - Analyte detected in the blank
C - Result confirmed by reanalysis
E - Concentration exceeds the calibration range
J (or G, I, X) - estimated value ≥ the Method Detection Limit (MDL or DL) and the < Limit of Quantitation (LOQ or RL)
P - Concentration difference between the primary and confirmation column >40%. The lower result is reported.
U - Analyte was not detected at the value indicated
V - Concentration difference between the primary and confirmation column >100%. The reporting limit is raised due to this disparity and evident interference...

Additional Organic and Inorganic CLP qualifiers may be used with Form 1 reports as defined by the CLP methods. Qualifiers specific to Dioxin/Furans and PCB Congeners are detailed on the individual Analysis Report.

Analytical test results meet all requirements of the associated regulatory program (i.e., NELAC (TNI), DoD, ISO17025) unless otherwise noted under the individual analysis.

Measurement uncertainty values, as applicable, are available upon request.

Tests results relate only to the sample tested. Clients should be aware that a critical step in a chemical or microbiological analysis is the collection of the sample. Unless the sample analyzed is truly representative of the bulk of material involved, the test results will be meaningless. If you have questions regarding the proper techniques of collecting samples, please contact us. We cannot be held responsible for sample integrity, however, unless sampling has been performed by a member of our staff.

Times are local to the area of activity. Parameters listed in the 40 CFR Part 136 Table II as "analyze immediately" are not performed within 15 minutes.

WARRANTY AND LIMITS OF LIABILITY - In accepting analytical work, we warrant the accuracy of test results for the sample as submitted. THE FOREGOING EXPRESS WARRANTY IS EXCLUSIVE AND IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. WE DISCLAIM ANY OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING A WARRANTY OF FITNESS FOR PARTICULAR PURPOSE AND WARRANTY OF MERCHANTABILITY. IN NO EVENT SHALL EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL, LLC BE LIABLE FOR INDIRECT, SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFIT OR GOODWILL REGARDLESS OF (A) THE NEGLIGENCE (EITHER SOLE OR CONCURRENT) OF EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL AND (B) WHETHER EUROFINS LANCASTER LABORATORIES ENVIRONMENTAL HAS BEEN INFORMED OF THE POSSIBILITY OF SUCH DAMAGES. We accept no legal responsibility for the purposes for which the client uses the test results. No purchase order or other order for work shall be accepted by Eurofins Lancaster Laboratories Environmental which includes any conditions that vary from the Standard Terms and Conditions, and Eurofins Lancaster Laboratories Environmental hereby objects to any conflicting terms contained in any acceptance or order submitted by client.

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OMIC USA Inc.

A Member of OMIC Group of Companies
Independent Analytical Laboratory

Report Date: *July 28, 2015*

Koster Keunen Inc.

1021 Echo Lake Road
Watertown, CT 06795

ANALYTICAL REPORT

Sample ID : B#20048 **Matrix:** ***RICE BRAN WAX 224P***

Date Received: *July 06, 2015*

Lab ID # : *AB81761*

Chemical Residue

	Analyte	Result	Units	LOQ
1	2,4-Dichlorobenzophenone	ND	ppm	0.02
2	2,6-Diisopropylnaphthalene	ND	ppm	0.04
3	4,4-Dichlorobenzophenone	ND	ppm	0.02
4	Abamectin	ND	ppm	0.05
5	Acephate	ND	ppm	0.1
6	Acetamiprid	ND	ppm	0.05
7	Acetochlor	ND	ppm	0.02
8	Acibenzolar-S-methyl	ND	ppm	0.05
9	Acrinathrin	ND	ppm	0.02
10	Alachlor	ND	ppm	0.02
11	Aldicarb	ND	ppm	0.05
12	Aldicarb-sulfone	ND	ppm	0.05
13	Aldicarb-sulfoxide	ND	ppm	0.1
14	Aldrin	ND	ppm	0.02
15	Allethrin	ND	ppm	0.2
16	Ametryn	ND	ppm	0.05
17	Amitraz	ND	ppm	0.05
18	Anilofos	ND	ppm	0.05
19	Atrazine	ND	ppm	0.02
20	Azaconazole	ND	ppm	0.02
21	Azamethiphos	ND	ppm	0.05
22	Azinphos-ethyl	ND	ppm	0.05
23	Azinphos-methyl	ND	ppm	0.05
24	Azoxystrobin	ND	ppm	0.05
25	Benalaxyl	ND	ppm	0.02
26	Bendiocarb	ND	ppm	0.05
27	Benfluralin	ND	ppm	0.02
28	Benfuresate	ND	ppm	0.02
29	Benomyl (as Carbendazim)	ND	ppm	0.05
30	Benoxacor	ND	ppm	0.02
31	Bensulide	ND	ppm	0.05
32	Bentazone	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
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33	Benzobicyclon	ND	ppm	0.05
34	Benzofenap	ND	ppm	0.05
35	Benzyladenine	ND	ppm	0.05
36	BHC (alpha)	ND	ppm	0.02
37	BHC (beta)	ND	ppm	0.02
38	BHC (delta)	ND	ppm	0.02
39	Bifenazate	ND	ppm	0.05
40	Bifenox	ND	ppm	0.02
41	Bifenthrin	ND	ppm	0.02
42	Bioresmethrin (as Resmethrin)	ND	ppm	0.1
43	Bitertanol	ND	ppm	0.05
44	Boscalid	ND	ppm	0.02
45	Bromobutide	ND	ppm	0.02
46	Bromophos-ethyl	ND	ppm	0.05
47	Bromophos-methyl	ND	ppm	0.05
48	Bromopropylate	ND	ppm	0.02
49	Bupirimate	ND	ppm	0.02
50	Buprofezin	ND	ppm	0.02
51	Butachlor	ND	ppm	0.02
52	Butafenacil	ND	ppm	0.02
53	Butamifos	ND	ppm	0.05
54	Butralin	ND	ppm	0.02
55	Butylate	ND	ppm	0.02
56	Cadusafos	ND	ppm	0.05
57	Cafenstrole	ND	ppm	0.05
58	Captan	ND	ppm	0.1
59	Carbaryl	ND	ppm	0.05
60	Carbendazim	ND	ppm	0.05
61	Carbofuran	ND	ppm	0.05
62	Carbophenothion	ND	ppm	0.05
63	Carboxin	ND	ppm	0.02
64	Carfentrazone-ethyl	ND	ppm	0.02
65	Carpropamid	ND	ppm	0.02
66	Chlorantraniliprole	ND	ppm	0.05
67	Chlorbenside	ND	ppm	0.02
68	Chlorbufam	ND	ppm	0.02
69	Chlordane (cis)	ND	ppm	0.02
70	Chlordane (trans)	ND	ppm	0.02
71	Chlorethoxyfos	ND	ppm	0.02
72	Chlorfenapyr	ND	ppm	0.02
73	Chlorfenson	ND	ppm	0.02
74	Chlorfenvinphos	ND	ppm	0.05
75	Chloridazon	ND	ppm	0.05
76	Chlornitrofen	ND	ppm	0.02
77	Chlorobenzilate	ND	ppm	0.02
78	Chloroneb	ND	ppm	0.02
79	Chloroxuron	ND	ppm	0.05
80	Chlorpropham	ND	ppm	0.02
81	Chlorpyrifos	ND	ppm	0.05
82	Chlorpyrifos-methyl	ND	ppm	0.05
83	Chlorthal-dimethyl	ND	ppm	0.02
84	Chlorthiofos	ND	ppm	0.05
85	Chlozolinate	ND	ppm	0.02

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86	Chromafenozide	ND	ppm	0.05
87	Cinidon-ethyl	ND	ppm	0.05
88	Cinmethylin	ND	ppm	0.02
89	Clethodim	ND	ppm	0.02
90	Clodinafop-propargyl	ND	ppm	0.05
91	Clofentezine	ND	ppm	0.05
92	Clomazone	ND	ppm	0.02
93	Clomeprop	ND	ppm	0.05
94	Cloquintocet-mexyl	ND	ppm	0.05
95	Clothianidin	ND	ppm	0.05
96	CPMC (Etrofol)	ND	ppm	0.05
97	Cumyluron	ND	ppm	0.05
98	Cyanazine	ND	ppm	0.05
99	Cyanophenphos	ND	ppm	0.05
100	Cyanophos	ND	ppm	0.05
101	Cyazofamid	ND	ppm	0.05
102	Cycloate	ND	ppm	0.02
103	Cyflufenamid	ND	ppm	0.02
104	Cyfluthrin	ND	ppm	0.02
105	Cyhalofop-butyl	ND	ppm	0.02
106	Cyhalothrin (gamma)	ND	ppm	0.02
107	Cyhalothrin (lambda)	ND	ppm	0.02
108	Cymoxanil	ND	ppm	0.05
109	Cypermethrin	ND	ppm	0.02
110	Cyproconazole	ND	ppm	0.02
111	Cyprodinil	ND	ppm	0.05
112	Daimuron	ND	ppm	0.05
113	DDD	ND	ppm	0.02
114	DDE	ND	ppm	0.02
115	DDT	ND	ppm	0.02
116	Deltamethrin	ND	ppm	0.02
117	Demeton O & S	ND	ppm	0.05
118	Demeton-S-methyl	ND	ppm	0.05
119	Desmedipham	ND	ppm	0.1
120	Diafenthiuron	ND	ppm	0.1
121	Dialifos	ND	ppm	0.05
122	Di-allate	ND	ppm	0.02
123	Diazinon	ND	ppm	0.05
124	Dichlobenil	ND	ppm	0.02
125	Dichlofenthion (ECP)	ND	ppm	0.05
126	Dichlofluanid	ND	ppm	0.02
127	Dichlormid	ND	ppm	0.02
128	Dichlorvos	ND	ppm	0.05
129	Diclobutrazol	ND	ppm	0.05
130	Diclocymet	ND	ppm	0.02
131	Diclofop-methyl	ND	ppm	0.02
132	Diclomezine	ND	ppm	0.05
133	Dicloran	ND	ppm	0.02
134	Dicrotophos	ND	ppm	0.05
135	Dieldrin	ND	ppm	0.02
136	Diethofencarb	ND	ppm	0.02
137	Difenoconazole	ND	ppm	0.02
138	Difenzoquat	ND	ppm	0.05

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139	Diflubenzuron	ND	ppm	0.05
140	Diflufenican	ND	ppm	0.02
141	Dimepiperate	ND	ppm	0.02
142	Dimethametryn	ND	ppm	0.05
143	Dimethenamid	ND	ppm	0.02
144	Dimethoate	ND	ppm	0.05
145	Dimethylvinphos	ND	ppm	0.05
146	Diniconazole	ND	ppm	0.05
147	Dinotefuran	ND	ppm	0.05
148	Dioxathion	ND	ppm	0.05
149	Diphenamid	ND	ppm	0.02
150	Diphenylamine	ND	ppm	0.02
151	Disulfoton	ND	ppm	0.02
152	Disulfoton-sulfone	ND	ppm	0.02
153	Dithiopyr	ND	ppm	0.02
154	Diuron	ND	ppm	0.05
155	Edifenphos	ND	ppm	0.05
156	Emamectin-benzoate	ND	ppm	0.05
157	Endosulfan (alpha)	ND	ppm	0.02
158	Endosulfan (beta)	ND	ppm	0.02
159	Endosulfan-sulfate	ND	ppm	0.04
160	Endrin	ND	ppm	0.02
161	EPN	ND	ppm	0.05
162	Epoxiconazole	ND	ppm	0.02
163	EPTC	ND	ppm	0.02
164	Esfenvalerate	ND	ppm	0.04
165	Esprocarb	ND	ppm	0.02
166	Ethalfluralin	ND	ppm	0.02
167	Ethion	ND	ppm	0.05
168	Ethiprole	ND	ppm	0.05
169	Ethofumesate	ND	ppm	0.02
170	Ethoprophos	ND	ppm	0.025
171	Ethoxyquin	N/A	ppm	0.1
172	Ethychlozate	ND	ppm	0.05
173	Etobenzanid	ND	ppm	0.02
174	Etofenprox	ND	ppm	0.02
175	Etoxazole	ND	ppm	0.02
176	Etridiazole	ND	ppm	0.02
177	Etrimfos	ND	ppm	0.05
178	Famphur	ND	ppm	0.02
179	Fenamidone	ND	ppm	0.02
180	Fenamiphos	ND	ppm	0.05
181	Fenamiphos-sulfone	ND	ppm	0.05
182	Fenarimol	ND	ppm	0.02
183	Fenbuconazole	ND	ppm	0.05
184	Fenchlorphos	ND	ppm	0.05
185	Fenhexamid	ND	ppm	0.05
186	Fenitrothion	ND	ppm	0.05
187	Fenobucarb	ND	ppm	0.05
188	Fenothiocarb	ND	ppm	0.05
189	Fenoxanil	ND	ppm	0.05
190	Fenoxaprop-ethyl	ND	ppm	0.02
191	Fenoxycarb	ND	ppm	0.05

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192	Fenpropathrin	ND	ppm	0.02
193	Fenpropimorph	ND	ppm	0.02
194	Fenpyroximate	ND	ppm	0.05
195	Fensulfothion	ND	ppm	0.05
196	Fenthion	ND	ppm	0.05
197	Fentrazamide	ND	ppm	0.05
198	Fenvalerate	ND	ppm	0.04
199	Ferimzone E	ND	ppm	0.05
200	Ferimzone Z	ND	ppm	0.05
201	Fipronil	ND	ppm	0.01
202	Flamprop-methyl	ND	ppm	0.02
203	Fluacrypyrim	ND	ppm	0.05
204	Fluazifop-butyl	ND	ppm	0.02
205	Fluazinam	ND	ppm	0.05
206	Flucythrinate	ND	ppm	0.02
207	Fludioxonil	ND	ppm	0.05
208	Flufenacet	ND	ppm	0.02
209	Fluometuron	ND	ppm	0.05
210	Fluquinconazole	ND	ppm	0.02
211	Fluridone	ND	ppm	0.05
212	Flusilazole	ND	ppm	0.02
213	Flusulfamide	ND	ppm	0.05
214	Fluthiacet-methyl	ND	ppm	0.05
215	Flutolanil	ND	ppm	0.02
216	Flutriafol	ND	ppm	0.05
217	Fluvalinate	ND	ppm	0.02
218	Fonofos	ND	ppm	0.05
219	Forchlorfenuron	ND	ppm	0.05
220	Fosthiazate	ND	ppm	0.05
221	Fthalide	ND	ppm	0.02
222	Furametpyr	ND	ppm	0.02
223	Furathiocarb	ND	ppm	0.05
224	Furilazole	ND	ppm	0.02
225	Halfenprox	ND	ppm	0.02
226	Haloxyfop	ND	ppm	0.01
227	Haloxyfop-methyl	ND	ppm	0.02
228	Heptachlor	ND	ppm	0.02
229	Heptachlor-epoxide	ND	ppm	0.02
230	Hexachlorobenzene	ND	ppm	0.02
231	Hexaconazole	ND	ppm	0.05
232	Hexazinone	ND	ppm	0.02
233	Hexythiazox	ND	ppm	0.05
234	Imazalil	ND	ppm	0.05
235	Imazamethabenz-methyl-ester	ND	ppm	0.05
236	Imibenconazole	ND	ppm	0.05
237	Imidacloprid	ND	ppm	0.05
238	Inabenfide	ND	ppm	0.05
239	Indoxacarb	ND	ppm	0.05
240	Iprobenfos	ND	ppm	0.05
241	Iprodione	ND	ppm	0.05
242	Iprovalicarb	ND	ppm	0.05
243	Isazophos	ND	ppm	0.05
244	Isocarbophos	ND	ppm	0.05

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
*LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted*

245	Isofenphos	ND	ppm	0.05
246	Isofenphos-methyl	ND	ppm	0.05
247	Isoprocarb	ND	ppm	0.05
248	Isoprothiolane	ND	ppm	0.02
249	Isotianil	ND	ppm	0.02
250	Isouron	ND	ppm	0.05
251	Isoxadifen-ethyl	ND	ppm	0.02
252	Isoxaflutole	ND	ppm	0.05
253	Isoxathion	ND	ppm	0.05
254	Kresoxim-methyl	ND	ppm	0.02
255	Lenacil	ND	ppm	0.05
256	Lindane	ND	ppm	0.02
257	Linuron	ND	ppm	0.05
258	Malathion	ND	ppm	0.05
259	Mandipropamid	ND	ppm	0.05
260	Mecarbam	ND	ppm	0.05
261	Mefenacet	ND	ppm	0.05
262	Mefenpyr-Diethyl	ND	ppm	0.05
263	Mepanipyrim	ND	ppm	0.02
264	Mephosfolan	ND	ppm	0.05
265	Mepronil	ND	ppm	0.02
266	Metalaxyl	ND	ppm	0.02
267	Metconazole	ND	ppm	0.02
268	Methabenzthiazuron	ND	ppm	0.05
269	Methacrifos	ND	ppm	0.05
270	Methamidophos	ND	ppm	0.05
271	Methidathion	ND	ppm	0.05
272	Methiocarb	ND	ppm	0.05
273	Methomyl	ND	ppm	0.05
274	Methoprene	ND	ppm	0.02
275	Methoxychlor	ND	ppm	0.02
276	Methoxyfenozide	ND	ppm	0.05
277	Metolachlor	ND	ppm	0.02
278	Metominostrobin	ND	ppm	0.02
279	Metribuzin	ND	ppm	0.02
280	Mevinphos	ND	ppm	0.05
281	Mirex	ND	ppm	0.02
282	Molinate	ND	ppm	0.02
283	Monocrotophos	ND	ppm	0.05
284	Monolinuron	ND	ppm	0.05
285	Myclobutanil	ND	ppm	0.02
286	Naled (screened as Dichlorvos)	ND	ppm	0.05
287	Naproanilide	ND	ppm	0.02
288	Napropamide	ND	ppm	0.02
289	Nitenpyram	ND	ppm	0.05
290	Nitrofen	ND	ppm	0.02
291	Nitrothal-isopropyl	ND	ppm	0.02
292	Norflurazon	ND	ppm	0.02
293	Novaluron	ND	ppm	0.05
294	Ofurace	ND	ppm	0.05
295	Omethoate	ND	ppm	0.05
296	o-Phenylphenol	ND	ppm	0.1
297	Orysastrobin	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
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298	Oryzalin	ND	ppm	0.05
299	Oxadiazon	ND	ppm	0.02
300	Oxadixyl	ND	ppm	0.1
301	Oxamyl	ND	ppm	0.05
302	Oxaziclomefone	ND	ppm	0.05
303	Oxpoconazole-fumarate	ND	ppm	0.1
304	Oxycarboxin	ND	ppm	0.05
305	Oxydemeton-methyl	ND	ppm	0.05
306	Oxyfluorfen	ND	ppm	0.02
307	Paclobutrazol	ND	ppm	0.02
308	Parathion	ND	ppm	0.05
309	Parathion-methyl	ND	ppm	0.05
310	Pebulate	ND	ppm	0.02
311	Penconazole	ND	ppm	0.02
312	Pencycuron	ND	ppm	0.05
313	Pendimethalin	ND	ppm	0.02
314	Pentoxazone	ND	ppm	0.02
315	Permethrin	ND	ppm	0.02
316	Perthane	ND	ppm	0.02
317	Phenmedipham	ND	ppm	0.05
318	Phenothiol	ND	ppm	0.02
319	Phenothrin	ND	ppm	0.02
320	Phenthoate	ND	ppm	0.05
321	Phorate	ND	ppm	0.05
322	Phorate-sulfone	ND	ppm	0.05
323	Phosalone	ND	ppm	0.05
324	Phosmet	ND	ppm	0.05
325	Phosphamidon	ND	ppm	0.05
326	Phoxim	ND	ppm	0.05
327	Picolinafen	ND	ppm	0.05
328	Piperonyl-butoxide	ND	ppm	0.02
329	Piperophos	ND	ppm	0.05
330	Pirimicarb	ND	ppm	0.02
331	Pirimioxyphos	ND	ppm	0.05
332	Pirimiphos-ethyl	ND	ppm	0.05
333	Pirimiphos-methyl	ND	ppm	0.05
334	Pretilachlor	ND	ppm	0.02
335	Prochloraz	ND	ppm	0.02
336	Procymidone	ND	ppm	0.02
337	Profenofos	ND	ppm	0.05
338	Prohydrojasmon	ND	ppm	0.1
339	Prometryn	ND	ppm	0.02
340	Propachlor	ND	ppm	0.02
341	Propanil	ND	ppm	0.02
342	Propaphos	ND	ppm	0.05
343	Propargite	ND	ppm	0.05
344	Propazine	ND	ppm	0.02
345	Propetamphos	ND	ppm	0.05
346	Propiconazole	ND	ppm	0.02
347	Propoxur	ND	ppm	0.05
348	Propyzamide	ND	ppm	0.05
349	Prothiofos	ND	ppm	0.05
350	Pyraclofos	ND	ppm	0.05

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*LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted*

351	Pyraclonil	ND	ppm	0.02
352	Pyraclostrobin	ND	ppm	0.05
353	Pyraflufen-ethyl	ND	ppm	0.02
354	Pyrazolynate	ND	ppm	0.05
355	Pyrazophos	ND	ppm	0.05
356	Pyrazoxyfen	ND	ppm	0.05
357	Pyrethrins	ND	ppm	0.25
358	Pyributicarb	ND	ppm	0.02
359	Pyridaben	ND	ppm	0.02
360	Pyridafenthion	ND	ppm	0.05
361	Pyrifenox	ND	ppm	0.02
362	Pyriftalid	ND	ppm	0.05
363	Pyrimethanil	ND	ppm	0.02
364	Pyrimidifen	ND	ppm	0.02
365	Pyriminobac-methyl	ND	ppm	0.02
366	Pyriproxyfen	ND	ppm	0.02
367	Pyroquilon	ND	ppm	0.02
368	Quinalphos	ND	ppm	0.05
369	Quinoclamine	ND	ppm	0.05
370	Quinoxyfen	ND	ppm	0.05
371	Quintozene	ND	ppm	0.02
372	Quizalofop-ethyl	ND	ppm	0.02
373	Salithion	ND	ppm	0.05
374	Sethoxydim	ND	ppm	0.05
375	Silafluofen	ND	ppm	0.02
376	Simazine	ND	ppm	0.02
377	Simeconazole	ND	ppm	0.05
378	Simetryn	ND	ppm	0.02
379	Spinosad	ND	ppm	0.05
380	Spiromesifen	ND	ppm	0.1
381	Sulfotep	ND	ppm	0.05
382	Sulprofos	ND	ppm	0.05
383	TCMTB	ND	ppm	0.05
384	Tebuconazole	ND	ppm	0.02
385	Tebufenozide	ND	ppm	0.1
386	Tebufenpyrad	ND	ppm	0.02
387	Tebupirimfos	ND	ppm	0.05
388	Tebuthiuron	ND	ppm	0.05
389	Tecnazene	ND	ppm	0.02
390	Tefluthrin	ND	ppm	0.02
391	Terbacil	ND	ppm	0.05
392	Terbufos	ND	ppm	0.05
393	Terbutryn	ND	ppm	0.02
394	Tetrachlorvinphos	ND	ppm	0.05
395	Tetraconazole	ND	ppm	0.02
396	Tetradifon	ND	ppm	0.02
397	Tetrahydrophthalimide	ND	ppm	0.1
398	Tetramethrin	ND	ppm	0.02
399	Thenylchlor	ND	ppm	0.02
400	Thiabendazole	ND	ppm	0.05
401	Thiacloprid	ND	ppm	0.05
402	Thiamethoxam	ND	ppm	0.05
403	Thiazopyr	ND	ppm	0.02

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
*LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted*

404	Thidiazuron	ND	ppm	0.05
405	Thifluzamide	ND	ppm	0.02
406	Thiobencarb	ND	ppm	0.02
407	Thiometon	ND	ppm	0.02
408	Tiadinil	ND	ppm	0.05
409	Tolclofos-methyl	ND	ppm	0.05
410	Tralomethrin	ND	ppm	0.02
411	Triadimefon	ND	ppm	0.02
412	Triadimenol	ND	ppm	0.05
413	Tri-allate	ND	ppm	0.02
414	Triazophos	ND	ppm	0.05
415	Tribuphos	ND	ppm	0.05
416	Trichlamide	ND	ppm	0.02
417	Trichlorfon	ND	ppm	0.05
418	Tricyclazole	ND	ppm	0.05
419	Tridiphane	ND	ppm	0.02
420	Trifloxystrobin	ND	ppm	0.05
421	Triflumizole	ND	ppm	0.02
422	Triflumuron	ND	ppm	0.05
423	Trifluralin	ND	ppm	0.02
424	Triforine	ND	ppm	0.05
425	Triticonazole	ND	ppm	0.05
426	Uniconazole-P	ND	ppm	0.05
427	Vinclozolin	ND	ppm	0.02
428	XMC	ND	ppm	0.05
429	Xylylcarb	ND	ppm	0.05
430	Zoxamide	ND	ppm	0.05

Persistent Organic Pollutants

	Analyte	Result
1	**Dioxins/Furans/WHO-12 PCBs	Completed - see attached eurofins Analysis Report

Microbiological Tests

	Analyte	Result	Units
1	Aerobic Plate Count (APC)	<10	CFU/g
2	Coliform, Plate Count	<10	CFU/g
3	E Coli, Plate Count	<10	CFU/g
4	Listeria Genus (by PCR)	Negative	
5	Mold	<10	CFU/g
6	Salmonella (by PCR)	Negative	
7	Yeast	<10	CFU/g

Minerals / Metals Screen

	Analyte	Result	Units	LOQ
1	Arsenic	ND	ppb	10
2	Cadmium	ND	ppb	10
3	Lead	10	ppb	10
4	Mercury	ND	ppb	5

**This analysis is outside the scope of OMIC USA operations and has been subcontracted to eurofins laboratory. Their report analysis is attached in its entirety. OMIC USA assumes no responsibility for its interpretations or use.

Negative = < 10 CFU/g; CFU=Colony Forming Unit; ppb=parts per billion (mcg/Kg or mcg/L); ppm=parts per million (mg/Kg or mg/L)
*LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted*

Mycotoxins Screen

	Analyte	Result	Units	LOQ
1	Aflatoxin B1	ND	ppb	5.0
2	Aflatoxin B2	ND	ppb	5.0
3	Aflatoxin G1	ND	ppb	5.0
4	Aflatoxin G2	ND	ppb	5.0

PAH'S Screen

	Analyte	Result	Units	LOQ
1	*Acenaphthene	ND	ppm	140
2	*Acenaphthylene	ND	ppm	130
3	*Anthracene	ND	ppm	220
4	*Benz(a)anthracene	ND	ppm	160
5	*Benzo(a)pyrene	ND	ppm	110
6	*Benzo(b)fluoranthene	ND	ppm	130
7	*Benzo(g,h,i)perylene	ND	ppm	130
8	*Benzo(k)fluoranthene	ND	ppm	130
9	*Chrysene	ND	ppm	110
10	*Dibenzo(a,h)anthracene	ND	ppm	180
11	*Flouranthene	ND	ppm	140
12	*Fluorene	ND	ppm	230
13	*Indeno((1,2,3-cd)pyrene	ND	ppm	160
14	*Napthalene	ND	ppm	140
15	*Phenanthrene	ND	ppm	130
16	*Pyrene	ND	ppm	110

Solvent Screen

	Analyte	Result	Units	LOQ
1	Hexane	ND	ppb	10

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*LOQ= Limit of Quantification; ND=Not Detected; N/A=Not Applicable; Trace=Qualitative result < LOQ; * = Analysis subcontracted*

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Analysis Report

REVISED

Sample Description: AB81761:Rice Bran Wax Composite Solid
OMIC USA INC

LL Sample # G5 7957463
LL Group # 1574979
Account # 30091

Project Name: OMIC USA

Collected: 07/06/2015 10:00 by DF

Submitted: 07/08/2015 08:10
Reported: 07/27/2015 11:00

OMIC USA Inc.
3344 NW Industrial St
Portland OR

CAT No.	Analysis Name	CAS Number	As Received Result	As Received EDL	Dilution Factor
Dioxins/Furans	**EPA 1613B modified**		**ng/kg**	**ng/kg**	
12963	2378-TCDD	1746-01-6	< 0.112	0.112	1
12963	2378-TCDF	51207-31-9	< 0.0576	0.0576	1
12963	12378-PeCDD	40321-76-4	< 0.0818	0.0818	1
12963	12378-PeCDF	57117-41-6	< 0.0375	0.0375	1
12963	23478-PeCDF	57117-31-4	< 0.0367	0.0367	1
12963	123478-HxCDD	39227-28-6	< 0.0430	0.0430	1
12963	123678-HxCDD	57653-85-7	< 0.0441	0.0441	1
12963	123789-HxCDD	19408-74-3	< 0.0469	0.0469	1
12963	123478-HxCDF	70648-26-9	< 0.0392	0.0392	1
12963	123678-HxCDF	57117-44-9	< 0.0381	0.0381	1
12963	123789-HxCDF	72918-21-9	< 0.0434	0.0434	1
12963	234678-HxCDF	60851-34-5	< 0.0367	0.0367	1
12963	1234678-HpCDD	35822-46-9	< 0.0339	0.0339	1
12963	1234678-HpCDF	67562-39-4	< 0.0306	0.0306	1
12963	1234789-HpCDF	55673-89-7	< 0.0315	0.0315	1
12963	OCDD	3268-87-9	< 0.0703	0.0703	1
12963	OCDF	39001-02-0	0.277	0.0723	1
D/F Toxic Equivalents	**EPA 1613B modified**		**ng/kg**	**ng/kg**	
12963	WHO2005 PCDD/F TEQ Lower Bound	n.a.	0.0000830		1
12963	WHO2005 PCDD/F TEQ Upper Bound	n.a.	0.242		1
WHO 12 PCBs	**EPA 1668 modified**		**ng/kg**	**ng/kg**	
12942	PCB77	32598-13-3	< 0.0845	0.0845	1
12942	PCB81	70362-50-4	0.164	0.0864	1
12942	PCB105	32598-14-4	6.15	0.0927	1
12942	PCB114	74472-37-0	0.503	0.106	1
12942	PCB118	31508-00-6	36.9	0.0984	1
12942	PCB123	65510-44-3	< 0.0989	0.0989	1
12942	PCB126	57465-28-8	0.332	0.0849	1
12942	PCB156	38380-08-4	5.53	0.0765	1
12942	PCB157	69782-90-7	0.655	0.0736	1
12942	PCB167	52663-72-6	4.48	0.0901	1
12942	PCB169	32774-16-6	< 0.0710	0.0710	1
12942	PCB189	39635-31-9	0.493	0.0442	1
PCB Toxic Equivalents	**EPA 1668 modified**		**ng/kg**	**ng/kg**	
12942	TEQ PCB WHO 2005 -EDLx0.0	n.a.	0.0349		1
12942	TEQ PCB WHO 2005 -EDLx1.0	n.a.	0.0370		1

General Sample Comments

WHO(2005)-PCDD/F + DLPCB TEQ (lower-bound) = 0.0350 pg/g
WHO(2005)-PCDD/F + DLPCB TEQ (upper-bound) = 0.279 pg/g

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Analysis Report

REVISED

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Submitted: 07/08/2015 08:10
Reported: 07/27/2015 11:00

OMIC USA Inc.
3344 NW Industrial St
Portland OR

Laboratory Sample Analysis Record

CAT No.	Analysis Name	Method	Trial#	Batch#	Analysis Date and Time	Analyst	Dilution Factor
12963	Solid Dioxins and Furans	EPA 1613B modified	1	15190001	07/10/2015 22:52	Joseph D Anderson	1
12942	Solid WHO12 + 6 Indicators	EPA 1668 modified	1	15190001	07/10/2015 19:23	Joseph D Anderson	1
12961	Dioxins/Furans/PCBs in Oil	EPA 1613B modified	1	15190001	07/09/2015 06:25	Ginelle L McQuaid	1

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Explanation of Symbols and Abbreviations

The following defines common symbols and abbreviations used in reporting technical data:

RL	Reporting Limit	**BMQL**	Below Minimum Quantitation Level
N.D.	none detected	**MPN**	Most Probable Number
TNTC	Too Numerous To Count	**CP Units**	cobalt-chloroplatinate units
IU	International Units	**NTU**	nephelometric turbidity units
umhos/cm	micromhos/cm	**ng**	nanogram(s)
C	degrees Celsius	**F**	degrees Fahrenheit
meq	milliequivalents	**lb.**	pound(s)
g	gram(s)	**kg**	kilogram(s)
µg	microgram(s)	**mg**	milligram(s)
mL	milliliter(s)	**L**	liter(s)
m3	cubic meter(s)	**µL**	microliter(s)
		pg/L	picogram/liter

<	less than
>	greater than
ppm	parts per million - One ppm is equivalent to one milligram per kilogram (mg/kg) or one gram per million grams. For aqueous liquids, ppm is usually taken to be equivalent to milligrams per liter (mg/l), because one liter of water has a weight very close to a kilogram. For gases or vapors, one ppm is equivalent to one microliter per liter of gas.
ppb	parts per billion
Dry weight basis	Results printed under this heading have been adjusted for moisture content. This increases the analyte weight concentration to approximate the value present in a similar sample without moisture. All other results are reported on an as-received basis.

Laboratory Data Qualifiers:

B - Analyte detected in the blank
C - Result confirmed by reanalysis
E - Concentration exceeds the calibration range
J (or G, I, X) - estimated value ≥ the Method Detection Limit (MDL or DL) and the < Limit of Quantitation (LOQ or RL)
P - Concentration difference between the primary and confirmation column >40%. The lower result is reported.
U - Analyte was not detected at the value indicated
V - Concentration difference between the primary and confirmation column >100%. The reporting limit is raised due to this disparity and evident interference…

Additional Organic and Inorganic CLP qualifiers may be used with Form 1 reports as defined by the CLP methods.
Qualifiers specific to Dioxin/Furans and PCB Congeners are detailed on the individual Analysis Report.

Analytical test results meet all requirements of the associated regulatory program (i.e., NELAC (TNI), DoD, ISO17025) unless otherwise noted under the individual analysis.

Measurement uncertainty values, as applicable, are available upon request.

Tests results relate only to the sample tested. Clients should be aware that a critical step in a chemical or microbiological analysis is the collection of the sample. Unless the sample analyzed is truly representative of the bulk of material involved, the test results will be meaningless. If you have questions regarding the proper techniques of collecting samples, please contact us. We cannot be held responsible for sample integrity, however, unless sampling has been performed by a member of our staff.

This report shall not be reproduced except in full, without the written approval of the laboratory.

Times are local to the area of activity. Parameters listed in the 40 CFR Part 136 Table II as "analyze immediately" are not performed within 15 minutes.

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APPENDIX C

Stability Testing Results

Stability Data for Wax 224 Rice Bran Wax

Batch	Date tested	Acid Value	Date tested	Acid Value	Date tested	Acid Value	Date tested	Acid Value	Date tested	Acid Value
11935	1/28/09	4.6	8/24/11	4.8	6/12/13	4.9				
13115	2/17/10	5.3	9/14/11	5.5	9/26/12	6.1	6/28/13	5.9	2/24/15	5.5
15010	9/9/11	6.7	6/3/13	6.2	9/10/15	6.8				
16139	7/9/12	6.1	6/11/13	6.4	12/4/14	6.4	9/2/15	6.1		
17399	6/3/13	8.5	6/11/15	8.3						

APPENDIX D

Intake Assessment Report

Estimated Daily Intake of Rice Bran Wax

FEBRUARY 27, 2017

ToxStrategies

Innovative solutions
Sound science

Estimated Daily Intake of Rice Bran Wax

FEBRUARY 27, 2017

PREPARED FOR:
J.M. Smucker Co.
1 Strawberry Lane
Orrville, Ohio 44667

PREPARED BY:
ToxStrategies, Inc.
9390 Research Blvd
Suite 100
Austin, Texas 78759

Table of Contents

List of Tables

List of Acronyms and Abbreviations

ARS	Agricultural Research Service
CDC	Centers for Disease Control and Prevention
EDI	estimated daily intake
FNDDS	Food and Nutrient Database for Dietary Studies
g/day	grams per day
g/kg BW/day	grams per kilogram body weight per day
NHANES	National Health and Nutrition Examination Survey
USDA	United States Department of Agriculture
WWEIA	What We Eat in America

1.0 Executive Summary

ToxStrategies, Inc. (ToxStrategies) has conducted an intake assessment to estimate the mean and 90th percentile daily intake of the ingredient rice bran wax based on its new proposed use in foods. The proposed use of rice bran wax is as a texturizing agent soley in peanut butter in bar-form products, allowing peanut butter to be the primary ingredient in nutritional/snack bars with a similar form and texture to granola bars and nutritional/energy bars. It was assumed for the purpose of this estimate that such unique bars would replace 10% of the bars currently consumed, reflecting a very high assumed future market share, in order to produce conservative (high) estimates of potential rice bran wax consumption.

A use level of 3% of rice bran wax in nutritional/snack bars was assessed. Analyzing dietary survey data from the National Health and Nutrition Examination Survey (NHANES) at a 3% use level and for a 10% market share of the foods yielded a *per user* mean (sd) and 90th percentile (sd) estimated daily intake (EDI) of rice bran wax for the US population ages 2+ of 0.077 (0.047) and 0.207 (0.245) g/day, respectibely. Adjusted for body weight (BW), the *per user* mean (sd) and 90th percentile (sd) EDI of rice bran wax for the US population ages 2+ was 0.0013 (0.0009) and 0.0029 (0.0037) g/kg BW/day, respectively.

2.0 Data

To calculate the EDI of rice bran wax, information about its proposed use in a new peanut butter nutritional/snack bar was combined with up-to-date, publicly available marketing and dietary intake survey data. Data sources are described in the following sections.

2.1 Proposed Uses and Use Levels of Rice Bran Wax

J.M. Smucker Co. proposes to use rice bran wax at the following use level in a peanut butter-based nutritional/snack bar (Table 1).

Table 1. Proposed use and use level of rice bran wax

Food Category	Proposed Technical Use of Rice Bran Wax	Proposed Use Level (%)
Nutritional/snack bar	Texturizing agent	3

2.2 Market Share Data

Market share was assessed using the Information Resources, Inc. (IRI) Worldwide database to gather annual sales data for granola-based bars (including those with peanut butter[1]) using the Total MultiOutlet sales for 2016. The IRI-defined category "Granola Based Bars" is composed of segments such as all family cereal or breakfast bars, cookies & biscuits in the granola aisle,

[1] Granola-based bars include peanut butter as a consumer attribute designated as "SuperFlavor" by the IRI database.

kids' cereal bars, and mainstream fiber bars; this category most accurately captures the market in which peanut butter-based bars would be sold.

2.3 Dietary Survey Data

Dietary survey data were obtained from What We Eat in America (WWEIA), the dietary interview portion of NHANES. NHANES is carried out in two-year cycles by the Centers for Disease Control and Prevention (CDC) in order to characterize the general health and nutritional status of children and adults across the US. The five most recent biennials for which dietary intake data are available were included in this analysis (2003-2004, 2005-2006, 2007-2008, 2009-2010, and 2011-2012).

The first day of the WWEIA dietary questionnaire was administered in person, in conjunction with the participants' interviews and examinations for the other NHANES lifestyle and laboratory assessments. The second day of the survey was collected via a phone interview at some point three to ten days after the first survey day. Data collected during the dietary interview includes foods as consumed by the participant, encoded by a US Department of Agriculture (USDA) food code, and amount eaten.

Respondents who provided complete records for both days were designated reliable by WWEIA, and only those respondents were considered in this analysis (N = 2,683). A small percentage of participants (< 0.1%) did not provide body weight information and were therefore excluded from the statistics estimating intake on a per kilogram body weight basis.

2.4 Recipe Data

Recipe data were obtained from the Food and Nutritional Data for Dietary Studies (FNDDS), released by the Agricultural Research Service (ARS) of USDA as a companion to NHANES WWEIA. For each food, the most recent available recipe was applied (*i.e.*, foods reported in the 2009-2010 WWEIA survey were analyzed using recipes from the 2011-2012 release of FNDDS, if possible). As the contents of FNDDS are continually updated and refined, this method ensures that EDI estimates reflect the most up-to-date information about foods consumed in the US.

3.0 Methods

To estimate the intake of rice bran wax from its proposed use, ToxStrategies performed the following steps:

- Step 1: Identified foods and their components to which rice bran wax could be added
- Step 2: Estimated individual intake of rice bran wax for individual survey participants
- Step 3: Estimated population statistics estimating intake of rice bran wax

Details of each step are provided in the following sections.

3.1 Identification of Foods and Their Components to Which Rice Bran Wax Could Be Added

To identify the new foods that are proposed to contain rice bran wax, ToxStrategies performed a thorough search of food codes reported in WWEIA. Food code descriptions from WWEIA and associated ingredients listed in FNDDS were queried for keywords pertaining to nutritional/snack bars and breakfast bars/tarts. In order to generate the most conservative estimate, J.M. Smucker Co. assumed that 10% of all of these foods would be replaced by the new peanut butter products stiffened with rice bran wax. Food codes included in the analysis are listed in the appendix.

In some cases, the future peanut butter bar component would not replace the entire food (*e.g.*, it would replace only the bar portion of a bar covered in a chocolate or yogurt coating). Relevant proportions of each food were determined by reviewing the recipe for that food item from FNDDS, with further development by ToxStrategies. An asterisk in the appendix indicates that the nutrition bar was a fraction of the total food by weight; in these cases, the use level of rice bran wax was applied to less than 100% of the reported food.

3.2 Estimation of Individual Intake of Rice Bran Wax for Individual Survey Participants

Market Share Assessment

The total Granola Based Bars sales during 2016 were 28,055,568 EU[2]. Ten items were identified that launched in the last year and for which dollar share information for the segment was reported. Of these, the best-selling newly-launched bar (Product 9 in Table 2) had reported sales of 280,705 EU, approximately 1% of the total sales for the entire category during that same year. For comparison, the best-selling J.M. Smucker bar (Product 15) reported sales of 72,186 EU after its first year, accounting for about 0.25% of total sales.

Table 2. Worldwide sales for Granola Based Bars using IRI MultiOutlet database

	UPC	Consistency	SuperFlavor	Sales (EU)[B]
Total Granola-Based Bar Sales 2016[A]				**28,055,568**
Granola-Based Bars Launched in 2016[A]				
Product 1	1600046675	SOFT	ALL OTHER	25,164
Product 2	1862710474	CHEWY	HONEY/MAPLE	6,901
Product 3	1862710468	CRUNCHY	NUT	13,302
Product 4	1862710466	CHEWY	DARK CHOCOLATE	16,060
Product 5	1862710478	CHEWY	DARK CHOCOLATE	18,346
Product 6	1862710167	CHEWY	CHOCOLATE	62,884
Product 7	1600043269	CRUNCHY	CINNAMON	143,245
Product 8	1600047196	CHEWY	NUT	91,417
Product 9	1600043268	CRUNCHY	OATS/SEEDS/GRAIN	280,705
Product 10	3000056031	CHEWY	NUT	32,664

[2] 1 EU = 9 pounds

Product 11 (JMS brand)[C]	5150024447	CHEWY	CHOCOLATE	5,566
Product 12 (JMS brand)[C]	5150024449	CHEWY	CHOCOLATE	11,333
JMS Peanut Butter Granola-Based Bars[D]				
Product 13 (JMS brand)	5150021004	CHEWY	PEANUT BUTTER	55,909
Product 14 (JMS brand)	5150021015	CHEWY	PEANUT BUTTER	25,695
Product 15 (JMS brand)	5150021007	CHEWY	PEANUT BUTTER	72,186

[A]52 weeks ending December 25, 2016 unless otherwise noted
[B]1 EU = 9 pounds
[C]Partial year sales, June-December 2016 only
[D]Sales at end of first year after launching

Based on the available market share data for 2016 presented here, and using the best-selling bar as the most conservative comparator, the maximum potential market share of the newly proposed bar to contain rice bran wax is estimated to be 1%. This is 4-fold higher than the 0.25% market share that has been demonstrated for J.M. Smucker-specific bar products. Taking this approach makes the conservative assumption that the best-selling bar will be replaced completely with the newly proposed bar containing rice bran wax. To add a further layer of conservatism, we increased this estimate by a factor of 10 and assumed an estimated market share of 10%, as described below.

Intake Assessment
All individuals participating in NHANES who consumed any of the identified foods were included in this assessment. A conservative market share of 10% of the foods was assumed in simulations, i.e. for each of 5,000 simulations, 10% of the foods were designated as containing rice bran wax to the 3 % use level requested. This approach was taken to ensure that the higher exposure to rice bran wax in consumers who ate a particular food frequently was captured in the population distribution of potential consumption.

Only those respondents designated as reliable were included in this assessment. Both days of the NHANES WWEIA dietary interviews from the five biennials (2003-2012) were analyzed. Participants' consumption of the rice bran wax was averaged over the two response days, *i.e.*, (Day1 consumption + Day2 consumption)/2. Raw consumption of rice bran wax was calculated using the grams of the relevant food consumed as reported in NHANES, multiplied by the proportion of the food that was relevant to the technical use of rice bran wax (see Section 3.1), multiplied by its proposed use level. For example, for the food "53714300 Granola bar, high fiber, coated with non-chocolate yogurt coating", the relevant proportion of that food (the bar only), was 0.78, and the use level was 0.03. Thus, for a survey participant who consumed 28.3g (1 oz.) of this food, approximately 0.66g, or (28.3 * 0.78 * 0.03), of rice bran wax would be consumed.

For the calculations of intake per kilogram body weight, individuals' own body weights as reported in NHANES were used rather than any general assumption of adults' or children's body weights, reflecting the true population distribution of g/kg BW consumption.

3.3 Calculation of Population Statistics Describing Rice Bran Wax Estimated Daily Intake

To ensure that the most up-to-date data on consumption were used for this analysis, the five most recent NHANES biennials for which there are published dietary survey data available were used: 2003-2004, 2005-2006, 2007-2008, 2009-2010, and 2011-2012. The dietary and sample weighting data from the five biennials were combined according to the NHANES analytic guidelines for combining surveys. From the combined dataset we estimated survey design weighted descriptive statistics for the population consumption per day. Population statistics were estimated using the 'survey' package (Lumley, 2004) in the R 3.1.2 environment for statistical computing (R Core Team, 2015) using the appropriate adjustment to sampling weights for combining biennials, then incorporating survey sampling units and strata from the survey design to ensure that sub-populations and areas were correctly represented.

The market share simulations generated distributions of the population descriptive statistics (mean, 90th percentile) and were calculated for consumers of the nutritional/snack bars. Means and standard deviations of these statistics are provided, broken down by age range and body weight adjustment.

4.0 Results

Table 3 presents the EDI for rice bran wax in grams per day (g/day) and in grams per kilogram body weight per day (g/kg BW/day) for the following age groups in the US populations: 2 years and older, 2 to 5 years, 6 to 18 years, and 19 years and older. The "number of users" refers to the number of survey participants in a given age group who consumed at least one of the identified food items.

Table 3. Estimated daily intake for rice bran wax (g/day and g/kg BW/day) at a 3% use level

Nutrition/snack bar	Number of Users NHANES 2003-2012	EDI *per User* (g/day)		EDI *per User* (g/kg BW/day)*	
		Mean (sd)	90th Percentile (sd)	Mean	90th Percentile
US Population, Ages 2+					
Rice bran wax consumption	2683	0.077 (0.047)	0.207 (0.245)	0.0013 (0.0009)	0.0029 (0.0037)
US Population, Ages 2-5					
Rice bran wax consumption	253	0.058 (0.046)	0.190 (0.217)	0.0034 (0.0029)	0.0104 (0.0126)
US Population, Ages 6-18					
Rice bran wax consumption	844	0.063 (0.043)	0.176 (0.221)	0.0016 (0.0012)	0.0038 (0.0052)
US Population, Ages 19+					

Nutrition/snack bar	Number of Users NHANES 2003-2012	EDI *per User* (g/day)		EDI *per User* (g/kg BW/day)*	
		Mean (sd)	90th Percentile (sd)	Mean	90th Percentile
Rice bran wax consumption	1586	0.082 (0.051)	0.225 (0.260)	0.0011 (0.0007)	0.0028 (0.0033)

* Body weight was not reported for < 0.1% of survey participants. Users with missing body weight data were excluded from this analysis.

5.0 References

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Appendix: List of Food Codes

Food Codes					Main food description
2003-2004	2005-2006	2007-2008	2009-2010	2011-2012	
NA	NA	41435000	41435000	NA	Fiber One Fulfill Bar
41435110	41435110	41435110	41435110	53720700	High protein bar, candy-like, soy and milk base
NA	NA	41435120	41435120	53720800	Zone Perfect Classic Crunch nutrition bar
NA	NA	41435300	41435300	53720100	Balance Original Bar
NA	NA	41435500	41435500	53720200	Clif Bar
NA	NA	41435700	41435700	53720610	South Beach Living High Protein Cereal Bar
NA	NA	41435710	41435710	53720600	South Beach Living Meal Replacement Bar
42202000	42202000	42202000	42202000	42202000	Peanut butter
42202010	42202010	42202010	42202010	42202010	Peanut butter, low sodium
NA	42202100	42202100	42202100	42202100	Peanut butter, reduced sodium and reduced sugar
NA	42202130	42202130	42202130	42202130	Peanut butter, reduced sugar
42202150	42202150	42202150	42202150	42202150	Peanut butter, reduced fat
42202200	42202200	42202200	42202200	42202200	Peanut butter, vitamin and mineral fortified
42203000	42203000	42203000	42203000	42203000	Peanut butter and jelly*
53234000	53234000	53234000	53234000	53234000	Cookie, peanut butter
53234010	53234010	53234010	53234010	NA	Cookie, peanut butter, with oatmeal
53234100	53234100	53234100	53234100	53234100	Cookie, peanut butter, with chocolate
53234250	53234250	53234250	53234250	53234250	Cookie, peanut butter with rice cereal (no-bake)
53235000	53235000	53235000	53235000	53235000	Cookie, peanut
53235500	53235500	53235500	53235500	53235500	Cookie, with peanut butter filling, chocolate-coated
53530000	53530000	53530000	53530000	53530000	Breakfast tart*
53530010	53530010	53530010	53530010	53530010	Breakfast tart, lowfat*
53540000	53540000	53540000	53540000	53714500	Breakfast bar, NFS
53540200	53540200	53540200	53540200	53714520	Breakfast bar, cereal crust with fruit filling, lowfat*
NA	NA	53540300	53540300	53710400	Fiber One Chewy Bar
NA	NA	53540400	53540400	53710500	Kellogg's Nutri-Grain Cereal Bar
NA	NA	53540402	53540402	53710502	Kellogg's Nutri-Grain Yogurt Bar
NA	NA	53540404	53540404	53710504	Kellogg's Nutri-Grain Fruit and Nut Bar
53540500	53540500	53540500	53540500	53714510	Breakfast bar, date, with yogurt coating*
53540600	53540600	53540600	53540600	53710600	Milk 'n Cereal bar
NA	53540700	53540700	53540700	53710700	Kellogg's Special K bar
NA	NA	53540800	53540800	53710800	Kashi GOLEAN Chewy Bars
NA	NA	53540802	53540802	53710802	Kashi TLC Chewy Granola Bar

NA	NA	53540804	53540804	53710804	Kashi GOLEAN Crunchy Bars
NA	NA	53540806	53540806	53710806	Kashi TLC Crunchy Granola Bar
NA	NA	NA	53540900	53710900	Nature Valley Chewy Trail Mix Granola Bar
NA	NA	NA	53540902	53710902	Nature Valley Chewy Granola Bar with Yogurt Coating*
NA	NA	NA	53540904	53710904	Nature Valley Sweet and Salty Nut Granola Bar
NA	NA	NA	53540906	53710906	Nature Valley Crunchy Granola Bar
NA	NA	NA	53541000	53711000	Quaker Chewy Granola Bar
NA	NA	NA	53541002	53711002	Quaker Chewy 90 Calorie Granola Bar
NA	NA	NA	53541004	53711004	Quaker Chewy 25% Less Sugar Granola Bar
NA	NA	NA	53541006	53711006	Quaker Chewy Dipps Granola Bar
53541200	53541200	53541200	53541200	53729000	Meal replacement bar
NA	NA	NA	53541300	53720400	Slim Fast Original Meal Bar
NA	NA	53542000	53542000	53712000	Snack bar, oatmeal
NA	NA	NA	53542100	53712100	Granola bar, NFS
NA	NA	NA	53542200	53712200	Granola bar, lowfat, NFS
53542210	53542210	53542210	53542210	53712210	Granola bar, nonfat
NA	NA	NA	53543000	53713000	Granola bar, reduced sugar, NFS
53543100	53543100	53543100	53543100	53713100	Granola bar, peanuts, oats, sugar, wheat germ
NA	NA	53544200	53544200	53714200	Granola bar, chocolate-coated, NFS*
53544210	53544210	53544210	53544210	53714210	Granola bar, with coconut, chocolate-coated*
53544220	53544220	53544220	53544220	53714220	Granola bar with nuts, chocolate-coated*
NA	NA	53544230	53544230	53714230	Granola bar, oats, nuts, coated with non-chocolate coating*
53544250	53544250	53544250	53544250	53714250	Granola bar, coated with non-chocolate coating*
53544300	53544300	53544300	53544300	53714300	Granola bar, high fiber, coated with non-chocolate yogurt coating*
53544400	53544400	53544400	53544400	53714400	Granola bar, with rice cereal*
NA	NA	53544410	53544410	53711100	Quaker Granola Bites
53544450	53544450	53544450	53544450	53720300	PowerBar (fortified high energy bar)
54327950	54327950	54327950	54327950	54327950	Crackers, cylindrical, peanut-butter filled
54328100	54328100	54328100	54328100	54328100	Cracker, sandwich-type, peanut butter filled
NA	54328110	54328110	54328110	54328110	Cracker, sandwich-type, peanut butter filled, reduced fat
91732000	91732000	91732000	91732000	91732000	Peanut bar
91732100	91732100	91732100	91732100	91732100	Planters Peanut Bar
91733000	91733000	91733000	91733000	91733000	Peanut brittle
91733200	91733200	91733200	91733200	91733200	Peanut Bar, chocolate covered candy*
91734100	91734100	91734100	91734100	91734100	Reese's Peanut Butter Cup
91734200	91734200	91734200	91734200	91734200	Reese's Pieces
NA	91734300	91734300	91734300	91734300	Reese's Sticks

91734400	91734400	91734400	91734400	91734400	Reese's Fast Break
NA	NA	91734450	91734450	91734450	Reese's Crispy Crunchy Bar
NA	91780010	91780010	91780010	53720510	Snickers Marathon Energy bar
NA	91781010	91781010	91781010	53720500	Snickers Marathon Protein bar

* Rice bran wax was present in a subcomponent of the food item. See section 3.1 of this report.

EXHIBIT I

Report of the Expert Panel

OPINION OF AN EXPERT PANEL ON THE SAFETY AND GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF RICE BRAN WAX FOR USE IN SPECIFIED FOOD PRODUCTS

Introduction

An independent panel of experts (Expert Panel), qualified by scientific training and experience to evaluate the safety of food and food ingredients, was requested by The J. M. Smucker Company (Smucker) to determine the safety and Generally Recognized as Safe (GRAS) status of the use of rice bran wax as an ingredient for use in a specified food for human consumption. Rice bran wax is intended for use as a texturizing agent in peanut butter used in nutrition and granola-type snack bar products. The intended use of rice bran wax is solely in the peanut butter used in these bar products and will allow peanut butter to be the primary ingredient in nutritional/snack bars with a similar form and texture to granola bars and nutritional/energy bars. The rice bran wax ingredient is manufactured in accordance with current Good Manufacturing Practice (cGMP) and meets the proposed specifications.

A detailed review based on the existing scientific literature (through June 2017) on the safety of rice bran wax was conducted by ToxStrategies, Inc. (ToxStrategies) and is summarized in the attached dossier. The Expert Panel members independently reviewed the dossier prepared by ToxStrategies and other pertinent information and convened on July 12, 2017 via teleconference. Based on their independent, critical evaluation of all of the available information and discussions during the July 12, 2017 teleconference, the Expert Panel unanimously concluded that the intended uses described herein for Smucker's rice bran wax ingredient, meeting appropriate food-grade specifications as described in the supporting dossier (**GRAS Determination of Rice Bran Wax for Use in Specified Food Products**) and manufactured according to cGMP, is safe, suitable, and GRAS based on scientific procedures. A summary of the basis for the Expert Panel's conclusion is provided below.

Summary and Basis for GRAS Determination

Description

Rice bran wax (CAS No. 8016-60-2) is a hard, crystalline vegetable wax obtained from rice husks. It primarily consists of high molecular weight monoesters ranging from C48 to C64. Rice bran wax is typically yellow to light brown in color with a melting point of 75 - 85.5°C. The rice bran wax that is the subject of this safety evaluation is processed from rice bran oil obtained from rice husks, and is not hydrogenated.

Manufacturing Process

The starting material, crude rice bran wax, is weighed and added to a clean melt tank and melted. During this process, settling separates out the non-rice bran wax solids. Next, the melted rice bran wax is transferred to a tank containing one or more safe and suitable decoloring agents, and the wax is mixed and recirculated in the tank. Prior to continuing on to the filter process, a filter medium consisting of common and approved processing

aids used in food manufacturing processes is added. Once the filtering medium is adequately incorporated, the mixture is sent through the filter press and then back into the tank until the wax becomes clear. Once the wax is clear, a sample is collected and sent to the laboratory for aesthetics (color and odor) testing. If the wax does not meet aesthetics specifications, it is pumped into another tank, and cooling water is turned on, a safe and suitable decoloring agent is added, and the temperature is raised in a controlled manner in order to remove the decoloring agent. A sample is again collected and tested for compliance with aesthetic (color/odor) specifications. If the wax meets the aesthetic specification (either with the first or second lab result), it is filtered through a cartridge filter and sent on to the pastillating step (i.e., process of pelleting into uniform half spheres). If the wax is tested twice and fails, it is discarded. Once pastillated, the wax is sampled for quality testing, packaged, and labeled. The finished ingredient that passes all quality control measures is released for sale and placed into inventory. If a sample fails established quality parameters, the wax is discarded.

Analytical (chemical and microbiological) results for the rice bran wax product confirm that the finished product meets the proposed analytical specifications as demonstrated by the consistency of production, the lack of impurities and contaminants (e.g., heavy metals, pesticides, mycotoxins, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and dioxin-like polychlorinated biphenyls), and is stable for two years from the date of manufacture, if stored under proper conditions.

Rice Bran Wax and Related Data Considered in the Safety Assessment

The majority (87%–98%) of the rice bran wax components are monoesters; the remaining components (2-13% total) of the rice bran wax product consist of free long-chain fatty alcohols, free long-chain fatty acids, or triglycerides from rice bran oil. The long-chain fatty acid esters present in plant-based waxes such as rice bran wax are generally thought to be poorly absorbed in the gastrointestinal tract (EFSA, 2012a,b) as uptake of wax esters decreases as chain length and hydrophobicity increase (Hargrove et al., 2004). While some toxicological data are available for rice bran wax, information on its main constituents and other plant-based waxes with similar chemical structures, and thus similar potential for absorption, were also evaluated as part of the GRAS assessment. These oils and waxes are composed of the same primary monoester constituents as rice bran wax, and have been shown to have the same absorption, metabolism, and excretion properties. A similar approach has been taken for the evaluation of other plant-based waxes. In 2007, the European Food Safety Authority (EFSA, 2007) applied a similar approach for beeswax, bridging safety data from main constituents and other similar waxes. The EFSA Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC) concluded that "the use of beeswax as an additive for the existing food uses and the proposed new food use is not of safety concern." EFSA also applied a similar approach to candelilla wax in their 2012 assessment (EFSA, 2012c).

In the current assessment, toxicity studies conducted on carnauba wax, candelilla wax, beeswax, lanolin wax, and jojoba oil/wax were identified and deemed suitable for inclusion in the safety assessment of rice bran wax and considered by the Expert Panel in its evaluation. Jojoba wax consists almost entirely of long-chain monoesters (97%), and is therefore directly comparable to the primary component of rice bran wax (87%–98%

monoesters), providing toxicological data specific to this fraction. Carnauba wax, candelilla wax, beeswax, and lanolin wax also have a large fraction of these monoesters and so provide additional safety information related to these components. Importantly, minor components present in rice bran wax (e.g., free fatty alcohols, free fatty acids) are present in one or more of these waxes at higher concentrations, thus providing additional safety information on these constituents. However, these waxes also contain various other constituents not relevant to rice bran wax that may impart toxicities of their own or may be of unknown toxicity. As such, these other waxes are considered appropriate and conservative comparators to rice bran wax, which is purer and consists almost exclusively of esters or their fatty acid and alcohol components.

In addition, chain length and saturation have been shown to predict physio-chemical behavior of waxes and oils, including their potential for toxicity (EFSA, 2007; Maru et al., 2012; Smith et al., 1996). As demonstrated by Smith et al. (1996), the potential for toxicity of waxes decreases with increasing chain length. Of the waxes evaluated in this GRAS assessment, rice bran wax contains the longest alcohol and acid chain lengths and has one of the largest monoester fraction (comparable to jojoba) and thus would be the least bioavailable, positioning it to have the least potential for toxicity. Thus, any negative findings in safety studies conducted with carnauba wax, candelilla wax, beeswax, lanolin wax, or jojoba wax can be confidently extended to rice bran wax.

Taken together, the available data on these various waxes provides sufficient information to assess the safety of rice bran wax and its constituents for its intended use.

History of Use

Rice, brown rice, and their derivatives have a long history of human consumption, with rice cultivation documented back to prehistoric times, starting in Asia and eventually spreading across Europe around the sixth century (Burlando and Cornara, 2014). Currently, rice is produced on most continents and serves as a dietary staple for many populations across the world (Burlando and Cornara, 2014). Once harvested, the rice is hulled and the resulting brown rice can be further processed to generate derivatives such as rice bran oil, rice bran extract, and hydrolyzed rice protein. As referenced in the manufacturing process outlined above, rice bran wax comes from the bran, which is the part between the husk and endosperm of rice, and is a byproduct of bran oil (Burlando and Cornara, 2014; Andersen, 2006; Sabale et al., 2007). Rice bran wax is used in food as a release agent, brightener, coatings for confectioneries, chocolates, cakes, and tablets, treatment of vegetables and fruits and as a plasticizing material for chewing gum base. Rice bran wax (CAS No. 8016-60-2) has been approved for use in various food applications in the US. It is permitted as a direct human food additive (21 CFR §172.890) when used in candy (maximum 50 ppm as a coating), fresh fruits and fresh vegetables (maximum 50 ppm as a coating), and chewing gum (maximum 2.5% in gum when used as a plasticizing material in chewing gum base, 21CFR §172.615). It is also permitted as an indirect food additive as Type VIII in table 1of 176.170(c), at a maximum level of 1.0 percent by weight of the polymer. After reviewing the available safety data, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that rice-derived ingredients, including rice bran wax, are safe as cosmetic ingredients (e.g., 1% in lipstick) in the practices of use and concentrations as described in their safety assessment (Andersen, 2006). In addition, rice bran wax is eligible for use as an active ingredient or

excipient in listed medicines in Australia, with no restrictions (Australian Government, 2007).

Intended Use and Intake Assessment

The proposed use of rice bran wax is as a texturizing agent solely in peanut butter that is used in bar-form products, allowing peanut butter to be the primary ingredient in bar products that include cereal bars, breakfast bars, cookies and biscuits, nutritional bars, and energy snack bars with similar form and texture.

The US FDA's Office of Food Additive Safety, in the Center for Food Safety and Applied Nutrition, has performed a dietary exposure estimate of rice bran wax intake from nutritional and energy bars based on its new proposed use in foods using two different approaches (FDA, 2017). The outcome of this assessment was made available to ToxStrategies for review in response to a Freedom of Information Act request (FOI Request No. 2017-4008). While some of the data used in this assessment are proprietary, and therefore not available to the Expert Panel for review, they are appropriate for consideration as "other information available to FDA."

The first intake estimate determined by FDA was based on two-day average intake data obtained from the "What We Eat in America" (WWEIA) National Health and Nutrition Examination Survey (NHANES). The estimates prepared by FDA based on NHANES data for the Estimated Dietary Intake (EDI) of rice bran wax were 0.01 and 0.03 g/kg-bw/day, respectively, for the mean and 90th percentile in the population aged 2+ years. However, as stated by FDA (2017) in its memorandum, the available information suggests that the bars included in the assessment are eaten infrequently. As such, the two-day survey data "are likely to significantly overestimate the actual consumption." In order to prepare a more appropriate estimate of intake, FDA conducted a second assessment using longer term survey data, which more accurately reflect intake of these bars. To do so, 10- to 14-day dietary recall data from the NPD Group, Inc.'s, "National Eating Trends-Nutrient Intake Database" (NET-NID) were used. Using the longer-term survey data, FDA estimated the daily average mean and 90th percentile dietary intakes of rice bran wax to be 0.003 and 0.005 g/kg-bw/day, respectively, for ages 2+ years. For the 2- to 5-year-old population, the EDIs of rice bran wax were determined to be 0.007 and 0.014 g/kg-bw/day, respectively. Importantly, the analysis by FDA included any and all bars, and as such, is very conservative when applied to the types of bars containing peanut butter that are the focus of this GRAS determination. As such, the results of the FDA intake assessment will overestimate of the actual consumption of rice bran wax as intended for use.

In addition, ToxStrategies, Inc. (ToxStrategies), has conducted an intake assessment incorporating market share to provide supplemental information related to the mean and 90th percentile daily intake of the ingredient rice bran wax. The results of this intake estimate were similar to that of the FDA described above. The background exposure to rice bran wax from its approved uses in gum, candy, and fresh fruit and fresh vegetables is estimated to be approximately 100 mg/day, about half of which is estimated to come from fresh fruit/vegetables and the other half from chewing gum. This estimate is based on reported consumption levels for chewing gum (approximately 30 mg/kg/day for a 60 kg individual or 1.8 g gum/day), candy (mean intake of approximately 40 g candy/day), and fresh fruit and fresh vegetables (approximately 900 g fruits and vegetables/day)

(Revolymer Limited, 2011; Cook, 2011; Orlich et al., 2014; Shumow et al., 2012). Given the approved 2.5% maximum use level of rice bran wax in chewing gum, the background exposure estimates for rice bran wax from its use in chewing gum would be higher for heavy users of chewing gum (estimated to be on the order of 2-3x) as compared to mean intake estimates. Therefore, the background exposure to rice bran wax from current approved uses is estimated to be as high as 200 - 300 mg/day.

We believe this background exposure estimate is extremely conservative given that other waxes are more commonly used as confectionery coatings (e.g., carnauba wax) and as a coating for fruits and vegetables and alternative waxes and plasticizers are approved and used in chewing gum base in the USA. In addition, it is generally acknowledged that waxes and plasticizers in gum base remain with the gum cud during chewing and are not released and subsequently ingested.

Safety Data

Brown rice and its derivatives, such as rice bran wax, have a long history of human consumption, with rice cultivation documented back to prehistoric times (Burlando and Cornara, 2014). Rice bran wax has been approved for use in various food applications in the US and is permitted as a direct human food additive when used in candy, fruits and vegetables, and chewing gum (21CFR §172.890).

The safety of of rice bran wax was evaluated based on preclinical safety studies of rice bran wax and other compositionally similar waxes and constituents of these waxes. Rice bran wax consists primarily of high-molecular-weight monoesters ranging from C48 to C64 (87%–98%); the remaining components of the rice bran wax product consist of free long-chain fatty alcohols, free long-chain fatty acids, and triglycerides. While some toxicological data are available for rice bran wax, information on its main constituents and other plant-based waxes with similar chemical structures, and thus similar potential for absorption, was also evaluated as part of this safety assessment. Studies conducted on carnauba wax, candelilla wax, beeswax, lanolin wax, and jojoba wax were identified and deemed suitable for inclusion in the safety assessment of rice bran wax and were considered by the Expert Panel in its evaluation. Taken together, the available data presented here allow for sufficient evaluation of the safety of rice bran wax.

Subchronic toxicity and/or reproductive/developmental toxicity studies were identified for carnauba wax and candelilla wax. In each of the studies with carnauba wax, the NOAEL was the highest dose level administered and ranged from 250 to 10,800 mg/kg-bw/day, the highest of which was a concentration of 10% (equivalent to 8,800 and 10,200 mg/kg-bw/day in males and females, respectively) administered in the diet of rats for 90 days. Chronic studies with candelilla wax were also identified, and the NOAELs in these studies were also the highest dose tested, up to 2,400 mg/kg-bw-day.

The history of use in foods of other vegetable-based waxes, in particular carnauba wax, provides additional information relevant to the safety assessment of rice bran wax. Hargrove et al. (2004) reviewed the intake of wax worldwide and noted that the intake in some populations can average as high as 4 g/day. Rice bran wax has been approved for use

in various food applications in the US. It is permitted as a direct human food additive (21 CFR §172.890) when used in candy (maximum 50 ppm as a coating), fresh fruits and fresh vegetables (maximum 50 ppm as a coating), and chewing gum (maximum 2.5% in gum when used as a plasticizing material in chewing gum base, 21CFR §172.615). It is also permitted as an indirect food additive as Type VIII in Table 1of 176.170(c), at a maximum level of 1.0 percent by weight of the polymer. Carnauba wax is similarly permitted as a GRAS direct human food ingredient, with no limitation other than cGMP, in baked goods and baking mixes, chewing gum, confections and frostings, fresh fruits and fruit juices, gravies and sauces, processed fruits and fruit juices, and soft candy (21 CFR § 184.1978). The FDA has listed carnauba wax, beeswax, and candelilla wax as GRAS as a direct food substances for human consumption with no specific limitation other than good manufacturing practice (21 CFR § 184.1978; 1973; and 1976, respectively). Candelilla wax is also considered GRAS by the Flavor & Extract Manufacturer's Association (GRAS No. 3479; Oser and Ford, 1977).

As noted above, FDA has also conducted an intake assessment of rice bran wax using the NET-NID 10-14-day survey data, which reflect a more accurate estimation of the long-term consumption of the bar products intended to contain the rice bran wax product (FDA, 2017). Margins of Exposure (MOEs) for rice bran wax for its intended use in bars were calculated based on the EDIs determined by FDA. Estimated mean and 90th percentile intakes of rice bran wax of 0.003 g/kg-bw/day and 0.005 g/kg-bw/day, respectively, were calculated (assuming a 3% use level) for the U.S. population ages 2 and over. This provides margins of exposure of approximately 223× and 134×, respectively, for mean and 90th percentile intakes when compared to the lowest NOAEL reported in the 2-generation study with carnauba wax (Parent et al., 1983). When considering the population with the highest EDI, ages 2–5 years, the estimated mean and 90th percentile intakes of rice bran wax were 0.007 g/kg/day and 0.014 g/kg/day, respectively. This provides margins of exposure of approximately 96× and 48×, respectively, for the mean and 90th percentile. Therefore, all calculated MOEs were determined to be at or greater than 100x, with the exception of the 90th percentile in the 2-5-year age group.

More importantly, all EDIs calculated by FDA are at or near the JECFA ADI for carnauba wax of 0-7 mg/kg-bw/day. Only the 90th percentile in the 2-5-year age group had an EDI marginally above the JECFA ADI. However, an EDI marginally above the ADI for the 90th percentile of only one age group – 2-5 year olds – is of limited concern given the inherent over-conservatism in both the EDI calculations (i.e., inclusion of any/all bar types) and the basis of the ADI determination. An ADI, as determined by JECFA, is "an estimate of the amount of the additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (notionally "zero" risk). JECFA does not make a quantitative estimate of risk at an intake corresponding to the ADI, but concludes that the risk is so small as to be negligible from a public health point of view"[1]. JECFA goes on to state that this evaluation "can be considered to be mainly the hazard characterization step". In other words, the ADI is not a threshold above which the risk of health effects will suddenly be of concern. In addition, the ADI for carnauba wax

[1] http://www.fao.org/docrep/008/ae922e/ae922e05.htm

was developed assuming ingestion over a lifetime. The EDI for the age group in question, 2-5 years, is a transient time period that has limited relevance to a lifetime exposure.

The analysis as presented in this GRAS assessment demonstrates that all EDIs for rice bran wax are at or near the most relevant ADI. Together with the supporting safety data, the available information demonstrates the rice bran wax product to be safe for the intended use described herein.

General Recognition of the Safety of Rice Bran Wax

The intended use of rice bran wax has been determined to be safe through scientific procedures as set forth in 21 CFR§170.3(b), thus satisfying the so-called "technical" element of the GRAS determination and this is based on the following:

- The rice bran wax that is the subject of this notification is a high melting point vegetable wax obtained from rice husks. The rice bran wax product is manufactured consistent with current cGMP for food (21 CFR Part 110). The raw materials and processing aids used in the manufacturing process are food grade and/or approved for use in food.

- Brown rice, and its derivatives have a long history of human consumption with rice cultivation documented back to prehistoric times. Importantly, the known history of use of rice bran wax in food such as candy, chewing gum, and fresh fruit and vegetables (21 CFR § 172.890 and 21 CFR § 172.615) is also supportive of its safe use in food and specifically the intended use and use levels specified in this dossier.

- Rice bran wax consists primarily of high-molecular-weight monoesters ranging from C48 to C64 (87%–98% A); the remaining components of the rice bran wax product consist of free long-chain fatty alcohols, free long-chain fatty acids, or rice bran oil. While some toxicological data are available for rice bran wax, information on its main constituents and other plant-based waxes with similar chemical structures, and thus similar potential for absorption, was also evaluated as part of the GRAS assessment. Studies conducted on carnauba wax, candelilla wax, beeswax, lanolin wax, and jojoba wax were identified and deemed suitable for inclusion in the safety assessment of rice bran wax.

- Subchronic toxicity and/or reproductive/developmental toxicity studies were identified for carnauba wax, candelilla wax, and jojoba oil. In each of the published studies on carnauba wax, the NOAEL was the highest dose level administered and ranged from 250 to 10,800 mg/kg/day, the highest of which was a concentration of 10% (equivalent to 8,800 and 10,200 mg/kg-bw/day in males and females, respectively) administered in the diet of rats for 90 days. Chronic studies with candelilla wax were also identified, and the NOAELs in these studies were also the highest dose tested, up to 2,400 mg/kg-bw-day.

- Given that rice bran wax contains little to no protein, which is the component responsible for imparting any allergic potential, rice bran wax is not likely to pose an allergenic risk.

- There is no concern with arsenic as the intake of total and inorganic arsenic from the intended use of rice bran wax is negligible and would not be expected to contribute to the background dietary intake.

- The intake analysis conducted by FDA resulted in EDIs below the JECFA ADI for carnauba wax of 0–7 mg/kg-bw/day, apart from the 90th percentile of

the 2- to 5-year-old age group. More accurate intake frequency data (e.g., surveys of longer durations) or a lower market share factor would likely result in an EDI for this group below the ADI. Regardless, an EDI marginally above the ADI for the 90th percentile of only one age group—2- to 5-year–olds—is of limited concern given the inherent over-conservatism in both the EDI calculations (i.e., incorporates any and all bar types) and the basis of the JECFA ADI determination developed for a lifetime exposure.

- The publicly available scientific literature on the consumption and safety of both rice bran wax and carnauba wax is sufficient to support the safety and GRAS determination relative to the intended use and use level of rice bran wax as a texturizing agent in peanut butter used as an ingredient in nutrition and granola-type bar products.

Conclusions of the Expert Panel

We, the undersigned members of the Expert Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of Smucker's rice bran wax product as described in the safety dossier titled **GRAS Determination of Rice Bran Wax for Use in Specified Food Products**. We conclude that the rice bran wax ingredient produced under the conditions described in the attached dossier and meeting the proposed specifications is safe.

We further unanimously conclude that the intended use of the rice bran wax as a texturizing agent in peanut butter used in nutrition and granola-type bar products at a maximum level of 3%, meeting the specifications described above, is Generally Recognized as Safe (GRAS) based on scientific procedures and that other experts qualified to assess the safety of foods and food additives, and critically evaluating the same information, would concur with these conclusions.

_____ _____

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