ToxStrategies

Innovative solutions
Sound science

RECEIVED
AUG 0 6 2020
OFFICE OF FOOD ADDITIVE SAFETY

July 31, 2020

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740-3835

Subject: GRAS Notification – Rice Bran Wax

Dear Sir:

On behalf of McCain Foods Ltd., 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 food.

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,

[redacted]

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

GRAS Determination of Rice Bran Wax for Use in the Frying Oil of Potato Products

JULY 24, 2020

ToxStrategies

Innovative solutions
Sound science

GRAS Determination of Rice Bran Wax for Use in the Frying Oil of Potato Products

SUBMITTED BY:

McCain Foods Ltd.
439 King Street W
Toronto, ON M5V 1K4, Canada

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

Donald F. Schmitt, MPH
ToxStrategies, Inc.
931 W. 75th St., Suite 137, PMB 255
Naperville, IL 60565

JULY 24, 2020

Table of Contents

List of Figures

List of Tables

Acronyms

ADI	acceptable daily intake
ADME	absorption, distribution, metabolism, and excretion
ANS	Scientific Panel on Food Additives and Nutrient Sources (EFSA)
bw	body weight
CAS	Chemical Abstracts Service
CEDI	cumulative estimated daily intake
CFR	Code of Federal Regulations
cGMP	current Good Manufacturing Practice
CIR	Cosmetic Ingredient Review
EDI	estimated daily intake
EFSA	European Food Safety Authority
EPA	U.S. Environmental Protection Agency
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
GI	gastrointestinal
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe
GRN	GRAS Notification
JECFA	Joint FAO/WHO Expert Committee on Food Additives
KOH	potassium hydroxide
LD_{50}	median lethal dose
MOE	margin of exposure
NET	National Eating Trends Database
NOAEL	no-observed-adverse-effect level
PCB	polychlorinated biphenyls
ppb	parts per billion
ppm	parts per million
RBW	rice bran wax
REACH	Registration, Evaluation, and Authorisation of Chemicals
U.S.C.	United States Code
USDA	U.S. Department of Agriculture
USP	U.S. Pharmacopeia
WHO	World Health Organization

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

(1) GRAS Notice Submission

McCain Foods Ltd. (McCain), 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 the use of rice bran wax in the frying oil of potato products for human consumption, in accordance with Subpart E of 21 CFR § 170.

(2) Name and Address

McCain Foods Ltd.
439 King Street W
Toronto, ON M5V 1K4
Canada

(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 vegetable wax obtained from rice husks. The rice bran wax is processed from rice bran oil obtained from rice husks. Rice bran wax is not hydrogenated and consists primarily of high-molecular-weight monoesters ranging from C48 to C64.

(4) Intended Use in Food

McCain proposes to use rice bran wax in oil(s) used in frying operations at a maximum concentration of 0.15% to improve rheological and thermal properties of the oils used with selected fried potato products. The amount used will not exceed the amount reasonably required to accomplish its intended technical effect.

(5) Statutory Basis for GRAS Determination

McCain Foods Ltd. (McCain), 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

McCain 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 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. McCain 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. In addition, recent reviews of the scientific literature indicated no concerns for potential adverse health effects.

(10) Name/Position of Notifier

July 29, 2020
Date

Donald F. Schmitt, M.P.H.
Senior Managing Scientist
ToxStrategies, Inc.
Agent for McCain Foods Ltd.

(11) FSIS Statement

Rice bran wax will not be used in products under the jurisdiction of the U.S. Department of Agriculture (USDA).

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

Identity

Rice bran wax is a crystalline vegetable wax obtained from rice husks. It consists primarily of high-molecular-weight monoesters ranging from C48 to C64. The rice bran wax ingredient that is the subject of this GRAS determination is the same rice bran wax ingredient that was reviewed in GRAS Notification (GRN) 720 (FDA, 2018); therefore, the gas chromatographs in Appendix A of GRN 720 are directly relevant to this GRAS determination and are referenced herein. Rice bran wax is typically yellow to light brown in color, with a melting point of 75–85.5°C. The rice bran wax ingredient is processed from rice bran oil obtained from rice husks and is not hydrogenated. The rice bran wax ingredient is the same rice bran wax described in GRN 720 (FDA, 2018).

Common or Chemical Names

The ingredient 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.

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 that complies with the manufacturer's and Food Chemicals Codex (FCC) specifications. The manufacturing process below and manufacturer are the same as in GRN 720, but using fewer processing aids, all of which are safe and suitable for the intended purpose in the 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 (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 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
Bentonite	1302-78-9	21 CFR §170.3
Fuller's Earth	8031-18-3	--
Diatomaceous Earth	68855-54-9	21 CFR § 176.170; 21 CFR § 182.90

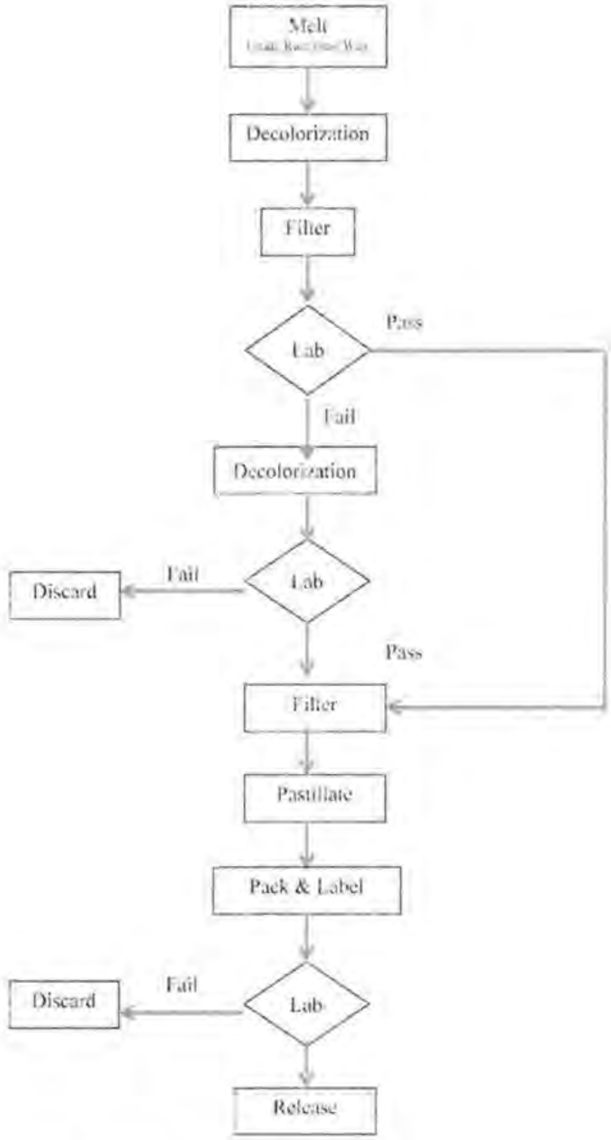

Figure 1. Process flow diagram

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 total arsenic levels in all analyzed lots were below the limit of quantitation for total arsenic of 10 ppb. Given a projected 90_{th} percentile intake of rice bran wax of approximately 324 mg per day (5.4 mg/kg bw/day for a 60 kg individual), 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 0.00324 μg/person/day, and the inorganic arsenic intake is 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, and trace component analyses including additional pesticides, mycotoxins, polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and dioxin-like polychlorinated biphenyls [PCBs]). Analytical results for the three non-consecutive lots of rice bran wax are provided in Appendix A.

Table 2. Ingredient specification for rice bran wax

Parameter	Specification	Assay/Analytical Method
Melting point	77–82 °C	USP 741, Class II
Acid value (mg KOH/g)	≤13	USP 401
Saponification value (mg KOH/g)	75–120	USP 401
Iodine value (g/100 g)	≤20.0	USP 401
Color	Yellow to light brown	Visual
Lead (ppm)	0.2 max.	AOAC 984.27 Mod[1], 2015.01 Mod[2], 993.14 Mod.

[1]Modified method

[2]Analysis performed with an open vessel microwave system with a hot plate digestion process, followed by analysis on ICP-MS.

The proposed rice bran wax ingredient is yellow to light brown-colored pastillates with a melting point of 77–82 °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); the FCC specification is provided in Table 4. 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 3. Analytical results of three lots of rice bran wax compared to ingredient specification

Parameter	Specification	Result 1 Lot No. 2000887	Result 2 Lot No. 2000375	Result 3 Lot No. 1902183
Melting point	77–82 °C	82	81.5	81
Acid value	≤13	2.2	2.1	1.5
Saponification value	75–120	78	76	80
Iodine value[a]	≤20.0	Passes	Passes	Passes
Color	Yellow to light brown	Passes	Passes	Passes
Lead	0.2 ppm	<0.005	<0.005	<0.005

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

Table 4. Ingredient specifications compared to FCC specifications for rice bran wax

Parameter	Rice Bran Wax (#224P) Specification	FCC Specification
Melting point	77–82 °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	3 ppm max

*See test results in Appendix A

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 indicating 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.

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 A 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, solvents dioxin/furans, polycyclic aromatic hydrocarbons, 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 are shown below (Table 5).

Table 5. Stability testing results

Batch No.	Testing Date	Acid Value	Testing Date	Acid Value	Testing Date	Acid Value	Testing Date	Acid Value	Testing Date	Acid Value
11935	01/28/09	4.6	08/24/11	4.8	06/12/13	4.9	-	-	-	-
13115	02/17/10	5.3	09/14/11	5.5	09/26/12	6.1	06/28/13	5.9	02/24/15	5.5
15010	09/09/11	6.7	06/03/13	6.2	09/10/15	6.8	-	-	-	-
16139	07/09/12	6.1	06/11/13	6.4	12/04/14	6.4	09/02/15	6.1	-	-
17399	06/03/13	8.5	06/11/15	8.3	-	-	-	-	-	-

Rice bran wax is considered to be stable by the supplier Koster Kuenen at the proposed par-frying temperatures. If there were to be any breakdown of the rice bran wax component, it would form free fatty alcohols and free fatty acids of molecular weight >C-24 (see Table 9).

In addition, McCain conducted a search of the publicly available literature using ProQuest Dialog™ (Intertek, 2019) for any issues reported in the scientific literature regarding food safety and the addition of rice bran wax to oil used in frying operations. Searched databases included Adis Clinical Trial Insight, AGRICOLA, AGRIS, Allied & complementary Medicine, BIOSIS Toxicology, BIOSIS Previews, CAB ABSTRACTS, Embase, Foodline, SCIENCE, FSTA, Gale Group Health Periodicals Database, Global Health, MEDLINE, NTIS: National Technical Information Service, and ToxFile. The literature search results did not reveal any food safety concerns related to rice bran wax and frying operations. Lim et al. (2017) has evaluated the use of a soybean oil-carnauba wax oleogel as an alternative to high saturated fat frying media for instant fried noodles and observed that less oil was absorbed by the noodles and the level of saturated fatty acids in the oleogel-fried noodles were reduced.

§ 170.235 Part 3, Dietary Exposure

Purpose

McCain is proposing to use rice bran wax in oil(s) used in frying operations to improve rheological and thermal properties of the oil(s) used with selected fried potato products.

Any concern about acrylamide formation during the par-frying of potatoes in oil containing rice bran wax at the factory level is minimal. Acrylamide formation in the frying of potato products primarily occurs when the product is being prepared by the consumer or commercial operation for consumption (e.g., oven, deep fry preparation). The addition of rice bran wax in the oils will improve heat transfer and stability and would further reduce the current par-fry oil temperature during potato processing as well as any minimal acrylamide formation.

Food Uses

The final frozen commercial form of the fried food products includes the following: French fries, hash browns, home chips/steak-cut fries, waffle fries, crinkle cut fries, julienne/skinny fries, smiles, potato wedges, and curly/spiral fries (excluding sweet potatoes). The oil(s) containing rice bran wax are not intended for use beyond the frozen potato product manufacturing plant. The following process flow diagram illustrates the rice bran wax addition point in the par-frying process (Figure 2).

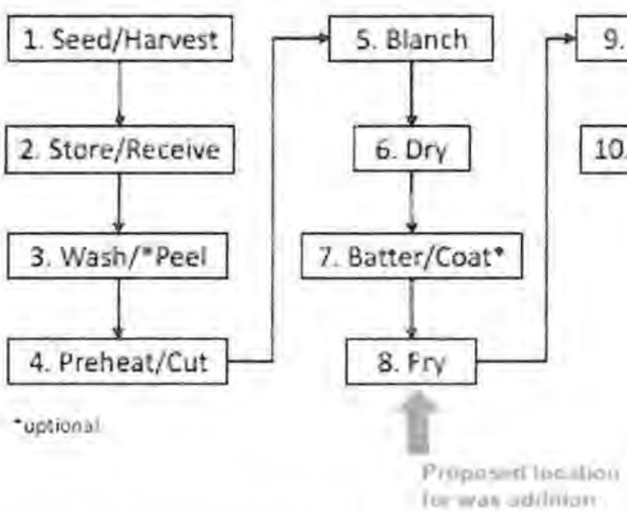

Figure 2. Potato products frying process flow diagram

There are no proposed uses of rice bran wax in food products under USDA jurisdiction.

Levels of Use and Residual Levels of RBW in Potato Products

The proposed rice bran wax use level in frying oils is a maximum concentration of 0.15%. The potato products are par- fried in oil at a temperature of 170–185°C and then frozen before packaging. For each potato category, the amount of oil present was identified as per average fat levels. The residual levels of rice bran wax in the potato products were then estimated by multiplying the estimated residual oil in various potato products by 0.15%. The resultant residual levels of rice bran wax in frozen par-fried potatoes ranged from 0.006% to 0.015%. In order to define the 'average' RBW level present in potatoes across all categories required for the RBW dietary intake assessment calculation, a weighted average based on product sales in the US was used. This is a more robust approach that reflects the varying patterns of consumer potato consumption for each category based on product sales (e.g., higher dietary intake of French fries than hash browns) rather than applying a straight average across categories. A weighted average value of 0.009103% was calculated using this approach and then used in the RBW dietary intake assessment as per NPD's data on reported potato intake by American consumers.

Estimated Exposure

The proposed use of rice bran wax is in oil(s) used in frying operations to improve rheological and thermal properties of the oils used with selected fried potato products.

McCain has performed a dietary exposure estimate of rice bran wax intake from total frozen fried potato products that were fried in oil(s) containing rice bran wax. To do so, 7-day dietary recall data from the NPD Group, Inc.'s, National Eating Trends Database (NET) were used. NET captures the food and beverage consumption habits of U.S. consumers both adults and children. Respondents report for all meals and snacks both in and away from home for up to seven consecutive days.

NPD captures this information via a mobile app-based approach that allows respondents to log in and out multiple times per day over the course of the reporting period. Respondents report what they ate and drank and provide situational details such as where consumed, how obtained, who else was present, occasion type, and more. Each day, a new wave of NET respondents begins their 7-day reporting period. The time period covered was from March 2019 to February 2020.

NET respondents report the amount consumed for each "end dish" food and beverage they consumed. NPD's application displays the standard serving size (e.g., 22 pieces) and then the respondent inputs the quantity they consumed. The analyzed potato items included frozen potato products: French fries, hash browns, home chips/steak-cut fries, waffle fries, crinkle cut fries, julienne/skinny fries, smiles, potato wedges, and curly/spiral fries (excluding sweet potatoes).

NET's Consumer Portion Size Report is summarized in Table 6.

Table 6. NET consumer portion size report

Category: Frozen Potatoes Italics = small base size			Average Daily Intake per Week (g)		
	Age Group	**No. of Users (n)**	**Median**	**Mean**	**90th Percentile**
Total Frozen Potatoes[a]	2+	1,733	16.7	22.8	42.0
	2–5	153	15.0	23.9	34.2
	6–18	358	16.7	23.0	42.0
	18+	1,222	16.7	22.5	43.2
Frozen Fries[b]	2+	1,498	16.7	22.0	39.4
	2–5	145	14.7	23.3	32.3
	6–18	316	16.7	22.0	40.5
	18+	1,037	16.7	21.8	39.4
Frozen Hash Browns	2+	249	17.7	21.2	42.0
	18+	191	17.7	21.4	42.0
Frozen French Fries	2+	572	16.7	23.4	39.0
	2–5	*65*	*16.3*	*29.2*	*32.3*
	6–18	114	16.7	22.7	42.0
	18+	393	16.7	22.6	39.0
Frozen Home Chips/Steak-Cut Fries	2+	209	12.6	17.1	34.3
	18+	152	12.0	16.7	34.3
Frozen Curly/Spiral Fries	2+	114	11.5	22.3	47.4
	18+	*74*	*14.7*	*24.2*	*47.4*

[a] includes French fries, spirals/curly fries, waffle fries, steak/thick cut fries, crinkle cut fries, julienne/skinny fries, smiles, all kinds of fries, hash browns, home chips, potato wedges (excluding sweet potatoes).

[b] includes French fries, spirals/curly fries, waffle fries, steak/thick cut fries, crinkle cut fries, julienne/skinny fries, smiles, all kinds of fries.

Table 6 below converts the g/day intake in Table 5 to mg/kg bw/day based on default body weights, as follows: 2+ years, 60 kg; 2–5 years, 16 kg; 6–18 years, 44 kg, 19+ years, 70 kg. Because residual levels of rice bran wax in frozen processed potatoes range from 0.006% to 0.015%, a weighted average rice bran wax (RBW) value of 0.009103% was used to estimate intakes. The residual levels of RBW in processed potatoes were derived from the level of RBW use in the frying oils and the actual levels of oil remaining in each potato product category. As discussed previously, the RBW residual level of 0.009103% was further determined as a "sales weighted average" based on volume, as it captures a wide array of potato products categories that are consumed at different rates/volumes.

Using the 7-day survey data, the average estimated daily mean and 90th percentile dietary intakes of rice bran wax from total frozen potatoes were 3.5 and 6.4 mg/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 13.6 and 19.5 mg/kg bw/day, respectively (Table 7).

Table 7. Daily intake of total frozen potatoes

		Average Daily Intake per Week in Grams			RBW residual level Wt. Avg: 0.009103%	
Age Group	No. of users (n)	Median	Mean	90th Percentile	Mean mg/kg/day RBW	90th %tile mg/kg/day RBW
2+	1,733	16.7	22.8	42	3.5	6.4
2-5	153	15	23.9	34.2	13.6	19.5
6-18	358	16.7	23	42	4.7	8.7
18+	1,222	16.7	22.5	43.2	2.9	5.6

Background Levels

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). A letter of no objection (GRN 720) was also received for the use of rice bran wax as a texturizing agent in peanut butter that is intended for use in bar-form products.

As summarized in GRN 720, "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) 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."

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. Furthermore, waxes and plasticizers in gum base generally remain with the gum during chewing and are not released and subsequently ingested.

In addition, GRN 720 estimated the daily mean and 90th percentile dietary intakes of rice bran wax to be 0.003 and 0.005 g/kg bw/day, respectively, for the 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). The dietary exposure analysis in GRN 720 included any and all bars (not just peanut butter bars), and therefore, was very conservative, and clearly resulted in an overestimate of the actual consumption.

Because the estimated intakes cannot be added together for statistical/methodological reasons, the cumulative estimated daily intake (CEDI) is certainly less than an estimated intake derived from addition of the intakes from GRN 720 and the proposed use in oil(s). If added together, the very conservative mean and 90th percentile CEDI would certainly be less than 6.5 and 11.4 mg/kg bw/day, respectively, for the total U.S. population, ages 2+years. For the 2- to 5-year-old population, the CEDIs of rice bran wax would be less than 20.6 and 33.5 mg/kg bw/day, respectively.

§ 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 in the frying oil(s). Rice bran wax is employed to improve oil(s) used in frying operations to improve rheological and thermal properties of the oils used with selected fried potato products. The amount used does not exceed the amount reasonably required to accomplish its intended technical effect.

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

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

§ 170.250 Part 6, GRAS Narrative

History of Use and Regulatory Approval of Rice Bran Wax

Rice and rice-derived products have a long history of human consumption (Burlando and Cornara, 2014). Currently, rice is produced worldwide and is a dietary staple for many populations around the world (Burlando and Cornara, 2014; Henderson et al., 2012). Once harvested, rice is hulled and the resulting brown rice processed further to generate derivatives such as rice bran oil, rice bran extract, and hydrolyzed rice protein. As reviewed in the manufacturing process section above, rice bran wax comes from the bran, which is the part between the husk and endosperm of rice and is a by-product 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; coating 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 the following food applications in the US.

- 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).
- As an indirect food additive as Type VIII in Table 1 of 176.170(c), at a maximum level of 1.0 percent by weight of the polymer.

Rice bran wax also received a letter of no objection from FDA for use as a texturizing agent in peanut butter used in bar-form products (GRN 720; FDA, 2018). Table 8 provides a summary list of all other rice-related GRAS notifications that are pending review or that have received letters of no objection from FDA in recent years.

In addition, while not a food use, a 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), as described in their safety assessment (Andersen, 2006).

Table 8. GRAS Notifications relevant to rice

GRN No.	GRAS Substance	Year of Closure
Rice-Related Notifications		
884	Rice bran extract	Pending
720	Rice bran wax	2018
609	Rice protein concentrate	2016
478	Rice hull fiber	2015
373	Rice bran fiber	2011

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 (EFSA, 2012b; 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 (see Appendix A of GRN 720). The rice bran wax ingredient that is the subject of this GRAS determination is the same rice bran wax described in GRN 720 and from the same manufacturer (FDA, 2018).

As shown in Table 9, below, 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 (Table 7). 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), because uptake of wax esters decreases as chain length and hydrophobicity increase (Hargrove et al., 2004; Krendlinger et al., 2002). When limited hydrolysis of the long-chain fatty monoesters in waxes does occur, the resulting long-chain fatty acid and fatty alcohol products are incorporated into normal cellular metabolic pathways (Hargrove et al., 2004; Place, 1992).

For the present GRAS determination of rice bran wax, comprehensive literature searches were performed using the PubMed and Embase databases pertinent to the safe use of rice bran wax. A detailed review of studies published more recently was performed (limited to studies published in 2017–May 2020, the period of time since the U.S. Food & Drug Administration's (FDA's) review of GRN 720). In addition, extensive searches in regulatory databases, including FDA and the European Food Safety Authority (EFSA) were performed. No new relevant standard toxicology studies were identified in the updated literature search. Therefore, this safety assessment relies upon the studies summarized and reviewed in GRN 720 (FDA, 2018). As before, 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 9).

Based on these similarities, toxicity studies conducted on carnauba wax, candelilla wax, beeswax, lanolin wax, and jojoba wax (or jojoba oil, see Table 10) were identified and have been included in the safety assessment of rice bran wax in GRN 720 as well as here, and considered by the current GRAS 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 9. As summarized in GRN 720, "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 9 (as found in GRN 720, 2018).

Furthermore, chain length and saturation can predict the physio-chemical behavior of waxes and oils, including their potential for toxicity (EFSA, 2007; Maru et al., 2012; Smith et al., 1996). Smith et al. (1996) demonstrated that the toxicity of waxes decreases with increasing chain length. Smith et al. administered seven white oils and five waxes 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) for 90 days. As the molecular weight of the various waxes increased, a decrease in incidence and severity of adverse effects was observed. Systemic exposure to lower weight waxes resulted in effects such as increased organ weights and inflammatory changes of the liver and mesenteric lymph nodes. Reduced severity of effects was noted in the other waxes as chain length increased. No adverse or biological effects were observed following exposure to the highest molecular weight waxes. Rice bran wax is composed of the longest alcohol and acid chain lengths employed in this GRAS safety assessment and has one of the largest monoester fractions (comparable to jojoba) and thus would be considered the least bioavailable and therefore have the least potential for toxicity. We believe that any negative findings noted in safety studies conducted with carnauba wax, candelilla wax, beeswax, lanolin wax, or jojoba wax can be extended to the more inert rice bran wax. Therefore, on the whole, 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 9. Typical composition of the waxes considered in this assessment, including their respective fatty alcohol and fatty acid chain length distributions (GRN 720, FDA, 2018; p.26)

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, GRN 720; 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, GRN 720; 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 chromatographs in Appendix A of GRN 720, 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).

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 ADME of rice bran wax has been extensively reviewed in GRN 720 (FDA, 2018) and is also summarized here. The bioavailability of wax esters and their constituents 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 classes of organisms. As with other 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). Therefore, the long-chain fatty acid esters present in plant-based waxes such as rice bran wax and the other waxes referenced here are thought to be poorly absorbed in the GI tract (Hargrove et al., 2004; Place, 1992). Any limited hydrolysis of the long-chain fatty monoesters 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 or via a fatty acid carrier (Hargrove et al., 2004). The resulting free fatty alcohols are then oxidized into the corresponding fatty acids or can be incorporated into the synthesis of phospholipids.

Available Studies

Then following studies were summarized in GRN 720, pp. 27-29 (FDA, 2018)

Hamm (1984) determined whether jojoba oil could act as a replacement for conventional edible fats and oils. 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 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[1]) 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. Jojoba oil was poorly absorbed, indicated by observed excretion of oils; the authors suggested that jojoba oil was resistant to digestion *in vivo*.

In another study (Hansen and Mead, 1965), rats were given oleyl palmitate (C-34 ester) in the diet to investigate effects such as seborrhea, as well as the digestibility and absorption of the wax esters. In two experiments, weanling male rats were fed *ad libitum* for either four weeks or 10 days.[2] EFSA (2007, 2012c) estimated the 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

[1] 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).

[2] 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.

palmitate was observed to be poorly absorbed, as evidenced by the excretion of intact monoesters, free fatty acids, and free fatty alcohols.

Heise et al. (1982) conducted a digestibility study in weanling rats that 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. After 2 and 4 weeks of treatment, the body-weight gain of animals on the jojoba-only diet was reduced by ~50% compared to controls but not compared to the other groups. The authors concluded that the reduced body-weight gain was due to the poorer digestibility of jojoba wax (41% versus 98% in controls), as evidenced by the amount of fat found in feces as a percent (%) of fecal dry matter (51% for jojoba wax versus 6% in controls).

Verschuren and Nugteren (1989) evaluated the effects of jojoba oil on digestion. 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. 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 both digestibility and absorption. The test-group animals decreased their consumption of jojoba oil–supplemented food, resulting in decreased growth possibly due to the reduced palatability of the jojoba oil. Jojoba oil did not influence the intestinal transit time of retinol, but retinol absorption appeared to be decreased in the experimental group. Some jojoba oil did appear to be absorbed (i.e., 35% excreted in the feces). Based on the analysis of free fatty acids in the feces, the authors concluded that the hydrolysis of jojoba oil likely took place after the small intestine. In addition, intestinal mucosal cells contained jojoba oil, an indication that wax esters were absorbed.

The absorption and distribution of jojoba wax was studied by Yaron et al. (1982). 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 1 (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 demonstrated that the labeled jojoba wax was incorporated into 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 at 0.5, 0.75, 1.13, or 1.69 mL/10 g body weight via oral gavage. The jojoba oil 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

Numerous acute oral toxicity studies have been identified that reported the LD_{50} value of rice bran wax, similar waxes, or its constituents (Table 10; as summarized in GRN 720, 2018, pp. 30–32). The LD_{50} values in all cases were found to be greater than the highest dose tested, which in most cases was >5,000 mg/kg bw. While not published in the peer-reviewed literature, but rather found in REACH registrations, a complete summary of 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. The studies demonstrate the lack of potential acute oral toxicity of rice bran wax.

Table 10. Available acute oral toxicity studies on rice bran wax, similar waxes, or its constituents (GRN 720, FDA, 2018; pp. 30-32)

Test Material	Species (strain)	LD_{50A} (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	SCF, 1992, as cited by EFSA, 2012c	Reviewed by EFSA, 2012c

Test Material	Species (strain)	LD_{50A} (mg/kg bw)	Reference	Access Information
		toxicological findings")		
Candelilla wax (as a cosmetic ingredient and in cosmetic formula-tions)	Rat (SD, Long Evans, and unde-fined)	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, units are mg/kg bw

Repeated-Exposure Toxicity

A summary of available repeated-exposure studies is provided in Table 11 (as found in GRN 720, 2018; pp. 32–39).

Carnauba Wax

Rowland et al. (1982; reviewed in GRN 720, p. 32) 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. 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.

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; reviewed in GRN 720, p.32). A NOAEL of 250 mg/kg-bw/day was determined for carnauba wax based on the highest dose tested in this study.

In addition, an EFSA ANS Panel (EFSA, 2012b; also in JECFA, 1993a) reviewed a report by Edwards (1998). Rats were administered carnauba wax in the diet at levels of 0, 15, 150, or 1500 mg/kg bw/day continuously for 90 days; five males and five females were also placed back on the control diet for another 90 days in a reversibility phase of the study. While some changes (clinical chemistry, organ weights, histopathology) were observed across treatment groups, these were found to be non-treatment related The NOAEL was considered to be 1500 mg/kg bw/day, the highest dose tested in the 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. 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. 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. No treatment-related effects were observed in either study, including survival, body-weight gain, food and water intake, urinalysis, hematology, or gross pathology. EFSA determined the NOAELs to be the highest doses tested, 980 and 1,800 mg/kg bw/day, respectively.

Harrisson (1949, as cited in EFSA, 2012c) also evaluated a different 50/50 candelilla wax and butadiene-styrene polymer mixture when given to male and female Wistar rats for 27 weeks. Dietary levels of 0, 1%, and 5% 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. While a slight decrease in body-weight gain was noted in the test-article groups, EFSA (2012c) considered the NOAEL to be the highest dose tested of 1,800 mg/kg bw/day.

Hodge (1973, as cited in EFSA, 2012c) conducted a 180-day study of candelilla wax, present at 4.1%–6.1% in a gum base, in male and female albino rats (n=12 per sex). Dietary concentrations ranged from 10% to 25%. 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 an 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 the low-dose and control groups; however, the authors did not state the cause of death. EFSA (2012c) considered the NOAEL to be the highest dose tested of 1,900 mg/kg bw/day.

Harrisson (1953, as cited in EFSA, 2012c) administered candelilla wax to male and female Sprague Dawley rats in the diet (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—750 mg candelilla wax/kg bw/day. Dietary concentrations administered were 0.8%, 2.0%, or 5%, equivalent to 0, 125, 300, and 750 mg candelilla wax/kg bw/day, respectively. EFSA considered the NOAEL to be 750 mg/kg bw/day, the highest dose tested.

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

Lanolin Wax

A GLP-compliant repeat-dose oral toxicity of lanolin fatty acids was submitted for the REACH registration dossier for Fatty Acids, Lanolin (referenced in the dossier as

Unnamed, 2013). 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 approximately 90 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

In a digestibility study 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. The authors 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; conference abstract). No pathological abnormalities were found in the liver, but increased serum transaminase and alkaline phosphatase activities were reported in both sexes. Decreased weight gain was reported in females only.

In a study by Hamm (1984) 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. 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 the 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. 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 considered related to "metabolic disturbances" (related to malabsorption of nutrients) and laxative effects, rather than direct toxicity, as was also the case for trialkoxytricarballylate, another non-digestible, non-absorbable oil. The authors suggested that the threshold or physiological limit for non-digestible, non-absorbable oils lies above 10,000 mg/kg bw/day.

A study by Verschuren (1989) evaluated jojoba oil as a replacement for other conventional dietary fats. Male and female SPF Wistar rats were divided into eight groups in which their diets were supplemented with varying amounts of jojoba oil for a 4-week period 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. During the study, no signs of overt toxicity were observed, 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% high-dose group. Absolute weights of organs evaluated, except for the spleen in females, were also decreased, particularly in the higher dose groups. 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 of the liver. However, no major treatment-related changes were observed in the liver or liver enzymes. In animals fed 9% jojoba oil, effects typically associated with malabsorption of nutrients and diarrhea were noted.

Weanling CD-1 mice (10 males, 10 females) were administered 1% or 2% jojoba oil in the diet for 3 weeks (Verbiscar et al., 1980). Results are also presented for weanling (3 weeks) and adult mice (1 week) receiving 10% dietary jojoba oil. Decreased body-weight gain was observed in the 2% group and above. Animals receiving 10% oil in the diet were reported to have done "poorly," with 30% mortality reported in the weanling mice. The authors concluded that the observed deaths were a result of malnutrition due to an inability to absorb nutrients and were not a direct toxicological effect.

Oleyl Palmitate

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[3] (Hansen and Mead, 1965). Body-weight gain was decreased in the oleyl palmitate groups, which was attributed to issues with test article palatability. In addition, animals in the high-dose group were reported to have oily skin and fur and/or diarrhea.

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.

Table 11. Available repeated dose oral toxicity studies on rice bran wax, similar waxes, or its constituents (GRN 720, FDA, 2018; pp. 37-39)

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

Test Material	Species (Sex[A])	Duration	Doses Tested (mg/kg-bw/day[B])	NOAEL (mg/kg-bw/day[B])	Reference	Publication and Access Information
Jojoba oil	Rat	7 days	10,000, 20,000, 40,000, or 60,000	10,000[E]	Hamm, 1984	http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2621.1984.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 reproductive and developmental toxicity studies is provided in Table 12 (as found in GRN 720, 2018; pp. 40-41).

Carnauba Wax

Parent et al. (1983b; reviewed in GRN 720; FDA, 2018, p.40) evaluated the potential reproductive effects of carnauba wax (0, 0.1, 0.3, or 1%) administered 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 together, and diet administration continued through mating, gestation, and lactation. Subsequently, F_1 generation rats were selected randomly 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. 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[4]; originally reviewed by JECFA, 1993a) also reviewed an unpublished developmental toxicity study report by FDRL (1977).[5] In this study 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.

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 of candelilla wax (50/50 mixture with styrene-butadiene polymer) for 5 months prior to mating, two of the three females were reported to have conceived and produced "normal" litters. No additional information was provided.

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

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

Table 12. Available reproductive and developmental toxicity studies on rice bran wax, similar waxes, or its constituents (GRN 720; FDA, 2018, p.41)

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 13 (as found in GRN 720; FDA, 2018, pp. 38-45).

Rice Bran Wax

In a GLP-compliant study, a rice bran wax product (Licocare RBW 106) was found to be non-mutagenic *in vitro* (Unnamed, 2015[6]; as reviewed in GRN 720, pp. 41–42). 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 1,600 µg/plate[7]; appropriate positive control substances were included. Cytotoxicity was observed in all strains, except TA1535, TA1537, and TA98 in the

6 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 attempting to obtain permission for its use.***

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

presence of S9-mix and WP2uvrA with and without metabolic activation. Rice bran wax was negative over the entire dose range in both *S. typhimurium* and *E. coli* reverse mutation assays, and no significant dose-related increases in the number of revertants were observed.

Rice bran wax ("Rice Wax") did not elicit a 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).

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; reviewed in GRN 720, p.42). No statistically significant increases in aberrant metaphases were reported in the chromosomal aberration test (without metabolic activation for 3 hours).

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 that there is no concern for genotoxicity for carnauba wax based on the available data and the lack of structural alerts (EFSA, 2012a). 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 reviewed studies evaluating the mutagenicity of carnauba wax. The available information on these studies is summarized in Table 11.

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 previously summarized by JECFA (1993b); candelilla wax was found to be negative for reverse mutation and gene conversion.

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.

Lanolin Wax

Three GLP-compliant studies evaluating the mutagenic potential of lanolin fatty acids have been reported as part of the REACH Registration for Fatty Acids, Lanolin and are summarized in GRN 720 (pp. 43-44) and Table 12 below.[8] Lanolin wax was not mutagenic in Bacterial Reverse Mutation Assays with and without metabolic activation (Unnamed, 2010a) or in an *in vitro* mammalian chromosome aberration test, with and without metabolic activation (Unnamed, 2010b). In addition, no statistically significant dose-related increases in mutant frequency occurred, with and without metabolic activation, with lanolin fatty acids, evaluated for gene mutation on the thymidine kinase, TK +/-, locus of the L5178Y mouse lymphoma cell line (Unnamed, 2010c).

Jojoba Wax

Jojoba esters were negative for mutagenicity at 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. The test material was concluded not to be mutagenic.

8 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-4328-4df0-9809-57d83c1adaac. ***Study information from this dossier is publicly available but may be subject to copyright laws; the authors of this GRAS assessment are attempting to obtain permission for its use.***

Table 13. Available mutagenicity and genotoxicity studies on rice bran wax, similar waxes, or its constituents (GRN 720; FDA, 2018, pp. 45-48)

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

Test Material	Endpoint	Test System	Doses Tested	Results	Reference	Publication and Access Information
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	
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	

Test Material	Endpoint	Test System	Doses Tested	Results	Reference	Publication and Access Information
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 mutationd	*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
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

Test Material	Endpoint	Test System	Doses Tested	Results	Reference	Publication and Access Information
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] 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

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 (Andersen, 2006; Burlando and Cornara, 2014). However, rice bran wax and rice are two different foods, and rice bran wax contains little to no protein (<0.10g/100g as reported). Also, 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. While Chowdury (2002) reported one case of contact dermatitis in reaction to carnauba wax, the EFSA CONTAM Panel (2012a) concluded that 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. Furthermore, rice is not listed as one of eight major allergen groups by the FDA under the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II).

Minor Components of Rice Bran Wax

As shown in Table 8, 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, and triglycerides from rice bran oil. As noted previously, when limited hydrolysis of wax esters occurs, the corresponding long-chain fatty acids and alcohols may be available for cellular uptake. Therefore, the presence of these components has been considered with regard to safety.

As noted in GRN 720 (FDA, 2018):

- Rice bran oil has a long history of use in human consumption as a cooking oil in Asian cultures (Andersen, 2006).
- The available body of safety data on rice bran oil includes several acute oral toxicity studies, a genotoxicity study, and a multi-generation reproductive toxicity study in rats, which 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).

Extensive toxicological testing has also been published on 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 for a number of health issues. Extensive preclinical tests have been performed on these mixtures, and all demonstrate a lack of toxicity (GRN 720; FDA, 2018, p. 51).

Finally, if a small amount of rice bran wax were 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. As concluded in GRN 720 (FDA, 2018), 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 when added to frying oils for specific potato products for human consumption is safe and GRAS based on 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 in oil(s) used in frying operations to improve rheological and thermal properties of selected fried potato products.

The amount used will not exceed the amount reasonably required to accomplish its intended technical effect. There is common knowledge of a long history of human consumption of rice and rice bran wax.

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 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.

As reviewed in GRN 720 (FDA, 2018), the available data continue to allow for a 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 the molecular weight of the wax increases. 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 the fact 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.*

The available published and unpublished safety data suggest that rice bran wax has little potential for toxicity when used in foods for human consumption. The chemical structure of rice bran wax, available genotoxicity data, and/or regulatory reviews of rice bran wax and related waxes do not 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). It is not expected that the intended uses and use levels of rice bran wax in the preparation of specified potato products would result in consumption levels causing diarrhea or other GI tract effects.

Rice is not listed among the major food allergens by FDA, as noted by its absence from the *Food Allergen Labeling and Consumer Protection Act of 2004*. Given that rice bran wax contains little to no protein, 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 10,200 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 male and female rats, respectively) administered in the diet for 90 days (Rowland et al., 1982). 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. A tabular summary of these studies is presented in Table 14.

The history of use in foods of other vegetable-based waxes, in particular carnauba wax, provides information relevant to the safety assessment of rice bran wax. It is notable that the intake of wax worldwide in some populations can average as high as 4 g/day (Hargrove et al., 2004).

Rice bran wax has been approved for use in various food applications in the U.S. 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 1 of 176.170(c), at a maximum level of 1.0 percent by weight of the polymer. In addition, the use of rice bran wax as a texturizing agent in peanut butter used in bar-form products received a letter of no objection from FDA (GRN 720; FDA, 2018).

Carnauba wax is 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).

Carnauba wax, beeswax, and candelilla wax are listed as GRAS direct food substances for human consumption, with no specific limitation other than GMP (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).

The proposed use of rice bran wax is in oil(s) used in frying operations to improve rheological and thermal properties of the oils used with selected fried potato products. McCain has performed a dietary exposure estimate of rice bran wax intake from selected fried potato products that were fried in oil(s) containing rice bran wax. To do so, 7-day dietary recall data from the NPD Group, Inc.'s, National Eating Trends Database (NET) were used. NET captures the food and beverage consumption habits of U.S. consumers, both adults and children. Respondents report for all meals and snacks, both in and away from home, for up to seven consecutive days.

Using the 7-day survey data, the estimated daily mean and 90th percentile dietary intakes of rice bran wax from total frozen potatoes were 3.5 and 6.4 mg/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 13.6 and 19.5 mg/kg bw/day, respectively.

Table 14. Long-term oral toxicity studies, adapted from Tables 10 and 11 (GRN 720; FDA, 2018, p. 56)

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

*Published, peer-reviewed studies are in bold type.

GRN 720 estimated the daily mean and 90th percentile dietary intakes of rice bran wax to be 0.003 and 0.005 g/kg bw/day, respectively, for the 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. The dietary exposure analysis in GRN 720 included any and all candy bars (not just peanut butter bars), and therefore, was very conservative, and clearly resulted in an overestimate of the actual consumption. Peanut butter bars containing rice bran wax are a niche product and represent only a small percentage of all candy bars as employed in the GRN 720 intake assessment.

While no ADI has been 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 MOEs 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 MOEs 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 potato products were calculated based on the EDIs summarized in Table 7. As presented in the Dietary Exposure section, estimated mean and 90th percentile intakes of rice bran wax of 3.5 mg/kg bw/day and 6.4 mg/kg bw/day, respectively, were calculated (assuming a 0.009103% residual level of RBW) for the U.S. population ages 2 and over. This provides MOEs of approximately 191× and 105×, respectively, for mean and 90th percentile intakes when compared to the lowest NOAEL (670 mg/kg bw/day) 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 13.6 mg/kg bw/day and 19.5 mg/kg bw/day, respectively. This provides MOEs of approximately 49× and 35×, respectively, for the mean and 90th percentile.

The estimated intakes from GRN 720 and the proposed new use cannot be added together for statistical/methodological reasons and would result in an overestimate of a cumulative estimated daily intake (CEDI); however, the CEDI is certainly less than the CEDI derived from addition of the intakes from GRN 720 and the proposed use in oil(s). When added together, the mean and 90th percentile CEDIs are 6.5 and 11.4 mg/kg bw/day respectively, for the total U.S. population, ages 2+years. For the 2- to 5-year-old population, the CEDIs of rice bran wax are 20.6 and 33.5 mg/kg bw/day, respectively. Incremental exposure to rice bran wax from its expanded use in frying oils for frozen potato products is expected to be minimal and would be less than the intake values as added above. Even so, the MOEs, if calculated from these intake values, would be approximately 103× and 59× for the total U.S. population, ages 2+ years, and 33× and 20× for the 2- to 5-year-old population.

It should be noted that the MOEs presented are based on comparison to the lowest published NOAEL of 670 mg/kg bw/day, the highest dose tested (Parent et al., 1983b). There are additional published studies with NOAELs up to 10,200 mg/kg bw/day, also based on the highest dose level tested. Therefore, the calculated MOEs based on the study by Parent et al. (1983b) are very conservative and represent minimum MOEs. The MOEs clearly would be more than 10× higher if compared to the highest NOAEL of 10,200 mg/kg bw/day (i.e., CEDI MOEs of greater than 200×–330× for the 2- to 5-year-old population).

Lambe et al. (2000) have stated that the overestimations of shorter-term surveys may be of more significance when comparing to standards, such as ADIs. It is possible that use of longer-term survey data (e.g., 30 days, as opposed to 7 days) would further reduce the within-person variability and result in even lower EDIs relative to an ADI or NOAEL. An ADI or NOAEL is not a threshold above which the risk of health effects will suddenly be of concern. The above EDIs for the age group 2–5 years represent a transient time period that has limited relevance to a lifetime of exposure. Therefore, we believe that the extremely conservative MOEs presented above for the age group 2–5 years are sufficient to support the safe use of rice bran wax in the proposed potato products. Furthermore, we believe that the supporting published safety data, along with the additional publicly 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 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 wax obtained from rice husks. The rice bran wax product is manufactured in a manner consistent with current cGMP for food (21 CFR Part 110), and 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 its derivatives have a long history of human consumption. 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; GRN 720) is supportive of its safe use in food.
- 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, 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 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. The reviewed safety studies have been conducted and are publicly available and/or have been previously reviewed and/or 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 10,200 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 male and female rats, respectively) administered in the diet for 90 days. Chronic studies with candelilla wax were also identified, and the NOAELs in these studies were up to 2,400 mg/kg bw/day, the highest dose tested.
- The dietary intake analysis resulted in EDIs (potato products only, as well as cumulative estimated daily intakes) with very conservative MOEs that are deemed sufficient to support the proposed use of rice bran wax in oil(s) used in frying operations to improve the rheological and thermal properties of oils used with selected fried potato products.
- Because rice bran wax contains little to no protein, 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 McCain Foods 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 McCain's opinion that other qualified scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. McCain 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.

McCain 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.

§ 170.255 Part 7, Supporting Data and Information

The following references are all generally available, unless otherwise noted. Appendices A-C and Exhibit 1 are not generally available but are attached for reference.

References

Andersen, FA. 2006. Amended final report on the safety assessment of oryza sativa (rice) bran oil, oryza sativa (rice) germ oil, rice bran acid, oryza sativa (rice) bran wax, hydrogenated rice bran wax, oryza sativa (rice) bran extract, oryza sativa (rice) extract, oryza sativa (rice) germ powder, oryza sativa (rice) starch, oryza sativa (rice) bran, hydrolyzed rice bran extract, hydrolyzed rice bran protein, hydrolyzed rice extract, and hydrolyzed rice protein. Int J Toxicol 25(Suppl 2):91–120.

Anonymous. 1984. Final report on the safety assessment of candelilla wax, carnauba wax, japan wax, and beeswax. J Am Coll Toxicol 3:1–41, Liebert MA. Inc. Publishers. ***Report not available; as cited in EFSA (2012b).***

Bassan, A, Fioravanzo, E, Pavan, M, Conto, A. 2012. European Food Safety Authority External Scientific Report: Reports on toxicokinetics, toxicity and allergenicity data on substances to be evaluated as acceptable previous cargoes for edible fats and oils (NP/EFSA/CONTAM/2011/01) – Batches n. 1, 2 and 3. EFSA Supporting Publications 2012:EN-274.

Bagby, MO. 1988. Comparison of Properties and function of jojoba oil and its substitutes. Proc. 7th Int. Conf. on Jojoba and Its Uses. Baldwin AR (Ed.). Available from: https://naldc.nal.usda.gov/download/24088/PDF.

Becker, L. 2008. Safety assessment of Simmondsia Chinensis (jojoba) seed oil, simmondsia chinensis (jojoba) seed wax, hydrogenated jojoba oil, hydrolyzed jojoba esters, isomerized jojoba oil, jojoba esters, Simmondsia Chinensis (jojoba) butter, jojoba alcohol, and synthetic jojoba oil. Available from: http://www.cir-safety.org/sites/default/files/115_buff3f_suppl.pdf.

Brusick, D. 1976. Mutagenic evaluation of compound FDA 75-43, MX8006-44-8 candelilla wax, L.F. refined. Project No. 2468, Litton Bionetics, Inc. ***Report not available; as cited in EFSA (2012c).***

Burlando, B, Cornara, L. 2014. Therapeutic properties of rice constituents and derivatives (Oryza sativa L.): A review update. Trends Food Sci Technol 40(1):82–98.

Celsis Laboratory Group. 1999. Evaluation of mutagenicity potential for Fluoaesters IPJ by the Ames mutagenicity assay. Unpublished data submitted by CTFA, September 17, 2007. **Report made available for this GRAS assessment by CIR; can be provided if requested.**

Chowdhury, MM. 2002. Allergic contact dermatitis from prime yellow carnauba wax and coathylene in mascara. Contact Dermat 46(4):244.

Cook, R. 2011. Tracking demographics and US fruit and vegetable consumption patterns. Department of Agricultural and Resource Economics, University of California, Davis. Available from: https://arefiles.ucdavis.edu/uploads/filer_public/2014/05/19/blueprintseoconsumptioncookfinaljan2012figures.pdf.

Consumer Product Testing Co. 1998f. Acute oral toxicity test in rats, rice bran wax S-100, Lot No. W90305. Unpublished data submitted by CTFA. 12 pages. ***Report not available; as cited in Andersen (2006).***

Elder RL (Ed.). 1980. Final report of the safety assessment for acetylated lanolin alcohol and related compounds. J Environ Pathol Toxicol 4(4):63–92.

Edwards AJ. 1996. A chromosome aberration study using human lymphocytes treated in vitro with carnauba wax. Study report from BIBRA International testing laboratory. Project No. 3066/1.Unpublished report. ***Report not available; as cited in EFSA (2012b).***

Edwards AJ. 1997. Addendum to a chromosome aberration study using human lymphocytes treated *in vitro* with carnauba wax. Study report from BIBRA International testing laboratory. Addendum to Project No. 3066/1. Unpublished report. ***Report not available; as cited in EFSA (2012b).***

Edwards AJ. 1998. A modified 90-day feeding study to investigate the potential for bioaccumulation of carnauba wax in the Fisher 344 rat. Study report from BIBRA International testing laboratory. Project No. 3180/1. Unpublished report. ***Report not available; as cited in EFSA (2012b)***.

EPA (U.S. Environmental Protection Agency). 1995. Jojoba oil exemption from tolerance requirement 10/95. Fed Reg 60(207):54,839–54,840.

Environmental Technical Laboratory, Ltd. 1998. Rice bran wax S-100: Bacterial mutation assay. Unpublished data submitted by CTFA. 5 pages). ***Report not available; as cited in Andersen (2006).***

EFSA (European Food Safety Authority). 2007. Beeswax (E 901) as a glazing agent and as carrier for flavours. Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC). EFSA Journal 615:1–28.

EFSA (European Food Safety Authority). 2012a. Scientific Opinion on the evaluation of the substances currently on the list in the Annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils – Part III of III. EFSA Journal 10(12):2984.

EFSA (European Food Safety Authority). 2012b. Scientific opinion on the re-evaluation of carnauba wax (E 903) as a food additive. EFSA Journal 10(10):2880.

EFSA (European Food Safety Authority). 2012c. Scientific Opinion on the re-evaluation of candelilla wax (E 902) as a food additive. EFSA Journal 10(11):2946.

Federation of American Societies for Experimental Biology. 1975. Evaluation of the health aspects of beeswax (yellow or white) as a food ingredient. Unpublished report, Contract No. FDA 223-75-2004. Submitted to Food and Drug Administration. Cited by WHO (1993). ***Report not available; as cited in JECFA (2006).***

FDA (U.S. Food and Drug Administration). 2007. GRN No. 217. GRAS Notification for tailored triglycerides containing approximately 12 percent medium-chain fatty acids. Prepared by The Nisshin OilliO Group USA, Inc.

FDA (U.S. Food and Drug Administration). 2011. GRN No. 355. GRAS Notification for eicosapentaenoic acid (EPA)-rich triglyceride oil from *Yarrowia lipolytica*. Prepared by DuPont Applied Biosciences.

FDA (U.S. Food and Drug Administration). 2011. GRN No. 373. GRAS Notification for Rice bran fiber. Prepared by CJ America, Inc.

FDA (U.S. Food and Drug Administration). 2015. GRN No. 478. GRAS Notification for Rice hull fiber. Prepared by SunOpta Ingredients Group.

FDA (U.S. Food and Drug Administration). 2015. GRN No. 609. GRAS Notification for Rice protein concentrate. Prepared by Axiom Foods

FDA (U.S. Food and Drug Administration). 2017. Memorandum: Dietary exposure estimate to rice bran wax. To: Administrative File, GRN 000655 in response to FOI Request No. 2017-4008.

FDA (U.S. Food and Drug Administration). 2018. GRN No. 720, GRAS notification for Rice bran wax. Prepared by The J.M. Smucker Co.

FDA (U.S. Food and Drug Administration). 2019. GRN No. 884, GRAS notification for rice bran extract. Prepared by Florida Foods Products, LLC. Pending.

FDRL (Food and Drug Research Laboratory). 1977. Evaluation of the effects of carnauba wax in FDRL/Wistar derived rats after dietary exposure through one full generation. Unpublished report of July 8, 1977 submitted to Brazilian Embassy, Washington, D.C. ***Report not available; as cited in EFSA (2012b).***

Hamm, DJ. 1984. Preparation and evaluation of trialkoxytricarballylate, trialkoxycitrate, trialkoxyglycerylether, jojoba oil and sucrose polyester as low calories replacements of edible fats and oils. J Food Sci 49:419–428.

Hansen, IA, Mead, JF. 1965. The fate of dietary wax esters in the rat. Proc Soc Exp Biol Med 120:527–532.

Hargrove, JL, Greenspan, P, Hartle, DK. 2004. Nutritional significance and metabolism of very long chain fatty alcohols and acids from dietary waxes. Exper Biol Med 229(3):215–226.

Harrisson JWE. 1946. Product No. 12, type III GRS. Rubber and candelilla wax. Report 33731. Unpublished Report. ***Report not available; as cited in EFSA (2012c).***

Harrisson JWE. 1948. Product No. 16, 50/50 mixture candelilla wax and heveatex (Styrene and Butadiene) Polymer N-1017. Report 38222. ***Report not available; as cited in EFSA (2012c).***

Harrisson JWE. 1949. Heveatex 50%, candelilla wax, hydrogenated fat. Report 39348. ***Report not available; as cited in EFSA (2012c).***

Harrisson JWE. 1953. Long-term safety studies. Resume of studies on young dogs and albino rats. ***Report not available; as cited in EFSA (2012c).***

Heise C, Decombaz J, Anantharaman K. 1982. Energy value of JO for the growing rat. Int J Vitam Nutr Res 52:216.

Henderson AJ, Ollila CA, Kumar A, Borresen EC, Raina K, Agarwal R, Ryan EP. 2012. Chemopreventive properties of dietary rice bran: current status and future prospects. Adv Nutr 3(5):643–53.

Hodge HC. 1973. A critical review at the 1) Feeding studies of candelilla wax incorporated in gum base, 2) together with studies of the possible carcinogenic potential by other routes of administration. University of California, San Francisco. ***Report not available; as cited in EFSA (2012c).***

JECFA (Joint FAO/WHO Expert Committee on Food Additives).1993a. Toxicological evaluation of certain food additives and naturally occurring toxicants. WHO Food Additive Series: 30 (758. Carnauba Wax).

JECFA (Joint FAO/WHO Expert Committee on Food Additives).1993b. Toxicological evaluation of certain food additives and naturally occurring toxicants. WHO Food Additive Series: 30 (757. Candelilla Wax).

JECFA (Joint FAO/WHO Expert Committee on Food Additives). 2006. Safety evaluation of certain food additives. WHO Food Additives Series: 56.

Krendlinger E, Wolfmeier U, Schmidt H, Heinrichs F, Michalczyk G, Payer W, et al. 2002. Ullmann's Encyclopedia of Industrial Chemistry. Wiley-VCH Verlag GmbH & Co. KGaA, publisher. Available from:
http://onlinelibrary.wiley.com/doi/10.1002/14356007.a28_103.pub2/abstract.

Lambe J, Kearney J, Leclercq C, Zunft HFJ, De Henauw S, Lamberg-Allardt CJE, et al. 2000. The influence of survey duration on estimates of food intakes and its relevance for public health nutrition and food safety issues. Eur J Clin Nutr 54:166–173.

Leberco Testing, Inc. 1988a. Acute oral toxicity study Floraesters® 15. Unpublished data submitted by CTFA, September 17, 2007. ***Report not available; as cited by Becker (2008).***

Leberco Testing, Inc. 1988b. Acute oral toxicity study Floraesters® 30. Unpublished data submitted by CTFA, September 17, 2007. ***Report not available; as cited by Becker (2008).***

Leberco Testing, Inc. 1988c. Acute oral toxicity study Floraesters® 60. Unpublished data submitted by CTFA, September 17, 2007. ***Report not available; as cited by Becker (2008).***

Leberco Testing, Inc. 1988d. Acute oral toxicity study Floraesters® 70. Unpublished data submitted by CTFA, September 17, 2007. ***Report not available; as cited by Becker (2008).***

Leberco Testing Inc. 1991a. Acute oral toxicity in rats—Hydrogenated Rice Bran Wax. Unpublished data submitted by CTFA. 3 pages. ***Report not available; as cited in Andersen, 2006.***

Liebert, MA. 1984. Final report on the safety assessment of candelilla wax, carnauba wax, Japan wax, and beeswax. J Am Coll Toxicol 3:1–41. ***Report not available; as cited in EFSA (2012a; c).***

Lim J, Jeong S, Oh IK, Lee S. 2017. Evaluation of soybean oil-carnauba wax oleogels as an alternative to high saturated fat frying media for instant fried noodles. LWT – Food Science and Technology 84:788-794.

Litton Bionetics, Inc. 1975. Mutagenic evaluation of compound MX8015869, carnauba wax (73-48). Unpublished report of April 15, 1975, submitted to Food and Drug Administration, Rockville, MD. ***Report not available;*** **quoted by** ***JECFA (1993a), as cited by EFSA (2012b).***

Locke RK. 1978. FDA memo from RK Locke to LJ Lin, 3/22/1978. ***Memo not available; as cited by EPA (1995).***

Loretz LJ, Api AM, Barraj LM, Burdick J, Dressler WE, Gettings SD, et al. 2005. Exposure data for cosmetic products: Lipstick, body lotion, and face cream. Food Chem Toxicol 43(2):279–291.

Maru AD, Surawase RK, Bodhe PV. 2012. Studies on physico-chemical properties of rice bran wax and its comparison with carnauba wax. Int J Pharmaceut Phytopharmacol Res 1(4):203–207.

McGee Laboratories. 1974. Unpublished report submitted to Research Institute for Fragrance Materials, 27 September 1974. Cited by American College of Toxicology (1984). ***Report not available; as cited in WHO (2006).***

Miwa TK. 1971. Jojoba oil wax esters and derived fatty acids and alcohols: Gas chromatographic analyses. J Am Oil Chemists' Soc 48(6):259–264.

Mortelmans KE, Eckford SL. 1979. Microbial mutagenesis testing of substances compound report: F76-048, candelilla wax. Unpublished report. Final Report, Project No. LSU-6909. SRI International. ***Report not available;* quoted by *JECFA (1993a), as cited by EFSA (2012c).***

Mortelmans KE, Griffin AF. 1981. Microbial mutagenesis testing of substances compound F73-048: Carnauba wax, yellow. Unpublished SRI Report LSU-6909 from Frank B. Ross & Co. Submitted to Food and Drug Administration by Frank B. Ross & Co. Report (LSU-6909). ***Report not available;* quoted by *JECFA (1993a), as cited by EFSA (2012b).***

Nippon Bio-Test Laboratories Inc. 1972. Acute oral toxicity test of rice bran wax in mice. Submitted by FDA in response to an FOI request—1997. 4 pages. ***Report not available; as cited in Andersen (2006).***

Orlich MJ, Jaceldo-Siegl K, Sabaté J, Fan J, Singh PN, Fraser GE. 2014. Patterns of food consumption among vegetarians and non-vegetarians. Brit J Nutr 112(10):1644–1653.

Oser, BL, Ford, RA. 1977. Recent progress in the consideration of flavoring ingredients under the food additives amendment. 10. GRAS substances. Food Technol 31(1):65–74.

Parent RA, Cox GE, Babish JG, Gallo MA, Hess FG, Becci PJ. 1983a. Subchronic feeding study of carnauba wax in beagle dogs. Food Chem Toxicol 21:85–87.

Parent RA, Re TA, Babish JG, Cox GE, Voss KA, Becci PJ. 1983b. Reproduction and subchronic feeding study of carnauba wax in rats. Food Chem Toxicol 21:89–93.

Place AR. 1992. Comparative aspects of lipid digestion and absorption: Physiological correlates of wax ester digestion. Am J Physiol 263(3 Pt 2):R464–R471.

Prival MJ, Simmon VF, Mortelmans KE, 1991. Bacterial mutagenicity testing of 49 food ingredients gives very few positive results. Mutat Res 260:321–329.

REACH Registration for Fatty Acids, Lanolin. 2015. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/13395. ***Study information is publicly available but may be subject to copyright laws; the authors of this GRAS assessment are attempting to obtain permission for its use.***

REACH Registration for Polar Modified Rice Bran Wax. 2016. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/18316. ***Study information is publicly available but may be subject to copyright laws; the authors of this GRAS assessment are attempting to obtain permission for its use.***

Reinhardt JG, Brown JH. 1990. Jojoba oil and derivatives—Safety and applications in cosmetics. Unpublished data submitted by Jojoba Growers and Processors, Inc., 1990. ***Report not available; as cited in Becker (2008).***

Revolymer Limited. 2011. GRN No. 374; Maleated isoprenyl polymer with methoxy-polyethylene glycol (MIP-MPEG). http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm269568.pdf.

Rowland IR, Butterworth KR, Gaunt IF, Grasso P, Gangolli SD. 1982. Short-term toxicity study of carnauba wax in rats. Food Chem Toxicol 20:467–471.

Sabale V, Sabale PM, Lakhotiya CL. 2007. In vitro studies on rice bran wax as skin moisturizer. Indian J Pharmaceut Sci 69(2):215.

SCF (European Commission Scientific Committee for Food). 1992. Report of the Scientific Committee for Food on a second series of food additives of various technological functions. Opinion expressed on 19 October 1990. In: Twenty-sixth report series. ***Report not available; as cited in EFSA (2012c).***

SCF (European Commission Scientific Committee for Food). 2001. Opinion of the Scientific Committee on Food on carnauba wax. SCF/CS/ADD/MsAd/194.

Sengupta A, Behera J. 2014. Comprehensive view on chemistry, manufacturing & applications of lanolin extracted from wool pretreatment. Am J Eng Res (AJER). 3(7):33–43.

Shumow L, Barraj LM, Murphy MM, Bi X, Bodor AR. 2012. Candy consumption in the United States. FASEB Journal 26:1005.3 (abstract).

Smith JH, Mallett AK, Priston RA, Brantom PG, Worrell NR, Sexsmith C, Simpson BJ. 1996. Ninety-day feeding study in Fischer-344 rats of highly refined petroleum-derived food-grade white oils and waxes. Toxicol Pathol 24(2):214–230.

Stalder R, Marchesini M, Bexter A. 1985. Effects of feeding jojoba waxes to rats. A 90-day study. American Oil Chemists Society Symposium, Philadelphia, 1985. J Am Oil Chem Soc. 62(4):600.

Taguchi N, Kunimoto T. 1977. Toxicity studies on jojoba oil for cosmetic uses. Cosmet Toilet 92:53.

Vali SR, Ju YH, Kaimal TNB, Chern YT. 2005. A process for the preparation of food-grade rice bran wax and the determination of its composition. J Amer Oil Chem Soc 82:57.

Verbiscar AJ, Banigan TF, Weber CW, Reid BL, Trei JE, Nelson EA, et al. 1980. Detoxification of jojoba meal. J Agric Food Chem 28:571–578.

Verschuren PM. 1989. Evaluation of jojoba oil as a low-energy fat. 1. A 4-week feeding study in rats. J Food Chem Toxicity 27:35–44.

Verschuren PM, Nugteren DH. 1989. Evaluation of jojoba oil as a low-energy fat. 2. Intestinal transit time, stomach emptying and digestibility in short-term feeding studies in rats. J Food Chem Toxicity 27:45–48.

Warth AH. 1956. The Chemistry and Technology of Waxes. New 2nd ed. Reinhold Publishing Co., New York.

Wisniak J. 1977. Jojoba oil and derivatives. Proc Chem Fats and Lipids 15(3):167–218.

Yaron A, Samoiloff V, Benzioni A. 1982. Absorption and distribution of orally administered jojoba wax in mice. Lipids 17:169–171.

APPENDIX A

Analytical Results

KOSTER KEUNEN, INC
WATERTOWN, CONNECTICUT 06795

TEL# (860) 945-3333
FAX# (860) 945-0330

DATE: July 14, 2020

CERTIFICATE OF ANALYSIS

CUSTOMER	ORDER NUMBER	ITEM NUMBER	BATCH NUMBER
			2000887

PRODUCT: RICE BRAN WAX
WAX# 224P

LABORATORY TESTS & METHODS	KOSTER KEUNEN, INC SPECIFICATIONS	ACTUAL RESULTS
MELTING POINT <USP 741, Class II>	77 - 82ºC	82.0ºC
ACID VALUE <USP 401>	≤ 13 mg KOH/g	2.2
SAPONIFICATION VALUE <USP 401 >	75 - 120 mg KOH/g	78
IODINE VALUE <USP 401>	≤ 20.0 g/100g	Passes
COLOR <Visual>	Yellow to Light Brown	Passes
DATE OF MANUFACTURE		April 28, 2020
RECOMMENDED RETEST DATE		April 28, 2022

SUBMITTED BY:____________________

eurofins Food Integrity & Innovation

Report Number:	**2928939-0**
Report Date:	**10-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927046-0**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000887**	**Eurofins Sample:**	**9618763**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000887	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Dioxin-like PCBs *	
PCB - Total Equivalence	0.031 ng/kg
Elements by ICP Mass Spectrometry	
Arsenic	<10.0 ppb
Cadmium	<5.00 ppb
Lead	<5.00 ppb
Mercury	<5.00 ppb
Dioxin/Furans *	
Dioxin - Total Equivalence	0.72 ng/kg
Multi-Residue Analysis (500+ Compounds)	
Matrix Type - To Determine Limit of Quantification (LOQ)	Spices - Botanicals - and other Specialty Samples
Fluvalinate tau- (sum of isomers)	0.013 mg/kg
Propargite	0.010 mg/kg
Other tested pesticides	Below LOQ
Abamectin	<0.05 mg/kg
Acephate	<0.01 mg/kg
Acetamiprid	<0.01 mg/kg
Acetochlor	<0.01 mg/kg
Acibenzolar-S-methyl	<0.01 mg/kg
Aclonifen	<0.01 mg/kg
Acrinathrin	<0.01 mg/kg
Alachlor	<0.01 mg/kg
Aldicarb	<0.01 mg/kg
Aldicarb sulfone (Aldoxycarb)	<0.01 mg/kg
Aldicarb sulfoxide	<0.01 mg/kg
Aldrin	<0.01 mg/kg
Allethrin	<0.01 mg/kg
Ametryn	<0.01 mg/kg
Amidosulfuron	<0.01 mg/kg
Aminocarb	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000887	Eurofins Sample:	9618763
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000887	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Amitraz metabolite DMF	<0.01 mg/kg
Amitraz metabolite DMPF	<0.01 mg/kg
Anilofos	<0.01 mg/kg
Atrazine	<0.01 mg/kg
Azaconazole	<0.01 mg/kg
Azamethiphos	<0.01 mg/kg
Azinphos-ethyl	<0.01 mg/kg
Azinphos-methyl	<0.01 mg/kg
Azoxystrobin	<0.01 mg/kg
Beflubutamid	<0.01 mg/kg
Benalaxyl	<0.01 mg/kg
Bendiocarb	<0.01 mg/kg
Benfluralin	<0.01 mg/kg
Benoxacor	<0.01 mg/kg
Bensulide	<0.01 mg/kg
Benzoximate	<0.01 mg/kg
Bifenazate	<0.01 mg/kg
Bifenox	<0.01 mg/kg
Bifenthrin	<0.01 mg/kg
Bispyribac	<0.01 mg/kg
Bitertanol	<0.01 mg/kg
Bixafen	<0.01 mg/kg
Boscalid	<0.01 mg/kg
Bromacil	<0.01 mg/kg
Bromophos-ethyl	<0.01 mg/kg
Bromophos-methyl	<0.01 mg/kg
Bromopropylate	<0.01 mg/kg
Bromuconazole (2 diastereoisomers)	<0.01 mg/kg
Bupirimate	<0.01 mg/kg
Buprofezin	<0.01 mg/kg
Butachlor	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000887	Eurofins Sample:	9618763
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000887	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Butafenacil	<0.01 mg/kg
Butocarboxim	<0.02 mg/kg
Butocarboxim sulfoxide	<0.01 mg/kg
Butoxycarboxim	<0.01 mg/kg
Butylate	<0.01 mg/kg
Cadusafos	<0.01 mg/kg
Captan (as THPI)	<0.01 mg/kg
Carbaryl	<0.01 mg/kg
Carbendazim	<0.01 mg/kg
Carbetamide	<0.01 mg/kg
Carbofuran	<0.01 mg/kg
Carbofuran-3-hydroxy-	<0.01 mg/kg
Carbophenothion	<0.01 mg/kg
Carboxin	<0.01 mg/kg
Carfentrazone-ethyl	<0.01 mg/kg
Chlorantraniliprole	<0.01 mg/kg
Chlorbromuron	<0.01 mg/kg
Chlordane, cis-	<0.01 mg/kg
Chlordane, trans-	<0.01 mg/kg
Chlordimeform	<0.01 mg/kg
Chlorfenapyr	<0.02 mg/kg
Chlorfenvinphos (E- and Z-isomers)	<0.01 mg/kg
Chlorfluazuron	<0.01 mg/kg
Chloridazon (Pyrazon)	<0.01 mg/kg
Chlorimuron-ethyl (Classic)	<0.01 mg/kg
Chlorobenzilate	<0.01 mg/kg
Chlorotoluron (Chlortoluron)	<0.01 mg/kg
Chloroxuron	<0.01 mg/kg
Chlorpropham (CIPC)	<0.01 mg/kg
Chlorpyrifos	<0.01 mg/kg
Chlorpyrifos-methyl	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000887	Eurofins Sample:	9618763
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000887	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Chlorsulfuron	<0.01 mg/kg
Clethodim (E- and Z-isomers)	<0.01 mg/kg
Clodinafop-propargyl	<0.01 mg/kg
Clofentezine	<0.01 mg/kg
Clomazone	<0.01 mg/kg
Cloquintocet-mexyl	<0.01 mg/kg
Clothianidin	<0.01 mg/kg
Coumaphos	<0.01 mg/kg
Cyanazine	<0.01 mg/kg
Cyanofenphos	<0.01 mg/kg
Cyazofamid	<0.01 mg/kg
Cycloate	<0.01 mg/kg
Cycloxydim	<0.01 mg/kg
Cycluron	<0.01 mg/kg
Cyflufenamid	<0.01 mg/kg
Cyfluthrin	<0.01 mg/kg
Cyhalothrin, lambda-	<0.01 mg/kg
Cymiazole	<0.01 mg/kg
Cymoxanil	<0.01 mg/kg
Cypermethrin	<0.01 mg/kg
Cyproconazole (2 diastereoisomers)	<0.01 mg/kg
Cyprodinil	<0.01 mg/kg
Cyromazine	<0.01 mg/kg
Dacthal (Chlorthal-dimethyl, DCPA)	<0.01 mg/kg
DDD, o,p'-	<0.01 mg/kg
DDD, p,p'-	<0.01 mg/kg
DDE, o,p'-	<0.01 mg/kg
DDE, p,p'-	<0.01 mg/kg
DDT, o,p'-	<0.01 mg/kg
DDT, p,p'-	<0.01 mg/kg
DEET (Diethyltoluamide)	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000887	Eurofins Sample:	9618763
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000887	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Deltamethrin	<0.01 mg/kg
Demeton-O	<0.01 mg/kg
Demeton-S	<0.01 mg/kg
Demeton-S-methyl	<0.01 mg/kg
Demeton-S-methyl sulfone	<0.01 mg/kg
Desmedipham	<0.01 mg/kg
Dialifos (Dialifor)	<0.01 mg/kg
Diazinon	<0.01 mg/kg
Diazinon oxon	<0.01 mg/kg
Dichlobenil	<0.01 mg/kg
Dichlofenthion	<0.01 mg/kg
Dichlofluanid	<0.01 mg/kg
Dichlorvos	<0.01 mg/kg
Diclobutrazol	<0.01 mg/kg
Diclocymet (2 diastereoisomers)	<0.01 mg/kg
Dicloran (DCNA)	<0.01 mg/kg
Dicofol	<0.01 mg/kg
Dicrotophos	<0.01 mg/kg
Dieldrin	<0.01 mg/kg
Diethofencarb	<0.01 mg/kg
Difenoconazole (cis- and trans-)	<0.01 mg/kg
Diflubenzuron	<0.01 mg/kg
Diflufenican	<0.01 mg/kg
Dimethachlor	<0.01 mg/kg
Dimethametryn	<0.01 mg/kg
Dimethenamid	<0.01 mg/kg
Dimethoate	<0.01 mg/kg
Dimethomorph (E- and Z-isomers)	<0.01 mg/kg
Dimetilan	<0.01 mg/kg
Dimoxystrobin	<0.01 mg/kg
Diniconazole	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000887	Eurofins Sample:	9618763
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000887	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Dinitramine	<0.02 mg/kg
Dinotefuran	<0.01 mg/kg
Dioxacarb	<0.01 mg/kg
Diphenamid	<0.01 mg/kg
Diphenylamine	<0.01 mg/kg
Dipropetryn	<0.01 mg/kg
Disulfoton	<0.01 mg/kg
Disulfoton sulfone	<0.01 mg/kg
Disulfoton sulfoxide	<0.01 mg/kg
Diuron	<0.01 mg/kg
DMST (Dimethylaminosulfotoluidide)	<0.01 mg/kg
Dodemorph (cis- and trans-)	<0.01 mg/kg
Dodine	<0.01 mg/kg
Doramectin	<0.05 mg/kg
Emamectin benzoate	<0.01 mg/kg
Endosulfan I (alpha-isomer)	<0.02 mg/kg
Endosulfan II (beta-isomer)	<0.02 mg/kg
Endosulfan sulfate	<0.02 mg/kg
Endrin	<0.01 mg/kg
EPN	<0.01 mg/kg
Epoxiconazole	<0.01 mg/kg
Eprinomectin	<0.02 mg/kg
Ethaboxam	<0.01 mg/kg
Ethalfluralin	<0.01 mg/kg
Ethidimuron (Sulfadiazole)	<0.01 mg/kg
Ethiofencarb	<0.01 mg/kg
Ethiofencarb sulfone	<0.01 mg/kg
Ethiofencarb sulfoxide	<0.01 mg/kg
Ethion	<0.01 mg/kg
Ethiprole	<0.01 mg/kg
Ethirimol	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000887	Eurofins Sample:	9618763
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000887	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Ethofumesate	<0.01 mg/kg
Ethoprophos (Ethoprop)	<0.01 mg/kg
Etofenprox	<0.01 mg/kg
Etoxazole	<0.01 mg/kg
Etrimfos	<0.01 mg/kg
Famoxadone	<0.01 mg/kg
Fenamidone	<0.01 mg/kg
Fenamiphos	<0.01 mg/kg
Fenamiphos sulfone	<0.01 mg/kg
Fenamiphos sulfoxide	<0.01 mg/kg
Fenarimol	<0.01 mg/kg
Fenazaquin	<0.01 mg/kg
Fenbuconazole	<0.01 mg/kg
Fenbutatin oxide	<0.01 mg/kg
Fenchlorphos (Ronnel)	<0.01 mg/kg
Fenchlorphos oxon	<0.01 mg/kg
Fenhexamid	<0.01 mg/kg
Fenitrothion	<0.01 mg/kg
Fenobucarb	<0.01 mg/kg
Fenoxanil (sum of isomers)	<0.01 mg/kg
Fenoxycarb	<0.01 mg/kg
Fenpropathrin	<0.01 mg/kg
Fenpropidin	<0.01 mg/kg
Fenpropimorph	<0.01 mg/kg
Fenpyroximate	<0.01 mg/kg
Fensulfothion	<0.01 mg/kg
Fensulfothion oxon	<0.01 mg/kg
Fensulfothion oxon sulfone	<0.01 mg/kg
Fensulfothion sulfone	<0.01 mg/kg
Fenthion	<0.01 mg/kg
Fenthion oxon	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000887	Eurofins Sample:	9618763
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000887	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Fenthion oxon sulfone	<0.01 mg/kg
Fenthion oxon sulfoxide	<0.01 mg/kg
Fenthion sulfone	<0.01 mg/kg
Fenthion sulfoxide	<0.01 mg/kg
Fentin	<0.01 mg/kg
Fentrazamide	<0.01 mg/kg
Fenuron	<0.01 mg/kg
Fenvalerate/Esfenvalerate (sum of isomers)	<0.02 mg/kg
Fipronil	<0.01 mg/kg
Fipronil desulfinyl	<0.01 mg/kg
Fipronil sulfone	<0.01 mg/kg
Flazasulfuron	<0.01 mg/kg
Flonicamid	<0.01 mg/kg
Fluazifop-butyl	<0.01 mg/kg
Flubendiamide	<0.05 mg/kg
Flucarbazone-sodium	<0.02 mg/kg
Flucythrinate (sum of isomers)	<0.01 mg/kg
Fludioxonil	<0.01 mg/kg
Flufenacet	<0.01 mg/kg
Flufenoxuron	<0.01 mg/kg
Flumethrin	<0.05 mg/kg
Flumetsulam	<0.01 mg/kg
Flumioxazin	<0.01 mg/kg
Fluometuron	<0.01 mg/kg
Fluopicolide	<0.01 mg/kg
Fluopyram	<0.01 mg/kg
Fluoxastrobin	<0.01 mg/kg
Fluquinconazole	<0.01 mg/kg
Fluridone	<0.01 mg/kg
Flusilazole	<0.01 mg/kg
Flutolanil	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

eurofins Food Integrity & Innovation

Report Number:	**2928939-0**
Report Date:	**10-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927046-0**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000887**	**Eurofins Sample:**	**9618763**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000887	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Flutriafol	<0.01 mg/kg
Fonofos	<0.01 mg/kg
Foramsulfuron	<0.01 mg/kg
Forchlorfenuron	<0.01 mg/kg
Formetanate hydrochloride	<0.01 mg/kg
Formothion	<0.01 mg/kg
Fosthiazate (sum of isomers)	<0.01 mg/kg
Fuberidazole	<0.01 mg/kg
Furalaxyl	<0.01 mg/kg
Furathiocarb	<0.01 mg/kg
Griseofulvin	<0.01 mg/kg
Halofenozide	<0.01 mg/kg
Halosulfuron-methyl	<0.01 mg/kg
Haloxyfop-methyl	<0.01 mg/kg
HCH, alpha- (alpha-BHC)	<0.01 mg/kg
HCH, beta- (beta-BHC)	<0.01 mg/kg
HCH, delta- (delta-BHC)	<0.01 mg/kg
Heptachlor	<0.01 mg/kg
Heptachlor endo-epoxide	<0.02 mg/kg
Heptachlor exo-epoxide	<0.01 mg/kg
Hexachlorobenzene (HCB)	<0.01 mg/kg
Hexaconazole	<0.01 mg/kg
Hexaflumuron	<0.01 mg/kg
Hexazinone	<0.01 mg/kg
Hexythiazox	<0.01 mg/kg
Hydramethylnon	<0.01 mg/kg
Hydroprene, S- (sum of isomers)	<0.01 mg/kg
Imazalil	<0.01 mg/kg
Imazamethabenz-methyl	<0.01 mg/kg
Imazethapyr	<0.01 mg/kg
Imidacloprid	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000887**	**Eurofins Sample:**	**9618763**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000887	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Indoxacarb	<0.01 mg/kg
Ipconazole	<0.01 mg/kg
Iprodione	<0.01 mg/kg
Iprodione isomer	<0.02 mg/kg
Iprodione metabolite	<0.01 mg/kg
Iprovalicarb	<0.01 mg/kg
Isocarbamid	<0.01 mg/kg
Isocarbophos	<0.01 mg/kg
Isofenphos	<0.01 mg/kg
Isofenphos-methyl	<0.01 mg/kg
Isoprocarb	<0.01 mg/kg
Isoprothiolane	<0.01 mg/kg
Isoproturon	<0.01 mg/kg
Isoxaben	<0.01 mg/kg
Isoxadifen-ethyl	<0.01 mg/kg
Isoxaflutole	<0.01 mg/kg
Isoxathion	<0.01 mg/kg
Ivermectin	<0.05 mg/kg
Kresoxim-methyl	<0.01 mg/kg
Lactofen	<0.01 mg/kg
Lenacil	<0.01 mg/kg
Lindane (gamma-HCH, gamma-BHC)	<0.01 mg/kg
Linuron	<0.01 mg/kg
Lufenuron	<0.01 mg/kg
Malaoxon	<0.01 mg/kg
Malathion	<0.01 mg/kg
Mandipropamid	<0.01 mg/kg
Mecarbam	<0.01 mg/kg
Mepanipyrim	<0.01 mg/kg
Mepanipyrim-2-hydroxypropyl	<0.01 mg/kg
Mephosfolan	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000887	Eurofins Sample:	9618763
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000887	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Mesosulfuron-methyl	<0.01 mg/kg
Metaflumizone	<0.01 mg/kg
Metalaxyl	<0.01 mg/kg
Metamitron	<0.01 mg/kg
Metazachlor	<0.01 mg/kg
Metconazole	<0.01 mg/kg
Methabenzthiazuron	<0.01 mg/kg
Methacrifos	<0.01 mg/kg
Methamidophos	<0.01 mg/kg
Methidathion	<0.01 mg/kg
Methiocarb	<0.01 mg/kg
Methiocarb sulfone	<0.01 mg/kg
Methiocarb sulfoxide	<0.01 mg/kg
Methomyl	<0.01 mg/kg
Methoprotryne	<0.01 mg/kg
Methoxychlor	<0.01 mg/kg
Methoxyfenozide	<0.01 mg/kg
Metobromuron	<0.01 mg/kg
Metolachlor	<0.01 mg/kg
Metolcarb	<0.01 mg/kg
Metosulam	<0.01 mg/kg
Metoxuron	<0.01 mg/kg
Metrafenone	<0.01 mg/kg
Metribuzin	<0.01 mg/kg
Metsulfuron-methyl	<0.01 mg/kg
Mevinphos (E- and Z-isomers)	<0.01 mg/kg
Mexacarbate	<0.01 mg/kg
MGK 264 (sum of isomers)	<0.01 mg/kg
Mirex	<0.01 mg/kg
Molinate	<0.01 mg/kg
Monocrotophos	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000887**	**Eurofins Sample:**	**9618763**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000887	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Monolinuron	<0.01 mg/kg
Moxidectin	<0.05 mg/kg
Myclobutanil	<0.01 mg/kg
Naled (Dibrom)	<0.01 mg/kg
Naphthol, 1-	<0.02 mg/kg
Napropamide	<0.01 mg/kg
Neburon	<0.01 mg/kg
Nicosulfuron	<0.01 mg/kg
Nitenpyram	<0.01 mg/kg
Nitralin	<0.01 mg/kg
Nitrofen	<0.01 mg/kg
Nonachlor, cis-	<0.01 mg/kg
Nonachlor, trans-	<0.01 mg/kg
Norflurazon	<0.01 mg/kg
Norflurazon-desmethyl	<0.01 mg/kg
Novaluron	<0.01 mg/kg
Nuarimol	<0.01 mg/kg
Ofurace	<0.01 mg/kg
Omethoate	<0.01 mg/kg
Oxadiazon	<0.01 mg/kg
Oxadixyl	<0.01 mg/kg
Oxamyl	<0.01 mg/kg
Oxamyl oxime	<0.01 mg/kg
Oxasulfuron	<0.01 mg/kg
Oxycarboxin	<0.01 mg/kg
Oxychlordane	<0.02 mg/kg
Oxydemeton-methyl	<0.01 mg/kg
Oxyfluorfen	<0.01 mg/kg
Paclobutrazol	<0.01 mg/kg
Paraoxon	<0.01 mg/kg
Paraoxon-methyl	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

eurofins Food Integrity & Innovation

Report Number:	**2928939-0**
Report Date:	**10-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927046-0**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000887**	**Eurofins Sample:**	**9618763**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000887	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Parathion	<0.01 mg/kg
Parathion-methyl	<0.01 mg/kg
Penconazole	<0.01 mg/kg
Pencycuron	<0.01 mg/kg
Pendimethalin	<0.01 mg/kg
Penoxsulam	<0.01 mg/kg
Pentachloroaniline	<0.01 mg/kg
Pentachloroanisole	<0.01 mg/kg
Pentachlorobenzene	<0.01 mg/kg
Pentachlorobenzonitrile	<0.01 mg/kg
Pentachlorothioanisole	<0.01 mg/kg
Permethrin (sum of isomers)	<0.01 mg/kg
Perthane (Ethylan)	<0.01 mg/kg
Phenmedipham	<0.01 mg/kg
Phenthoate	<0.01 mg/kg
Phenylphenol, 2- (OPP)	<0.02 mg/kg
Phorate	<0.01 mg/kg
Phorate sulfone	<0.01 mg/kg
Phorate sulfoxide	<0.01 mg/kg
Phosalone	<0.01 mg/kg
Phosmet	<0.01 mg/kg
Phosmet oxon	<0.01 mg/kg
Phosphamidon (E- and Z-isomers)	<0.01 mg/kg
Phoxim	<0.01 mg/kg
Picolinafen	<0.01 mg/kg
Picoxystrobin	<0.01 mg/kg
Piperonyl butoxide	<0.01 mg/kg
Piperophos	<0.01 mg/kg
Pirimicarb	<0.01 mg/kg
Pirimicarb-desmethyl	<0.01 mg/kg
Pirimiphos-ethyl	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000887**	**Eurofins Sample:**	**9618763**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000887	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Pirimiphos-methyl	<0.01 mg/kg
Pirimiphos-methyl, N-desethyl-	<0.01 mg/kg
Prallethrin	<0.01 mg/kg
Pretilachlor	<0.01 mg/kg
Primisulfuron-methyl	<0.01 mg/kg
Prochloraz	<0.01 mg/kg
Procymidone	<0.01 mg/kg
Prodiamine	<0.01 mg/kg
Profenofos	<0.01 mg/kg
Profluralin	<0.01 mg/kg
Promecarb	<0.01 mg/kg
Prometon	<0.01 mg/kg
Prometryn	<0.01 mg/kg
Propamocarb	<0.01 mg/kg
Propanil	<0.01 mg/kg
Propaquizafop	<0.01 mg/kg
Propetamphos	<0.01 mg/kg
Propham	<0.01 mg/kg
Propiconazole (sum of isomers)	<0.01 mg/kg
Propoxur	<0.01 mg/kg
Propyzamide (Pronamide)	<0.01 mg/kg
Proquinazid	<0.01 mg/kg
Prosulfocarb	<0.01 mg/kg
Prothioconazole-desthio	<0.01 mg/kg
Prothiofos	<0.01 mg/kg
Pymetrozine	<0.01 mg/kg
Pyracarbolid	<0.01 mg/kg
Pyraclostrobin	<0.01 mg/kg
Pyraflufen-ethyl	<0.01 mg/kg
Pyrazophos	<0.01 mg/kg
Pyrethrum (total)	<0.10 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000887	Eurofins Sample:	9618763
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000887	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Pyridaben	<0.01 mg/kg
Pyridalyl	<0.01 mg/kg
Pyridaphenthion	<0.01 mg/kg
Pyridate	<0.01 mg/kg
Pyrifenox (E- and Z-isomers)	<0.01 mg/kg
Pyrimethanil	<0.01 mg/kg
Pyriproxyfen	<0.01 mg/kg
Pyroquilon	<0.01 mg/kg
Pyroxsulam	<0.01 mg/kg
Quinalphos	<0.01 mg/kg
Quinmerac	<0.01 mg/kg
Quinoclamine	<0.01 mg/kg
Quinoxyfen	<0.01 mg/kg
Quintozene	<0.01 mg/kg
Quizalofop	<0.02 mg/kg
Quizalofop-ethyl	<0.01 mg/kg
Resmethrin (sum of isomers)	<0.01 mg/kg
Rimsulfuron	<0.01 mg/kg
Rotenone	<0.01 mg/kg
S421	<0.01 mg/kg
Schradan (Octamethylpyrophosphoramide)	<0.01 mg/kg
Secbumeton	<0.01 mg/kg
Sethoxydim (E- and Z-isomers)	<0.01 mg/kg
Siduron	<0.01 mg/kg
Silthiofam	<0.01 mg/kg
Simazine	<0.01 mg/kg
Simeconazole	<0.02 mg/kg
Simetryn	<0.01 mg/kg
Spinetoram (spinosyns J and L)	<0.01 mg/kg
Spinosad (spinosyns A and D)	<0.01 mg/kg
Spirodiclofen	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

eurofins | Food Integrity & Innovation

Report Number:	**2928939-0**
Report Date:	**10-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927046-0**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000887**	**Eurofins Sample:**	**9618763**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000887	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Spiromesifen	<0.01 mg/kg
Spiromesifen enol	<0.01 mg/kg
Spirotetramat	<0.01 mg/kg
Spiroxamine (2 diastereoisomers)	<0.01 mg/kg
Sulfallate	<0.01 mg/kg
Sulfentrazone	<0.01 mg/kg
Sulprofos	<0.01 mg/kg
Tebuconazole	<0.01 mg/kg
Tebufenozide	<0.01 mg/kg
Tebufenpyrad	<0.01 mg/kg
Tebupirimfos	<0.01 mg/kg
Tebuthiuron	<0.01 mg/kg
Tecnazene	<0.01 mg/kg
Teflubenzuron	<0.01 mg/kg
Tefluthrin	<0.01 mg/kg
Temephos	<0.01 mg/kg
Tepraloxydim (E- and Z-isomers)	<0.01 mg/kg
Terbacil	<0.01 mg/kg
Terbufos	<0.01 mg/kg
Terbufos sulfone	<0.01 mg/kg
Terbufos sulfoxide	<0.01 mg/kg
Terbumeton	<0.01 mg/kg
Terbuthylazine	<0.01 mg/kg
Terbutryn	<0.01 mg/kg
Tetrachloroaniline, 2,3,5,6-	<0.01 mg/kg
Tetrachloroanisole, 2,3,4,5-	<0.01 mg/kg
Tetrachlorvinphos	<0.01 mg/kg
Tetraconazole	<0.01 mg/kg
Tetradifon	<0.01 mg/kg
Tetramethrin (sum of isomers)	<0.01 mg/kg
Thiabendazole	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000887**	**Eurofins Sample:**	**9618763**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000887	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Thiabendazole-5-hydroxy-	<0.01 mg/kg
Thiacloprid	<0.01 mg/kg
Thiamethoxam	<0.01 mg/kg
Thiazopyr	<0.01 mg/kg
Thidiazuron	<0.01 mg/kg
Thifensulfuron-methyl	<0.01 mg/kg
Thiobencarb (Benthiocarb)	<0.01 mg/kg
Thiodicarb	<0.01 mg/kg
Thiofanox	<0.05 mg/kg
Thiofanox sulfone	<0.01 mg/kg
Thiofanox sulfoxide	<0.01 mg/kg
Thionazin (Zinophos)	<0.01 mg/kg
Thiophanate-methyl	<0.01 mg/kg
Tolclofos-methyl	<0.01 mg/kg
Tolfenpyrad	<0.01 mg/kg
Tolylfluanid	<0.01 mg/kg
Tralkoxydim	<0.01 mg/kg
Triadimefon	<0.01 mg/kg
Triadimenol	<0.01 mg/kg
Triasulfuron	<0.01 mg/kg
Triazophos	<0.01 mg/kg
Tribenuron-methyl	<0.01 mg/kg
Tribufos (DEF)	<0.01 mg/kg
Trichlorfon (Metrifonate)	<0.01 mg/kg
Trichloroanisole, 2,4,6-	<0.01 mg/kg
Tricyclazole	<0.01 mg/kg
Trietazine	<0.01 mg/kg
Trifloxystrobin	<0.01 mg/kg
Trifloxysulfuron	<0.01 mg/kg
Triflumizole	<0.01 mg/kg
Triflumuron	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

eurofins | Food Integrity & Innovation

Report Number:	**2928939-0**
Report Date:	**10-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927046-0**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000887**	**Eurofins Sample:**	**9618763**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000887	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Trifluralin	<0.01 mg/kg
Triforine	<0.01 mg/kg
Trimethacarb	<0.01 mg/kg
Triticonazole	<0.01 mg/kg
Uniconazole	<0.01 mg/kg
Vamidothion	<0.01 mg/kg
Vinclozolin	<0.01 mg/kg
Zoxamide	<0.01 mg/kg
Polycyclic Aromatic Hydrocarbons-Low Level	
Benz(a)anthracene	<0.250 ppb
Benzo(a)pyrene	<0.250 ppb
Benzo(b)fluoranthene	0.270 ppb
Benzo(g,h,i)perylene	<0.250 ppb
Benzo(k)fluoranthene	<0.250 ppb
Chrysene	0.397 ppb
Dibenz(a,h)anthracene	<0.250 ppb
Indeno(1,2,3-c,d)pyrene	<0.250 ppb
Pyrene	0.901 ppb

Analysis	Limit	Result	Pass/Fail
Mycotoxins in Raw Materials			
Aflatoxin B1		<0.300 ppb	
Aflatoxin B2		<0.300 ppb	
Aflatoxin G1		<0.300 ppb	
Aflatoxin G2		<0.300 ppb	
Aflatoxin M1		<0.300 ppb	
Aflatoxin M2		<0.300 ppb	
Deoxynivalenol		<56.0 ppb	
T-2 Toxin		<5.60 ppb	
HT-2 Toxin		<56.0 ppb	
Fumonisin B1		<14.3 ppb	

*** This analysis or component is not ISO accredited.**

eurofins Food Integrity & Innovation

Report Number:	2928939-0
Report Date:	10-Jul-2020
Report Status:	Final
Supercedes :	2927046-0

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000887**	**Eurofins Sample:**	**9618763**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000887	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	**Limit**	**Result**	**Pass/Fail**
Mycotoxins in Raw Materials			
Fumonisin B2		<14.0 ppb	
Ochratoxin A		<1.00 ppb	
Zearalenone		<16.7 ppb	

Analysis	**LOQ**	**Limit**	**Result**	**Pass/Fail**
Residual Solvents - Class 1, 2a and 2b				
1,1,1-Trichloroethane	10 ppm	10 ppm	<10 ppm	Pass
1,1-Dichloroethene	8 ppm	8 ppm	<8 ppm	Pass
1,2-Dichloroethane	5 ppm	5 ppm	<5 ppm	Pass
Benzene	2 ppm	2 ppm	<2 ppm	Pass
Carbon Tetrachloride	4 ppm	4 ppm	<4 ppm	Pass
1,2-Dimethoxyethane	100 ppm	100 ppm	<100 ppm	Pass
1,4-Dioxane	380 ppm	380 ppm	<380 ppm	Pass
Acetonitrile	410 ppm	410 ppm	<410 ppm	Pass
Chlorobenzene	360 ppm	360 ppm	<360 ppm	Pass
Chloroform	60 ppm	60 ppm	<60 ppm	Pass
1,2-Dichloroethene	1870 ppm	1870 ppm	<1870 ppm	Pass
Cumene	70 ppm	70 ppm	<70.0 ppm	Pass
Cyclohexane	3880 ppm	3880 ppm	<3880 ppm	Pass
Methanol	3000 ppm	3000 ppm	<3000 ppm	Pass
Methylbutylketone	50 ppm	50 ppm	<50 ppm	Pass
Methylcyclohexane	1180 ppm	1180 ppm	<1180 ppm	Pass
Methylene Chloride	600 ppm	600 ppm	<600 ppm	Pass
n-Hexane	290 ppm	290 ppm	<290 ppm	Pass
Nitromethane	50 ppm	50 ppm	<50 ppm	Pass
Pyridine	200 ppm	200 ppm	<200 ppm	Pass
Tetrahydrofuran	720 ppm	720 ppm	<720 ppm	Pass
Tetralin	96 ppm	96 ppm	<96.0 ppm	Pass

*** This analysis or component is not ISO accredited.**

eurofins | Food Integrity & Innovation

Report Number:	**2928939-0**
Report Date:	**10-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927046-0**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000887**	**Eurofins Sample:**	**9618763**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000887	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	LOQ	Limit	Result	Pass/Fail
Residual Solvents - Class 1, 2a and 2b				
Toluene	890 ppm	890 ppm	<890 ppm	Pass
Trichloroethylene	80 ppm	80 ppm	<80 ppm	Pass
Xylenes(O,M,P + EB)	2170 ppm	2170 ppm	<2170 ppm	Pass

Method References — **Testing Location**

Dioxin/Furans (DIOXIN_S) — **Eurofins Lancaster Laboratories Environmental LLC**
2425 New Holland Pike Lancaster, Pennsylvania 17601-443 USA

Dioxin-like PCBs (PCB_S) — **Eurofins Lancaster Laboratories Environmental LLC**
2425 New Holland Pike Lancaster, Pennsylvania 17601-443 USA

Elements by ICP Mass Spectrometry (ICP_MS_S) — **Food Integrity Innovation-Madison**
3301 Kinsman Blvd Madison, WI 53704 USA

Official Methods of Analysis, Method 2011.19 and 993.14, AOAC INTERNATIONAL, (Modified).
Paquette, L.H., Szabo, A., Thompson, J.J., "Simultaneous Determination of Chromium, Selenium, and Molybdenum in Nutritional Products by Inductively Coupled Plasma/Mass Spectrometry: Single-Laboratory Validation," Journal of AOAC International, 94(4): 1240 - 1252 (2011).

Multi-Residue Analysis (500+ Compounds) (PS05_S) — **Food Integrity Innovation-Madison**
3301 Kinsman Blvd Madison, WI 53704 USA

Official Methods of Analysis, AOAC Official Method 2007.01, Pesticide Residues in Foods by Acetonitrile Extraction and Partitioning with Magnesium Sulfate, AOAC INTERNATIONAL (modified).

CEN Standard Method EN 15662: Food of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE - QuEChERS method.

List of the tested pesticides and their limits of quantification (LOQs) are available upon request.

*** This analysis or component is not ISO accredited.**

eurofins | Food Integrity & Innovation

Report Number:	2928939-0
Report Date:	10-Jul-2020
Report Status:	Final
Supercedes :	2927046-0

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Method References | **Testing Location**

Mycotoxins in Raw Materials (MYCO_REG_S) — **Food Integrity Innovation-Madison**, 3301 Kinsman Blvd Madison, WI 53704 USA

Varga, E., Glauner, T., Koppen, R., Mayer, K., Sulyok, M., Schumacher, R., Krska, R. and Berthiller, F., "Stable isotope dilution assay for the accurate determination of mycotoxins in maize by UHPLC-MS/MS," Analytical and BioAnalytical Chemistry, 402:2675-2686 (2012).

Polycyclic Aromatic Hydrocarbons-Low Level (LLPAH_S) — **Food Integrity Innovation-Madison**, 3301 Kinsman Blvd Madison, WI 53704 USA

Internally Developed Method

Residual Solvents - Class 1, 2a and 2b (USPR_S) — **Food Integrity Innovation-Madison**, 3301 Kinsman Blvd Madison, WI 53704 USA

United States Pharmacopeia, 38nd Rev. - National Formulary 33th Ed., Method <467>, USP Convention, Inc., Rockville, MD (2015). (Modified).

Testing Location(s) | **Released on Behalf of Eurofins by**

Food Integrity Innovation-Madison | **Edward Ladwig - Director**

Eurofins Food Chemistry Testing Madison, Inc.
3301 Kinsman Blvd
Madison WI 53704
800-675-8375

ilac-MRA A2LA ACCREDITED
2918.01

These results apply only to the items tested. This certificate of analysis shall not be reproduced, except in its entirety, without the written approval of Eurofins.

*** This analysis or component is not ISO accredited.**

KOSTER KEUNEN, INC
WATERTOWN, CONNECTICUT 06795

TEL# (860) 945-3333
FAX# (860) 945-0330

DATE: July 14, 2020

CERTIFICATE OF ANALYSIS

CUSTOMER	ORDER NUMBER	ITEM NUMBER	BATCH NUMBER
			2000375

PRODUCT: RICE BRAN WAX
WAX# 224P

LABORATORY TESTS & METHODS	KOSTER KEUNEN, INC SPECIFICATIONS	ACTUAL RESULTS
MELTING POINT <USP 741, Class II>	77 - 82ºC	81.5ºC
ACID VALUE <USP 401>	≤ 13 mg KOH/g	2.1
SAPONIFICATION VALUE <USP 401 >	75 - 120 mg KOH/g	76.0
IODINE VALUE <USP 401>	≤ 20.0 g/100g	Passes
COLOR <Visual>	Yellow to Light Brown	Passes
DATE OF MANUFACTURE		February 24, 2020
RECOMMENDED RETEST DATE		February 24, 2022

SUBMITTED BY:____________________

eurofins Food Integrity & Innovation

Report Number:	**2928004-0**
Report Date:	**09-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927587-0**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000375**	**Eurofins Sample:**	**9618759**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000375	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Dioxin-like PCBs *	
PCB - Total Equivalence	0.020 ng/kg
Elements by ICP Mass Spectrometry	
Arsenic	<10.0 ppb
Cadmium	<5.00 ppb
Lead	<5.00 ppb
Mercury	<5.00 ppb
Dioxin/Furans *	
Dioxin - Total Equivalence	0.79 ng/kg
Multi-Residue Analysis (500+ Compounds)	
Matrix Type - To Determine Limit of Quantification (LOQ)	Spices - Botanicals - and other Specialty Samples
Fluvalinate tau- (sum of isomers)	0.024 mg/kg
Propargite	0.029 mg/kg
Abamectin	<0.05 mg/kg
Acephate	<0.01 mg/kg
Acetamiprid	<0.01 mg/kg
Acetochlor	<0.01 mg/kg
Acibenzolar-S-methyl	<0.01 mg/kg
Aclonifen	<0.01 mg/kg
Acrinathrin	<0.01 mg/kg
Alachlor	<0.01 mg/kg
Aldicarb	<0.01 mg/kg
Aldicarb sulfone (Aldoxycarb)	<0.01 mg/kg
Aldicarb sulfoxide	<0.01 mg/kg
Aldrin	<0.01 mg/kg
Allethrin	<0.01 mg/kg
Ametryn	<0.01 mg/kg
Amidosulfuron	<0.01 mg/kg
Aminocarb	<0.01 mg/kg
Amitraz metabolite DMF	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000375**	**Eurofins Sample:**	**9618759**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000375	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Amitraz metabolite DMPF	<0.01 mg/kg
Anilofos	<0.01 mg/kg
Atrazine	<0.01 mg/kg
Azaconazole	<0.01 mg/kg
Azamethiphos	<0.01 mg/kg
Azinphos-ethyl	<0.01 mg/kg
Azinphos-methyl	<0.01 mg/kg
Azoxystrobin	<0.01 mg/kg
Beflubutamid	<0.01 mg/kg
Benalaxyl	<0.01 mg/kg
Bendiocarb	<0.01 mg/kg
Benfluralin	<0.01 mg/kg
Benoxacor	<0.01 mg/kg
Bensulide	<0.01 mg/kg
Benzoximate	<0.01 mg/kg
Bifenazate	<0.01 mg/kg
Bifenox	<0.01 mg/kg
Bifenthrin	<0.01 mg/kg
Bispyribac	<0.01 mg/kg
Bitertanol	<0.01 mg/kg
Bixafen	<0.01 mg/kg
Boscalid	<0.01 mg/kg
Bromacil	<0.01 mg/kg
Bromophos-ethyl	<0.01 mg/kg
Bromophos-methyl	<0.01 mg/kg
Bromopropylate	<0.01 mg/kg
Bromuconazole (2 diastereoisomers)	<0.01 mg/kg
Bupirimate	<0.01 mg/kg
Buprofezin	<0.01 mg/kg
Butachlor	<0.01 mg/kg
Butafenacil	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000375	Eurofins Sample:	9618759
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000375	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Butocarboxim	<0.02 mg/kg
Butocarboxim sulfoxide	<0.01 mg/kg
Butoxycarboxim	<0.01 mg/kg
Butylate	<0.01 mg/kg
Cadusafos	<0.01 mg/kg
Captan (as THPI)	<0.01 mg/kg
Carbaryl	<0.01 mg/kg
Carbendazim	<0.01 mg/kg
Carbetamide	<0.01 mg/kg
Carbofuran	<0.01 mg/kg
Carbofuran-3-hydroxy-	<0.01 mg/kg
Carbophenothion	<0.01 mg/kg
Carboxin	<0.01 mg/kg
Carfentrazone-ethyl	<0.01 mg/kg
Chlorantraniliprole	<0.01 mg/kg
Chlorbromuron	<0.01 mg/kg
Chlordane, cis-	<0.01 mg/kg
Chlordane, trans-	<0.01 mg/kg
Chlordimeform	<0.01 mg/kg
Chlorfenapyr	<0.02 mg/kg
Chlorfenvinphos (E- and Z-isomers)	<0.01 mg/kg
Chlorfluazuron	<0.01 mg/kg
Chloridazon (Pyrazon)	<0.01 mg/kg
Chlorimuron-ethyl (Classic)	<0.01 mg/kg
Chlorobenzilate	<0.01 mg/kg
Chlorotoluron (Chlortoluron)	<0.01 mg/kg
Chloroxuron	<0.01 mg/kg
Chlorpropham (CIPC)	<0.01 mg/kg
Chlorpyrifos	<0.01 mg/kg
Chlorpyrifos-methyl	<0.01 mg/kg
Chlorsulfuron	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000375**	**Eurofins Sample:**	**9618759**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000375	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Clethodim (E- and Z-isomers)	<0.01 mg/kg
Clodinafop-propargyl	<0.01 mg/kg
Clofentezine	<0.01 mg/kg
Clomazone	<0.01 mg/kg
Cloquintocet-mexyl	<0.01 mg/kg
Clothianidin	<0.01 mg/kg
Coumaphos	<0.01 mg/kg
Cyanazine	<0.01 mg/kg
Cyanofenphos	<0.01 mg/kg
Cyazofamid	<0.01 mg/kg
Cycloate	<0.01 mg/kg
Cycloxydim	<0.01 mg/kg
Cycluron	<0.01 mg/kg
Cyflufenamid	<0.01 mg/kg
Cyfluthrin	<0.01 mg/kg
Cyhalothrin, lambda-	<0.01 mg/kg
Cymiazole	<0.01 mg/kg
Cymoxanil	<0.01 mg/kg
Cypermethrin	<0.01 mg/kg
Cyproconazole (2 diastereoisomers)	<0.01 mg/kg
Cyprodinil	<0.01 mg/kg
Cyromazine	<0.01 mg/kg
Dacthal (Chlorthal-dimethyl, DCPA)	<0.01 mg/kg
DDD, o,p'-	<0.01 mg/kg
DDD, p,p'-	<0.01 mg/kg
DDE, o,p'-	<0.01 mg/kg
DDE, p,p'-	<0.01 mg/kg
DDT, o,p'-	<0.01 mg/kg
DDT, p,p'-	<0.01 mg/kg
DEET (Diethyltoluamide)	<0.01 mg/kg
Deltamethrin	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000375**	**Eurofins Sample:**	**9618759**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000375	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Demeton-O	<0.01 mg/kg
Demeton-S	<0.01 mg/kg
Demeton-S-methyl	<0.01 mg/kg
Demeton-S-methyl sulfone	<0.01 mg/kg
Desmedipham	<0.01 mg/kg
Dialifos (Dialifor)	<0.01 mg/kg
Diazinon	<0.01 mg/kg
Diazinon oxon	<0.01 mg/kg
Dichlobenil	<0.01 mg/kg
Dichlofenthion	<0.01 mg/kg
Dichlofluanid	<0.01 mg/kg
Dichlorvos	<0.01 mg/kg
Diclobutrazol	<0.01 mg/kg
Diclocymet (2 diastereoisomers)	<0.01 mg/kg
Dicloran (DCNA)	<0.01 mg/kg
Dicofol	<0.01 mg/kg
Dicrotophos	<0.01 mg/kg
Dieldrin	<0.01 mg/kg
Diethofencarb	<0.01 mg/kg
Difenoconazole (cis- and trans-)	<0.01 mg/kg
Diflubenzuron	<0.01 mg/kg
Diflufenican	<0.01 mg/kg
Dimethachlor	<0.01 mg/kg
Dimethametryn	<0.01 mg/kg
Dimethenamid	<0.01 mg/kg
Dimethoate	<0.01 mg/kg
Dimethomorph (E- and Z-isomers)	<0.01 mg/kg
Dimetilan	<0.01 mg/kg
Dimoxystrobin	<0.01 mg/kg
Diniconazole	<0.01 mg/kg
Dinitramine	<0.02 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000375	Eurofins Sample:	9618759
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000375	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Dinotefuran	<0.01 mg/kg
Dioxacarb	<0.01 mg/kg
Diphenamid	<0.01 mg/kg
Diphenylamine	<0.01 mg/kg
Dipropetryn	<0.01 mg/kg
Disulfoton	<0.01 mg/kg
Disulfoton sulfone	<0.01 mg/kg
Disulfoton sulfoxide	<0.01 mg/kg
Diuron	<0.01 mg/kg
DMST (Dimethylaminosulfotoluidide)	<0.01 mg/kg
Dodemorph (cis- and trans-)	<0.01 mg/kg
Dodine	<0.01 mg/kg
Doramectin	<0.05 mg/kg
Emamectin benzoate	<0.01 mg/kg
Endosulfan I (alpha-isomer)	<0.02 mg/kg
Endosulfan II (beta-isomer)	<0.02 mg/kg
Endosulfan sulfate	<0.02 mg/kg
Endrin	<0.01 mg/kg
EPN	<0.01 mg/kg
Epoxiconazole	<0.01 mg/kg
Eprinomectin	<0.02 mg/kg
Ethaboxam	<0.01 mg/kg
Ethalfluralin	<0.01 mg/kg
Ethidimuron (Sulfadiazole)	<0.01 mg/kg
Ethiofencarb	<0.01 mg/kg
Ethiofencarb sulfone	<0.01 mg/kg
Ethiofencarb sulfoxide	<0.01 mg/kg
Ethion	<0.01 mg/kg
Ethiprole	<0.01 mg/kg
Ethirimol	<0.01 mg/kg
Ethofumesate	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000375	Eurofins Sample:	9618759
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000375	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Ethoprophos (Ethoprop)	<0.01 mg/kg
Etofenprox	<0.01 mg/kg
Etoxazole	<0.01 mg/kg
Etrimfos	<0.01 mg/kg
Famoxadone	<0.01 mg/kg
Fenamidone	<0.01 mg/kg
Fenamiphos	<0.01 mg/kg
Fenamiphos sulfone	<0.01 mg/kg
Fenamiphos sulfoxide	<0.01 mg/kg
Fenarimol	<0.01 mg/kg
Fenazaquin	<0.01 mg/kg
Fenbuconazole	<0.01 mg/kg
Fenbutatin oxide	<0.01 mg/kg
Fenchlorphos (Ronnel)	<0.01 mg/kg
Fenchlorphos oxon	<0.01 mg/kg
Fenhexamid	<0.01 mg/kg
Fenitrothion	<0.01 mg/kg
Fenobucarb	<0.01 mg/kg
Fenoxanil (sum of isomers)	<0.01 mg/kg
Fenoxycarb	<0.01 mg/kg
Fenpropathrin	<0.01 mg/kg
Fenpropidin	<0.01 mg/kg
Fenpropimorph	<0.01 mg/kg
Fenpyroximate	<0.01 mg/kg
Fensulfothion	<0.01 mg/kg
Fensulfothion oxon	<0.01 mg/kg
Fensulfothion oxon sulfone	<0.01 mg/kg
Fensulfothion sulfone	<0.01 mg/kg
Fenthion	<0.01 mg/kg
Fenthion oxon	<0.01 mg/kg
Fenthion oxon sulfone	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

eurofins | Food Integrity & Innovation

Report Number:	**2928004-0**
Report Date:	**09-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927587-0**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000375**	**Eurofins Sample:**	**9618759**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000375	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Fenthion oxon sulfoxide	<0.01 mg/kg
Fenthion sulfone	<0.01 mg/kg
Fenthion sulfoxide	<0.01 mg/kg
Fentin	<0.01 mg/kg
Fentrazamide	<0.01 mg/kg
Fenuron	<0.01 mg/kg
Fenvalerate/Esfenvalerate (sum of isomers)	<0.02 mg/kg
Fipronil	<0.01 mg/kg
Fipronil desulfinyl	<0.01 mg/kg
Fipronil sulfone	<0.01 mg/kg
Flazasulfuron	<0.01 mg/kg
Flonicamid	<0.01 mg/kg
Fluazifop-butyl	<0.01 mg/kg
Flubendiamide	<0.05 mg/kg
Flucarbazone-sodium	<0.02 mg/kg
Flucythrinate (sum of isomers)	<0.01 mg/kg
Fludioxonil	<0.01 mg/kg
Flufenacet	<0.01 mg/kg
Flufenoxuron	<0.01 mg/kg
Flumethrin	<0.05 mg/kg
Flumetsulam	<0.01 mg/kg
Flumioxazin	<0.01 mg/kg
Fluometuron	<0.01 mg/kg
Fluopicolide	<0.01 mg/kg
Fluopyram	<0.01 mg/kg
Fluoxastrobin	<0.01 mg/kg
Fluquinconazole	<0.01 mg/kg
Fluridone	<0.01 mg/kg
Flusilazole	<0.01 mg/kg
Flutolanil	<0.01 mg/kg
Flutriafol	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000375	Eurofins Sample:	9618759
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000375	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Fonofos	<0.01 mg/kg
Foramsulfuron	<0.01 mg/kg
Forchlorfenuron	<0.01 mg/kg
Formetanate hydrochloride	<0.01 mg/kg
Formothion	<0.01 mg/kg
Fosthiazate (sum of isomers)	<0.01 mg/kg
Fuberidazole	<0.01 mg/kg
Furalaxyl	<0.01 mg/kg
Furathiocarb	<0.01 mg/kg
Griseofulvin	<0.01 mg/kg
Halofenozide	<0.01 mg/kg
Halosulfuron-methyl	<0.01 mg/kg
Haloxyfop-methyl	<0.01 mg/kg
HCH, alpha- (alpha-BHC)	<0.01 mg/kg
HCH, beta- (beta-BHC)	<0.01 mg/kg
HCH, delta- (delta-BHC)	<0.01 mg/kg
Heptachlor	<0.01 mg/kg
Heptachlor endo-epoxide	<0.02 mg/kg
Heptachlor exo-epoxide	<0.01 mg/kg
Hexachlorobenzene (HCB)	<0.01 mg/kg
Hexaconazole	<0.01 mg/kg
Hexaflumuron	<0.01 mg/kg
Hexazinone	<0.01 mg/kg
Hexythiazox	<0.01 mg/kg
Hydramethylnon	<0.01 mg/kg
Hydroprene, S- (sum of isomers)	<0.01 mg/kg
Imazalil	<0.01 mg/kg
Imazamethabenz-methyl	<0.01 mg/kg
Imazethapyr	<0.01 mg/kg
Imidacloprid	<0.01 mg/kg
Indoxacarb	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000375**	**Eurofins Sample:**	**9618759**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000375	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Ipconazole	<0.01 mg/kg
Iprodione	<0.01 mg/kg
Iprodione isomer	<0.02 mg/kg
Iprodione metabolite	<0.01 mg/kg
Iprovalicarb	<0.01 mg/kg
Isocarbamid	<0.01 mg/kg
Isocarbophos	<0.01 mg/kg
Isofenphos	<0.01 mg/kg
Isofenphos-methyl	<0.01 mg/kg
Isoprocarb	<0.01 mg/kg
Isoprothiolane	<0.01 mg/kg
Isoproturon	<0.01 mg/kg
Isoxaben	<0.01 mg/kg
Isoxadifen-ethyl	<0.01 mg/kg
Isoxaflutole	<0.01 mg/kg
Isoxathion	<0.01 mg/kg
Ivermectin	<0.05 mg/kg
Kresoxim-methyl	<0.01 mg/kg
Lactofen	<0.01 mg/kg
Lenacil	<0.01 mg/kg
Lindane (gamma-HCH, gamma-BHC)	<0.01 mg/kg
Linuron	<0.01 mg/kg
Lufenuron	<0.01 mg/kg
Malaoxon	<0.01 mg/kg
Malathion	<0.01 mg/kg
Mandipropamid	<0.01 mg/kg
Mecarbam	<0.01 mg/kg
Mepanipyrim	<0.01 mg/kg
Mepanipyrim-2-hydroxypropyl	<0.01 mg/kg
Mephosfolan	<0.01 mg/kg
Mesosulfuron-methyl	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000375	Eurofins Sample:	9618759
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000375	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Metaflumizone	<0.01 mg/kg
Metalaxyl	<0.01 mg/kg
Metamitron	<0.01 mg/kg
Metazachlor	<0.01 mg/kg
Metconazole	<0.01 mg/kg
Methabenzthiazuron	<0.01 mg/kg
Methacrifos	<0.01 mg/kg
Methamidophos	<0.01 mg/kg
Methidathion	<0.01 mg/kg
Methiocarb	<0.01 mg/kg
Methiocarb sulfone	<0.01 mg/kg
Methiocarb sulfoxide	<0.01 mg/kg
Methomyl	<0.01 mg/kg
Methoprotryne	<0.01 mg/kg
Methoxychlor	<0.01 mg/kg
Methoxyfenozide	<0.01 mg/kg
Metobromuron	<0.01 mg/kg
Metolachlor	<0.01 mg/kg
Metolcarb	<0.01 mg/kg
Metosulam	<0.01 mg/kg
Metoxuron	<0.01 mg/kg
Metrafenone	<0.01 mg/kg
Metribuzin	<0.01 mg/kg
Metsulfuron-methyl	<0.01 mg/kg
Mevinphos (E- and Z-isomers)	<0.01 mg/kg
Mexacarbate	<0.01 mg/kg
MGK 264 (sum of isomers)	<0.01 mg/kg
Mirex	<0.01 mg/kg
Molinate	<0.01 mg/kg
Monocrotophos	<0.01 mg/kg
Monolinuron	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

eurofins Food Integrity & Innovation

Report Number:	**2928004-0**
Report Date:	**09-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927587-0**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000375**	**Eurofins Sample:**	**9618759**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000375	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Moxidectin	<0.05 mg/kg
Myclobutanil	<0.01 mg/kg
Naled (Dibrom)	<0.01 mg/kg
Naphthol, 1-	<0.02 mg/kg
Napropamide	<0.01 mg/kg
Neburon	<0.01 mg/kg
Nicosulfuron	<0.01 mg/kg
Nitenpyram	<0.01 mg/kg
Nitralin	<0.01 mg/kg
Nitrofen	<0.01 mg/kg
Nonachlor, cis-	<0.01 mg/kg
Nonachlor, trans-	<0.01 mg/kg
Norflurazon	<0.01 mg/kg
Norflurazon-desmethyl	<0.01 mg/kg
Novaluron	<0.01 mg/kg
Nuarimol	<0.01 mg/kg
Ofurace	<0.01 mg/kg
Omethoate	<0.01 mg/kg
Oxadiazon	<0.01 mg/kg
Oxadixyl	<0.01 mg/kg
Oxamyl	<0.01 mg/kg
Oxamyl oxime	<0.01 mg/kg
Oxasulfuron	<0.01 mg/kg
Oxycarboxin	<0.01 mg/kg
Oxychlordane	<0.02 mg/kg
Oxydemeton-methyl	<0.01 mg/kg
Oxyfluorfen	<0.01 mg/kg
Paclobutrazol	<0.01 mg/kg
Paraoxon	<0.01 mg/kg
Paraoxon-methyl	<0.01 mg/kg
Parathion	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000375**	**Eurofins Sample:**	**9618759**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000375	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Parathion-methyl	<0.01 mg/kg
Penconazole	<0.01 mg/kg
Pencycuron	<0.01 mg/kg
Pendimethalin	<0.01 mg/kg
Penoxsulam	<0.01 mg/kg
Pentachloroaniline	<0.01 mg/kg
Pentachloroanisole	<0.01 mg/kg
Pentachlorobenzene	<0.01 mg/kg
Pentachlorobenzonitrile	<0.01 mg/kg
Pentachlorothioanisole	<0.01 mg/kg
Permethrin (sum of isomers)	<0.01 mg/kg
Perthane (Ethylan)	<0.01 mg/kg
Phenmedipham	<0.01 mg/kg
Phenthoate	<0.01 mg/kg
Phenylphenol, 2- (OPP)	<0.02 mg/kg
Phorate	<0.01 mg/kg
Phorate sulfone	<0.01 mg/kg
Phorate sulfoxide	<0.01 mg/kg
Phosalone	<0.01 mg/kg
Phosmet	<0.01 mg/kg
Phosmet oxon	<0.01 mg/kg
Phosphamidon (E- and Z-isomers)	<0.01 mg/kg
Phoxim	<0.01 mg/kg
Picolinafen	<0.01 mg/kg
Picoxystrobin	<0.01 mg/kg
Piperonyl butoxide	<0.01 mg/kg
Piperophos	<0.01 mg/kg
Pirimicarb	<0.01 mg/kg
Pirimicarb-desmethyl	<0.01 mg/kg
Pirimiphos-ethyl	<0.01 mg/kg
Pirimiphos-methyl	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

eurofins Food Integrity & Innovation

Report Number:	**2928004-0**
Report Date:	**09-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927587-0**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000375**	**Eurofins Sample:**	**9618759**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000375	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Pirimiphos-methyl, N-desethyl-	<0.01 mg/kg
Prallethrin	<0.01 mg/kg
Pretilachlor	<0.01 mg/kg
Primisulfuron-methyl	<0.01 mg/kg
Prochloraz	<0.01 mg/kg
Procymidone	<0.01 mg/kg
Prodiamine	<0.01 mg/kg
Profenofos	<0.01 mg/kg
Profluralin	<0.01 mg/kg
Promecarb	<0.01 mg/kg
Prometon	<0.01 mg/kg
Prometryn	<0.01 mg/kg
Propamocarb	<0.01 mg/kg
Propanil	<0.01 mg/kg
Propaquizafop	<0.01 mg/kg
Propetamphos	<0.01 mg/kg
Propham	<0.01 mg/kg
Propiconazole (sum of isomers)	<0.01 mg/kg
Propoxur	<0.01 mg/kg
Propyzamide (Pronamide)	<0.01 mg/kg
Proquinazid	<0.01 mg/kg
Prosulfocarb	<0.01 mg/kg
Prothioconazole-desthio	<0.01 mg/kg
Prothiofos	<0.01 mg/kg
Pymetrozine	<0.01 mg/kg
Pyracarbolid	<0.01 mg/kg
Pyraclostrobin	<0.01 mg/kg
Pyraflufen-ethyl	<0.01 mg/kg
Pyrazophos	<0.01 mg/kg
Pyrethrum (total)	<0.10 mg/kg
Pyridaben	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000375**	**Eurofins Sample:**	**9618759**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000375	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Pyridalyl	<0.01 mg/kg
Pyridaphenthion	<0.01 mg/kg
Pyridate	<0.01 mg/kg
Pyrifenox (E- and Z-isomers)	<0.01 mg/kg
Pyrimethanil	<0.01 mg/kg
Pyriproxyfen	<0.01 mg/kg
Pyroquilon	<0.01 mg/kg
Pyroxsulam	<0.01 mg/kg
Quinalphos	<0.01 mg/kg
Quinmerac	<0.01 mg/kg
Quinoclamine	<0.01 mg/kg
Quinoxyfen	<0.01 mg/kg
Quintozene	<0.01 mg/kg
Quizalofop	<0.02 mg/kg
Quizalofop-ethyl	<0.01 mg/kg
Resmethrin (sum of isomers)	<0.01 mg/kg
Rimsulfuron	<0.01 mg/kg
Rotenone	<0.01 mg/kg
S421	<0.01 mg/kg
Schradan (Octamethylpyrophosphoramide)	<0.01 mg/kg
Secbumeton	<0.01 mg/kg
Sethoxydim (E- and Z-isomers)	<0.01 mg/kg
Siduron	<0.01 mg/kg
Silthiofam	<0.01 mg/kg
Simazine	<0.01 mg/kg
Simeconazole	<0.02 mg/kg
Simetryn	<0.01 mg/kg
Spinetoram (spinosyns J and L)	<0.01 mg/kg
Spinosad (spinosyns A and D)	<0.01 mg/kg
Spirodiclofen	<0.01 mg/kg
Spiromesifen	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000375	Eurofins Sample:	9618759
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000375	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Spiromesifen enol	<0.01 mg/kg
Spirotetramat	<0.01 mg/kg
Spiroxamine (2 diastereoisomers)	<0.01 mg/kg
Sulfallate	<0.01 mg/kg
Sulfentrazone	<0.01 mg/kg
Sulprofos	<0.01 mg/kg
Tebuconazole	<0.01 mg/kg
Tebufenozide	<0.01 mg/kg
Tebufenpyrad	<0.01 mg/kg
Tebupirimfos	<0.01 mg/kg
Tebuthiuron	<0.01 mg/kg
Tecnazene	<0.01 mg/kg
Teflubenzuron	<0.01 mg/kg
Tefluthrin	<0.01 mg/kg
Temephos	<0.01 mg/kg
Tepraloxydim (E- and Z-isomers)	<0.01 mg/kg
Terbacil	<0.01 mg/kg
Terbufos	<0.01 mg/kg
Terbufos sulfone	<0.01 mg/kg
Terbufos sulfoxide	<0.01 mg/kg
Terbumeton	<0.01 mg/kg
Terbuthylazine	<0.01 mg/kg
Terbutryn	<0.01 mg/kg
Tetrachloroaniline, 2,3,5,6-	<0.01 mg/kg
Tetrachloroanisole, 2,3,4,5-	<0.01 mg/kg
Tetrachlorvinphos	<0.01 mg/kg
Tetraconazole	<0.01 mg/kg
Tetradifon	<0.01 mg/kg
Tetramethrin (sum of isomers)	<0.01 mg/kg
Thiabendazole	<0.01 mg/kg
Thiabendazole-5-hydroxy-	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000375	Eurofins Sample:	9618759
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000375	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Thiacloprid	<0.01 mg/kg
Thiamethoxam	<0.01 mg/kg
Thiazopyr	<0.01 mg/kg
Thidiazuron	<0.01 mg/kg
Thifensulfuron-methyl	<0.01 mg/kg
Thiobencarb (Benthiocarb)	<0.01 mg/kg
Thiodicarb	<0.01 mg/kg
Thiofanox	<0.05 mg/kg
Thiofanox sulfone	<0.01 mg/kg
Thiofanox sulfoxide	<0.01 mg/kg
Thionazin (Zinophos)	<0.01 mg/kg
Thiophanate-methyl	<0.01 mg/kg
Tolclofos-methyl	<0.01 mg/kg
Tolfenpyrad	<0.01 mg/kg
Tolylfluanid	<0.01 mg/kg
Tralkoxydim	<0.01 mg/kg
Triadimefon	<0.01 mg/kg
Triadimenol	<0.01 mg/kg
Triasulfuron	<0.01 mg/kg
Triazophos	<0.01 mg/kg
Tribenuron-methyl	<0.01 mg/kg
Tribufos (DEF)	<0.01 mg/kg
Trichlorfon (Metrifonate)	<0.01 mg/kg
Trichloroanisole, 2,4,6-	<0.01 mg/kg
Tricyclazole	<0.01 mg/kg
Trietazine	<0.01 mg/kg
Trifloxystrobin	<0.01 mg/kg
Trifloxysulfuron	<0.01 mg/kg
Triflumizole	<0.01 mg/kg
Triflumuron	<0.01 mg/kg
Trifluralin	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

eurofins | Food Integrity & Innovation

Report Number:	**2928004-0**
Report Date:	**09-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927587-0**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000375**	**Eurofins Sample:**	**9618759**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000375	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Triforine	<0.01 mg/kg
Trimethacarb	<0.01 mg/kg
Triticonazole	<0.01 mg/kg
Uniconazole	<0.01 mg/kg
Vamidothion	<0.01 mg/kg
Vinclozolin	<0.01 mg/kg
Zoxamide	<0.01 mg/kg
Polycyclic Aromatic Hydrocarbons-Low Level	
Benz(a)anthracene	<0.250 ppb
Benzo(a)pyrene	<0.250 ppb
Benzo(b)fluoranthene	0.456 ppb
Benzo(g,h,i)perylene	<0.250 ppb
Benzo(k)fluoranthene	<0.250 ppb
Chrysene	0.519 ppb
Dibenz(a,h)anthracene	<0.250 ppb
Indeno(1,2,3-c,d)pyrene	<0.250 ppb
Pyrene	1.10 ppb

Analysis	Limit	Result	Pass/Fail
Mycotoxins in Raw Materials			
Aflatoxin B1		<0.300 ppb	
Aflatoxin B2		<0.300 ppb	
Aflatoxin G1		<0.300 ppb	
Aflatoxin G2		<0.300 ppb	
Aflatoxin M1		<0.300 ppb	
Aflatoxin M2		<0.300 ppb	
Deoxynivalenol		<56.0 ppb	
T-2 Toxin		<5.60 ppb	
HT-2 Toxin		<56.0 ppb	
Fumonisin B1		<14.3 ppb	

*** This analysis or component is not ISO accredited.**

eurofins

Food Integrity
& Innovation

Report Number:	**2928004-0**
Report Date:	**09-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927587-0**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 2000375**	**Eurofins Sample:**	**9618759**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	2000375	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	**Limit**	**Result**	**Pass/Fail**
Mycotoxins in Raw Materials			
Fumonisin B2		<14.0 ppb	
Ochratoxin A		<1.00 ppb	
Zearalenone		<16.7 ppb	

Analysis	**LOQ**	**Limit**	**Result**	**Pass/Fail**
Residual Solvents - Class 1, 2a and 2b				
1,1,1-Trichloroethane	10 ppm	10 ppm	<10 ppm	Pass
1,1-Dichloroethene	8 ppm	8 ppm	<8 ppm	Pass
1,2-Dichloroethane	5 ppm	5 ppm	<5 ppm	Pass
Benzene	2 ppm	2 ppm	<2 ppm	Pass
Carbon Tetrachloride	4 ppm	4 ppm	<4 ppm	Pass
1,2-Dimethoxyethane	100 ppm	100 ppm	<100 ppm	Pass
1,4-Dioxane	380 ppm	380 ppm	<380 ppm	Pass
Acetonitrile	410 ppm	410 ppm	<410 ppm	Pass
Chlorobenzene	360 ppm	360 ppm	<360 ppm	Pass
Chloroform	60 ppm	60 ppm	<60 ppm	Pass
1,2-Dichloroethene	1870 ppm	1870 ppm	<1870 ppm	Pass
Cumene	70 ppm	70 ppm	<70.0 ppm	Pass
Cyclohexane	3880 ppm	3880 ppm	<3880 ppm	Pass
Methanol	3000 ppm	3000 ppm	<3000 ppm	Pass
Methylbutylketone	50 ppm	50 ppm	<50 ppm	Pass
Methylcyclohexane	1180 ppm	1180 ppm	<1180 ppm	Pass
Methylene Chloride	600 ppm	600 ppm	<600 ppm	Pass
n-Hexane	290 ppm	290 ppm	<290 ppm	Pass
Nitromethane	50 ppm	50 ppm	<50 ppm	Pass
Pyridine	200 ppm	200 ppm	<200 ppm	Pass
Tetrahydrofuran	720 ppm	720 ppm	<720 ppm	Pass
Tetralin	96 ppm	96 ppm	<96.0 ppm	Pass

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 2000375	Eurofins Sample:	9618759
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	2000375	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	LOQ	Limit	Result	Pass/Fail
Residual Solvents - Class 1, 2a and 2b				
Toluene	890 ppm	890 ppm	<890 ppm	Pass
Trichloroethylene	80 ppm	80 ppm	<80 ppm	Pass
Xylenes(O,M,P + EB)	2170 ppm	2170 ppm	<2170 ppm	Pass

Method References	Testing Location
Dioxin/Furans (DIOXIN_S)	**Eurofins Lancaster Laboratories Environmental LLC** 2425 New Holland Pike Lancaster, Pennsylvania 17601-443 USA
Dioxin-like PCBs (PCB_S)	**Eurofins Lancaster Laboratories Environmental LLC** 2425 New Holland Pike Lancaster, Pennsylvania 17601-443 USA
Elements by ICP Mass Spectrometry (ICP_MS_S)	**Food Integrity Innovation-Madison** 3301 Kinsman Blvd Madison, WI 53704 USA

Official Methods of Analysis, Method 2011.19 and 993.14, AOAC INTERNATIONAL, (Modified).
Paquette, L.H., Szabo, A., Thompson, J.J., "Simultaneous Determination of Chromium, Selenium, and Molybdenum in Nutritional Products by Inductively Coupled Plasma/Mass Spectrometry: Single-Laboratory Validation," Journal of AOAC International, 94(4): 1240 - 1252 (2011).

Multi-Residue Analysis (500+ Compounds) (PS05_S) — **Food Integrity Innovation-Madison** 3301 Kinsman Blvd Madison, WI 53704 USA

Official Methods of Analysis, AOAC Official Method 2007.01, Pesticide Residues in Foods by Acetonitrile Extraction and Partitioning with Magnesium Sulfate, AOAC INTERNATIONAL (modified).

CEN Standard Method EN 15662: Food of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE - QuEChERS method.

List of the tested pesticides and their limits of quantification (LOQs) are available upon request.

* This analysis or component is not ISO accredited.

eurofins | Food Integrity & Innovation

Report Number:	**2928004-0**
Report Date:	**09-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927587-0**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Method References	**Testing Location**

Mycotoxins in Raw Materials (MYCO_REG_S) — **Food Integrity Innovation-Madison**
3301 Kinsman Blvd Madison, WI 53704 USA

Varga, E., Glauner, T., Koppen, R., Mayer, K., Sulyok, M., Schumacher, R., Krska, R. and Berthiller, F., "Stable isotope dilution assay for the accurate determination of mycotoxins in maize by UHPLC-MS/MS," Analytical and BioAnalytical Chemistry, 402:2675-2686 (2012).

Polycyclic Aromatic Hydrocarbons-Low Level (LLPAH_S) — **Food Integrity Innovation-Madison**
3301 Kinsman Blvd Madison, WI 53704 USA

Internally Developed Method

Residual Solvents - Class 1, 2a and 2b (USPR_S) — **Food Integrity Innovation-Madison**
3301 Kinsman Blvd Madison, WI 53704 USA

United States Pharmacopeia, 38nd Rev. - National Formulary 33th Ed., Method <467>, USP Convention, Inc., Rockville, MD (2015). (Modified).

Testing Location(s)	**Released on Behalf of Eurofins by**

Food Integrity Innovation-Madison

Eurofins Food Chemistry Testing Madison, Inc.
3301 Kinsman Blvd
Madison WI 53704
800-675-8375

Edward Ladwig - Director

ilac-MRA A2LA ACCREDITED
2918.01

*** This analysis or component is not ISO accredited.**

KOSTER KEUNEN, INC
WATERTOWN, CONNECTICUT 06795

TEL# (860) 945-3333
FAX# (860) 945-0330

DATE: July 14, 2020

CERTIFICATE OF ANALYSIS

CUSTOMER	ORDER NUMBER	ITEM NUMBER	BATCH NUMBER
			1902183

PRODUCT: RICE BRAN WAX
WAX# 224P

LABORATORY TESTS & METHODS	KOSTER KEUNEN, INC SPECIFICATIONS	ACTUAL RESULTS
MELTING POINT <USP 741, Class II>	77 - 82°C	81.0°C
ACID VALUE <USP 401>	≤ 13 mg KOH/g	1.5
SAPONIFICATION VALUE <USP 401 >	75 - 120 mg KOH/g	80.0
IODINE VALUE <USP 401>	≤ 20.0 g/100g	Passes
COLOR <Visual>	Yellow to Light Brown	Passes
DATE OF MANUFACTURE		November 21, 2019
RECOMMENDED RETEST DATE		November 21, 2021

SUBMITTED BY:____________________

eurofins | Food Integrity & Innovation

Report Number:	**2929308-0**
Report Date:	**10-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927045-0**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 1902183**	**Eurofins Sample:**	**9618761**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	1902183	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Dioxin-like PCBs *	
PCB - Total Equivalence	0.024 ng/kg
Elements by ICP Mass Spectrometry	
Arsenic	<10.0 ppb
Cadmium	<5.00 ppb
Lead	<5.00 ppb
Mercury	<5.00 ppb
Dioxin/Furans *	
Dioxin - Total Equivalence	0.78 ng/kg
Multi-Residue Analysis (500+ Compounds)	
Matrix Type - To Determine Limit of Quantification (LOQ)	Spices - Botanicals - and other Specialty Samples
Fluvalinate tau- (sum of isomers)	0.014 mg/kg
Abamectin	<0.05 mg/kg
Acephate	<0.01 mg/kg
Acetamiprid	<0.01 mg/kg
Acetochlor	<0.01 mg/kg
Acibenzolar-S-methyl	<0.01 mg/kg
Aclonifen	<0.01 mg/kg
Acrinathrin	<0.01 mg/kg
Alachlor	<0.01 mg/kg
Aldicarb	<0.01 mg/kg
Aldicarb sulfone (Aldoxycarb)	<0.01 mg/kg
Aldicarb sulfoxide	<0.01 mg/kg
Aldrin	<0.01 mg/kg
Allethrin	<0.01 mg/kg
Ametryn	<0.01 mg/kg
Amidosulfuron	<0.01 mg/kg
Aminocarb	<0.01 mg/kg
Amitraz metabolite DMF	<0.01 mg/kg
Amitraz metabolite DMPF	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 1902183	Eurofins Sample:	9618761
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	1902183	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Anilofos	<0.01 mg/kg
Atrazine	<0.01 mg/kg
Azaconazole	<0.01 mg/kg
Azamethiphos	<0.01 mg/kg
Azinphos-ethyl	<0.01 mg/kg
Azinphos-methyl	<0.01 mg/kg
Azoxystrobin	<0.01 mg/kg
Beflubutamid	<0.01 mg/kg
Benalaxyl	<0.01 mg/kg
Bendiocarb	<0.01 mg/kg
Benfluralin	<0.01 mg/kg
Benoxacor	<0.01 mg/kg
Bensulide	<0.01 mg/kg
Benzoximate	<0.01 mg/kg
Bifenazate	<0.01 mg/kg
Bifenox	<0.01 mg/kg
Bifenthrin	<0.01 mg/kg
Bispyribac	<0.01 mg/kg
Bitertanol	<0.01 mg/kg
Bixafen	<0.01 mg/kg
Boscalid	<0.01 mg/kg
Bromacil	<0.01 mg/kg
Bromophos-ethyl	<0.01 mg/kg
Bromophos-methyl	<0.01 mg/kg
Bromopropylate	<0.01 mg/kg
Bromuconazole (2 diastereoisomers)	<0.01 mg/kg
Bupirimate	<0.01 mg/kg
Buprofezin	<0.01 mg/kg
Butachlor	<0.01 mg/kg
Butafenacil	<0.01 mg/kg
Butocarboxim	<0.02 mg/kg

* This analysis or component is not ISO accredited.

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 1902183	Eurofins Sample:	9618761
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	1902183	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Butocarboxim sulfoxide	<0.01 mg/kg
Butoxycarboxim	<0.01 mg/kg
Butylate	<0.01 mg/kg
Cadusafos	<0.01 mg/kg
Captan (as THPI)	<0.01 mg/kg
Carbaryl	<0.01 mg/kg
Carbendazim	<0.01 mg/kg
Carbetamide	<0.01 mg/kg
Carbofuran	<0.01 mg/kg
Carbofuran-3-hydroxy-	<0.01 mg/kg
Carbophenothion	<0.01 mg/kg
Carboxin	<0.01 mg/kg
Carfentrazone-ethyl	<0.01 mg/kg
Chlorantraniliprole	<0.01 mg/kg
Chlorbromuron	<0.01 mg/kg
Chlordane, cis-	<0.01 mg/kg
Chlordane, trans-	<0.01 mg/kg
Chlordimeform	<0.01 mg/kg
Chlorfenapyr	<0.02 mg/kg
Chlorfenvinphos (E- and Z-isomers)	<0.01 mg/kg
Chlorfluazuron	<0.01 mg/kg
Chloridazon (Pyrazon)	<0.01 mg/kg
Chlorimuron-ethyl (Classic)	<0.01 mg/kg
Chlorobenzilate	<0.01 mg/kg
Chlorotoluron (Chlortoluron)	<0.01 mg/kg
Chloroxuron	<0.01 mg/kg
Chlorpropham (CIPC)	<0.01 mg/kg
Chlorpyrifos	<0.01 mg/kg
Chlorpyrifos-methyl	<0.01 mg/kg
Chlorsulfuron	<0.01 mg/kg
Clethodim (E- and Z-isomers)	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 1902183	Eurofins Sample:	9618761
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	1902183	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Clodinafop-propargyl	<0.01 mg/kg
Clofentezine	<0.01 mg/kg
Clomazone	<0.01 mg/kg
Cloquintocet-mexyl	<0.01 mg/kg
Clothianidin	<0.01 mg/kg
Coumaphos	<0.01 mg/kg
Cyanazine	<0.01 mg/kg
Cyanofenphos	<0.01 mg/kg
Cyazofamid	<0.01 mg/kg
Cycloate	<0.01 mg/kg
Cycloxydim	<0.01 mg/kg
Cycluron	<0.01 mg/kg
Cyflufenamid	<0.01 mg/kg
Cyfluthrin	<0.01 mg/kg
Cyhalothrin, lambda-	<0.01 mg/kg
Cymiazole	<0.01 mg/kg
Cymoxanil	<0.01 mg/kg
Cypermethrin	<0.01 mg/kg
Cyproconazole (2 diastereoisomers)	<0.01 mg/kg
Cyprodinil	<0.01 mg/kg
Cyromazine	<0.01 mg/kg
Dacthal (Chlorthal-dimethyl, DCPA)	<0.01 mg/kg
DDD, o,p'-	<0.01 mg/kg
DDD, p,p'-	<0.01 mg/kg
DDE, o,p'-	<0.01 mg/kg
DDE, p,p'-	<0.01 mg/kg
DDT, o,p'-	<0.01 mg/kg
DDT, p,p'-	<0.01 mg/kg
DEET (Diethyltoluamide)	<0.01 mg/kg
Deltamethrin	<0.01 mg/kg
Demeton-O	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 1902183**	**Eurofins Sample:**	**9618761**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	1902183	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Demeton-S	<0.01 mg/kg
Demeton-S-methyl	<0.01 mg/kg
Demeton-S-methyl sulfone	<0.01 mg/kg
Desmedipham	<0.01 mg/kg
Dialifos (Dialifor)	<0.01 mg/kg
Diazinon	<0.01 mg/kg
Diazinon oxon	<0.01 mg/kg
Dichlobenil	<0.01 mg/kg
Dichlofenthion	<0.01 mg/kg
Dichlofluanid	<0.01 mg/kg
Dichlorvos	<0.01 mg/kg
Diclobutrazol	<0.01 mg/kg
Diclocymet (2 diastereoisomers)	<0.01 mg/kg
Dicloran (DCNA)	<0.01 mg/kg
Dicofol	<0.01 mg/kg
Dicrotophos	<0.01 mg/kg
Dieldrin	<0.01 mg/kg
Diethofencarb	<0.01 mg/kg
Difenoconazole (cis- and trans-)	<0.01 mg/kg
Diflubenzuron	<0.01 mg/kg
Diflufenican	<0.01 mg/kg
Dimethachlor	<0.01 mg/kg
Dimethametryn	<0.01 mg/kg
Dimethenamid	<0.01 mg/kg
Dimethoate	<0.01 mg/kg
Dimethomorph (E- and Z-isomers)	<0.01 mg/kg
Dimetilan	<0.01 mg/kg
Dimoxystrobin	<0.01 mg/kg
Diniconazole	<0.01 mg/kg
Dinitramine	<0.02 mg/kg
Dinotefuran	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

eurofins Food Integrity & Innovation

Report Number:	**2929308-0**
Report Date:	**10-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927045-0**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 1902183**	**Eurofins Sample:**	**9618761**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	1902183	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Dioxacarb	<0.01 mg/kg
Diphenamid	<0.01 mg/kg
Diphenylamine	<0.01 mg/kg
Dipropetryn	<0.01 mg/kg
Disulfoton	<0.01 mg/kg
Disulfoton sulfone	<0.01 mg/kg
Disulfoton sulfoxide	<0.01 mg/kg
Diuron	<0.01 mg/kg
DMST (Dimethylaminosulfotoluidide)	<0.01 mg/kg
Dodemorph (cis- and trans-)	<0.01 mg/kg
Dodine	<0.01 mg/kg
Doramectin	<0.05 mg/kg
Emamectin benzoate	<0.01 mg/kg
Endosulfan I (alpha-isomer)	<0.02 mg/kg
Endosulfan II (beta-isomer)	<0.02 mg/kg
Endosulfan sulfate	<0.02 mg/kg
Endrin	<0.01 mg/kg
EPN	<0.01 mg/kg
Epoxiconazole	<0.01 mg/kg
Eprinomectin	<0.02 mg/kg
Ethaboxam	<0.01 mg/kg
Ethalfluralin	<0.01 mg/kg
Ethidimuron (Sulfadiazole)	<0.01 mg/kg
Ethiofencarb	<0.01 mg/kg
Ethiofencarb sulfone	<0.01 mg/kg
Ethiofencarb sulfoxide	<0.01 mg/kg
Ethion	<0.01 mg/kg
Ethiprole	<0.01 mg/kg
Ethirimol	<0.01 mg/kg
Ethofumesate	<0.01 mg/kg
Ethoprophos (Ethoprop)	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 1902183	Eurofins Sample:	9618761
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	1902183	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Etofenprox	<0.01 mg/kg
Etoxazole	<0.01 mg/kg
Etrimfos	<0.01 mg/kg
Famoxadone	<0.01 mg/kg
Fenamidone	<0.01 mg/kg
Fenamiphos	<0.01 mg/kg
Fenamiphos sulfone	<0.01 mg/kg
Fenamiphos sulfoxide	<0.01 mg/kg
Fenarimol	<0.01 mg/kg
Fenazaquin	<0.01 mg/kg
Fenbuconazole	<0.01 mg/kg
Fenbutatin oxide	<0.01 mg/kg
Fenchlorphos (Ronnel)	<0.01 mg/kg
Fenchlorphos oxon	<0.01 mg/kg
Fenhexamid	<0.01 mg/kg
Fenitrothion	<0.01 mg/kg
Fenobucarb	<0.01 mg/kg
Fenoxanil (sum of isomers)	<0.01 mg/kg
Fenoxycarb	<0.01 mg/kg
Fenpropathrin	<0.01 mg/kg
Fenpropidin	<0.01 mg/kg
Fenpropimorph	<0.01 mg/kg
Fenpyroximate	<0.01 mg/kg
Fensulfothion	<0.01 mg/kg
Fensulfothion oxon	<0.01 mg/kg
Fensulfothion oxon sulfone	<0.01 mg/kg
Fensulfothion sulfone	<0.01 mg/kg
Fenthion	<0.01 mg/kg
Fenthion oxon	<0.01 mg/kg
Fenthion oxon sulfone	<0.01 mg/kg
Fenthion oxon sulfoxide	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 1902183	Eurofins Sample:	9618761
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	1902183	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Fenthion sulfone	<0.01 mg/kg
Fenthion sulfoxide	<0.01 mg/kg
Fentin	<0.01 mg/kg
Fentrazamide	<0.01 mg/kg
Fenuron	<0.01 mg/kg
Fenvalerate/Esfenvalerate (sum of isomers)	<0.02 mg/kg
Fipronil	<0.01 mg/kg
Fipronil desulfinyl	<0.01 mg/kg
Fipronil sulfone	<0.01 mg/kg
Flazasulfuron	<0.01 mg/kg
Flonicamid	<0.01 mg/kg
Fluazifop-butyl	<0.01 mg/kg
Flubendiamide	<0.05 mg/kg
Flucarbazone-sodium	<0.02 mg/kg
Flucythrinate (sum of isomers)	<0.01 mg/kg
Fludioxonil	<0.01 mg/kg
Flufenacet	<0.01 mg/kg
Flufenoxuron	<0.01 mg/kg
Flumethrin	<0.05 mg/kg
Flumetsulam	<0.01 mg/kg
Flumioxazin	<0.01 mg/kg
Fluometuron	<0.01 mg/kg
Fluopicolide	<0.01 mg/kg
Fluopyram	<0.01 mg/kg
Fluoxastrobin	<0.01 mg/kg
Fluquinconazole	<0.01 mg/kg
Fluridone	<0.01 mg/kg
Flusilazole	<0.01 mg/kg
Flutolanil	<0.01 mg/kg
Flutriafol	<0.01 mg/kg
Fonofos	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

eurofins | Food Integrity & Innovation

Report Number:	**2929308-0**
Report Date:	**10-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927045-0**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 1902183**	**Eurofins Sample:**	**9618761**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	1902183	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Foramsulfuron	<0.01 mg/kg
Forchlorfenuron	<0.01 mg/kg
Formetanate hydrochloride	<0.01 mg/kg
Formothion	<0.01 mg/kg
Fosthiazate (sum of isomers)	<0.01 mg/kg
Fuberidazole	<0.01 mg/kg
Furalaxyl	<0.01 mg/kg
Furathiocarb	<0.01 mg/kg
Griseofulvin	<0.01 mg/kg
Halofenozide	<0.01 mg/kg
Halosulfuron-methyl	<0.01 mg/kg
Haloxyfop-methyl	<0.01 mg/kg
HCH, alpha- (alpha-BHC)	<0.01 mg/kg
HCH, beta- (beta-BHC)	<0.01 mg/kg
HCH, delta- (delta-BHC)	<0.01 mg/kg
Heptachlor	<0.01 mg/kg
Heptachlor endo-epoxide	<0.02 mg/kg
Heptachlor exo-epoxide	<0.01 mg/kg
Hexachlorobenzene (HCB)	<0.01 mg/kg
Hexaconazole	<0.01 mg/kg
Hexaflumuron	<0.01 mg/kg
Hexazinone	<0.01 mg/kg
Hexythiazox	<0.01 mg/kg
Hydramethylnon	<0.01 mg/kg
Hydroprene, S- (sum of isomers)	<0.01 mg/kg
Imazalil	<0.01 mg/kg
Imazamethabenz-methyl	<0.01 mg/kg
Imazethapyr	<0.01 mg/kg
Imidacloprid	<0.01 mg/kg
Indoxacarb	<0.01 mg/kg
Ipconazole	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 1902183	Eurofins Sample:	9618761
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	1902183	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Iprodione	<0.01 mg/kg
Iprodione isomer	<0.02 mg/kg
Iprodione metabolite	<0.01 mg/kg
Iprovalicarb	<0.01 mg/kg
Isocarbamid	<0.01 mg/kg
Isocarbophos	<0.01 mg/kg
Isofenphos	<0.01 mg/kg
Isofenphos-methyl	<0.01 mg/kg
Isoprocarb	<0.01 mg/kg
Isoprothiolane	<0.01 mg/kg
Isoproturon	<0.01 mg/kg
Isoxaben	<0.01 mg/kg
Isoxadifen-ethyl	<0.01 mg/kg
Isoxaflutole	<0.01 mg/kg
Isoxathion	<0.01 mg/kg
Ivermectin	<0.05 mg/kg
Kresoxim-methyl	<0.01 mg/kg
Lactofen	<0.01 mg/kg
Lenacil	<0.01 mg/kg
Lindane (gamma-HCH, gamma-BHC)	<0.01 mg/kg
Linuron	<0.01 mg/kg
Lufenuron	<0.01 mg/kg
Malaoxon	<0.01 mg/kg
Malathion	<0.01 mg/kg
Mandipropamid	<0.01 mg/kg
Mecarbam	<0.01 mg/kg
Mepanipyrim	<0.01 mg/kg
Mepanipyrim-2-hydroxypropyl	<0.01 mg/kg
Mephosfolan	<0.01 mg/kg
Mesosulfuron-methyl	<0.01 mg/kg
Metaflumizone	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 1902183**	**Eurofins Sample:**	**9618761**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	1902183	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Metalaxyl	<0.01 mg/kg
Metamitron	<0.01 mg/kg
Metazachlor	<0.01 mg/kg
Metconazole	<0.01 mg/kg
Methabenzthiazuron	<0.01 mg/kg
Methacrifos	<0.01 mg/kg
Methamidophos	<0.01 mg/kg
Methidathion	<0.01 mg/kg
Methiocarb	<0.01 mg/kg
Methiocarb sulfone	<0.01 mg/kg
Methiocarb sulfoxide	<0.01 mg/kg
Methomyl	<0.01 mg/kg
Methoprotryne	<0.01 mg/kg
Methoxychlor	<0.01 mg/kg
Methoxyfenozide	<0.01 mg/kg
Metobromuron	<0.01 mg/kg
Metolachlor	<0.01 mg/kg
Metolcarb	<0.01 mg/kg
Metosulam	<0.01 mg/kg
Metoxuron	<0.01 mg/kg
Metrafenone	<0.01 mg/kg
Metribuzin	<0.01 mg/kg
Metsulfuron-methyl	<0.01 mg/kg
Mevinphos (E- and Z-isomers)	<0.01 mg/kg
Mexacarbate	<0.01 mg/kg
MGK 264 (sum of isomers)	<0.01 mg/kg
Mirex	<0.01 mg/kg
Molinate	<0.01 mg/kg
Monocrotophos	<0.01 mg/kg
Monolinuron	<0.01 mg/kg
Moxidectin	<0.05 mg/kg

*** This analysis or component is not ISO accredited.**

eurofins Food Integrity & Innovation

Report Number:	**2929308-0**
Report Date:	**10-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927045-0**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 1902183**	**Eurofins Sample:**	**9618761**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	1902183	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Myclobutanil	<0.01 mg/kg
Naled (Dibrom)	<0.01 mg/kg
Naphthol, 1-	<0.02 mg/kg
Napropamide	<0.01 mg/kg
Neburon	<0.01 mg/kg
Nicosulfuron	<0.01 mg/kg
Nitenpyram	<0.01 mg/kg
Nitralin	<0.01 mg/kg
Nitrofen	<0.01 mg/kg
Nonachlor, cis-	<0.01 mg/kg
Nonachlor, trans-	<0.01 mg/kg
Norflurazon	<0.01 mg/kg
Norflurazon-desmethyl	<0.01 mg/kg
Novaluron	<0.01 mg/kg
Nuarimol	<0.01 mg/kg
Ofurace	<0.01 mg/kg
Omethoate	<0.01 mg/kg
Oxadiazon	<0.01 mg/kg
Oxadixyl	<0.01 mg/kg
Oxamyl	<0.01 mg/kg
Oxamyl oxime	<0.01 mg/kg
Oxasulfuron	<0.01 mg/kg
Oxycarboxin	<0.01 mg/kg
Oxychlordane	<0.02 mg/kg
Oxydemeton-methyl	<0.01 mg/kg
Oxyfluorfen	<0.01 mg/kg
Paclobutrazol	<0.01 mg/kg
Paraoxon	<0.01 mg/kg
Paraoxon-methyl	<0.01 mg/kg
Parathion	<0.01 mg/kg
Parathion-methyl	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 1902183	Eurofins Sample:	9618761
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	1902183	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Penconazole	<0.01 mg/kg
Pencycuron	<0.01 mg/kg
Pendimethalin	<0.01 mg/kg
Penoxsulam	<0.01 mg/kg
Pentachloroaniline	<0.01 mg/kg
Pentachloroanisole	<0.01 mg/kg
Pentachlorobenzene	<0.01 mg/kg
Pentachlorobenzonitrile	<0.01 mg/kg
Pentachlorothioanisole	<0.01 mg/kg
Permethrin (sum of isomers)	<0.01 mg/kg
Perthane (Ethylan)	<0.01 mg/kg
Phenmedipham	<0.01 mg/kg
Phenthoate	<0.01 mg/kg
Phenylphenol, 2- (OPP)	<0.02 mg/kg
Phorate	<0.01 mg/kg
Phorate sulfone	<0.01 mg/kg
Phorate sulfoxide	<0.01 mg/kg
Phosalone	<0.01 mg/kg
Phosmet	<0.01 mg/kg
Phosmet oxon	<0.01 mg/kg
Phosphamidon (E- and Z-isomers)	<0.01 mg/kg
Phoxim	<0.01 mg/kg
Picolinafen	<0.01 mg/kg
Picoxystrobin	<0.01 mg/kg
Piperonyl butoxide	<0.01 mg/kg
Piperophos	<0.01 mg/kg
Pirimicarb	<0.01 mg/kg
Pirimicarb-desmethyl	<0.01 mg/kg
Pirimiphos-ethyl	<0.01 mg/kg
Pirimiphos-methyl	<0.01 mg/kg
Pirimiphos-methyl, N-desethyl-	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 1902183	Eurofins Sample:	9618761
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	1902183	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Prallethrin	<0.01 mg/kg
Pretilachlor	<0.01 mg/kg
Primisulfuron-methyl	<0.01 mg/kg
Prochloraz	<0.01 mg/kg
Procymidone	<0.01 mg/kg
Prodiamine	<0.01 mg/kg
Profenofos	<0.01 mg/kg
Profluralin	<0.01 mg/kg
Promecarb	<0.01 mg/kg
Prometon	<0.01 mg/kg
Prometryn	<0.01 mg/kg
Propamocarb	<0.01 mg/kg
Propanil	<0.01 mg/kg
Propaquizafop	<0.01 mg/kg
Propargite	<0.01 mg/kg
Propetamphos	<0.01 mg/kg
Propham	<0.01 mg/kg
Propiconazole (sum of isomers)	<0.01 mg/kg
Propoxur	<0.01 mg/kg
Propyzamide (Pronamide)	<0.01 mg/kg
Proquinazid	<0.01 mg/kg
Prosulfocarb	<0.01 mg/kg
Prothioconazole-desthio	<0.01 mg/kg
Prothiofos	<0.01 mg/kg
Pymetrozine	<0.01 mg/kg
Pyracarbolid	<0.01 mg/kg
Pyraclostrobin	<0.01 mg/kg
Pyraflufen-ethyl	<0.01 mg/kg
Pyrazophos	<0.01 mg/kg
Pyrethrum (total)	<0.1 mg/kg
Pyridaben	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 1902183**	**Eurofins Sample:**	**9618761**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	1902183	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Pyridalyl	<0.01 mg/kg
Pyridaphenthion	<0.01 mg/kg
Pyridate	<0.01 mg/kg
Pyrifenox (E- and Z-isomers)	<0.01 mg/kg
Pyrimethanil	<0.01 mg/kg
Pyriproxyfen	<0.01 mg/kg
Pyroquilon	<0.01 mg/kg
Pyroxsulam	<0.01 mg/kg
Quinalphos	<0.01 mg/kg
Quinmerac	<0.01 mg/kg
Quinoclamine	<0.01 mg/kg
Quinoxyfen	<0.01 mg/kg
Quintozene	<0.01 mg/kg
Quizalofop	<0.02 mg/kg
Quizalofop-ethyl	<0.01 mg/kg
Resmethrin (sum of isomers)	<0.01 mg/kg
Rimsulfuron	<0.01 mg/kg
Rotenone	<0.01 mg/kg
S421	<0.01 mg/kg
Schradan (Octamethylpyrophosphoramide)	<0.01 mg/kg
Secbumeton	<0.01 mg/kg
Sethoxydim (E- and Z-isomers)	<0.01 mg/kg
Siduron	<0.01 mg/kg
Silthiofam	<0.01 mg/kg
Simazine	<0.01 mg/kg
Simeconazole	<0.02 mg/kg
Simetryn	<0.01 mg/kg
Spinetoram (spinosyns J and L)	<0.01 mg/kg
Spinosad (spinosyns A and D)	<0.01 mg/kg
Spirodiclofen	<0.01 mg/kg
Spiromesifen	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 1902183	Eurofins Sample:	9618761
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	1902183	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Spiromesifen enol	<0.01 mg/kg
Spirotetramat	<0.01 mg/kg
Spiroxamine (2 diastereoisomers)	<0.01 mg/kg
Sulfallate	<0.01 mg/kg
Sulfentrazone	<0.01 mg/kg
Sulprofos	<0.01 mg/kg
Tebuconazole	<0.01 mg/kg
Tebufenozide	<0.01 mg/kg
Tebufenpyrad	<0.01 mg/kg
Tebupirimfos	<0.01 mg/kg
Tebuthiuron	<0.01 mg/kg
Tecnazene	<0.01 mg/kg
Teflubenzuron	<0.01 mg/kg
Tefluthrin	<0.01 mg/kg
Temephos	<0.01 mg/kg
Tepraloxydim (E- and Z-isomers)	<0.01 mg/kg
Terbacil	<0.01 mg/kg
Terbufos	<0.01 mg/kg
Terbufos sulfone	<0.01 mg/kg
Terbufos sulfoxide	<0.01 mg/kg
Terbumeton	<0.01 mg/kg
Terbuthylazine	<0.01 mg/kg
Terbutryn	<0.01 mg/kg
Tetrachloroaniline, 2,3,5,6-	<0.01 mg/kg
Tetrachloroanisole, 2,3,4,5-	<0.01 mg/kg
Tetrachlorvinphos	<0.01 mg/kg
Tetraconazole	<0.01 mg/kg
Tetradifon	<0.01 mg/kg
Tetramethrin (sum of isomers)	<0.01 mg/kg
Thiabendazole	<0.01 mg/kg
Thiabendazole-5-hydroxy-	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	**RBW 224P 1902183**	**Eurofins Sample:**	**9618761**
Project ID	MCCAIN_FDS-20200620-0001	**Receipt Date**	20-Jun-2020
PO Number	CVD	**Receipt Condition**	Ambient temperature
Lot Number	1902183	**Login Date**	20-Jun-2020
Sample Serving Size		**Date Started**	22-Jun-2020
Description	Rice Bran Wax	**Sampled**	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Thiacloprid	<0.01 mg/kg
Thiamethoxam	<0.01 mg/kg
Thiazopyr	<0.01 mg/kg
Thidiazuron	<0.01 mg/kg
Thifensulfuron-methyl	<0.01 mg/kg
Thiobencarb (Benthiocarb)	<0.01 mg/kg
Thiodicarb	<0.01 mg/kg
Thiofanox	<0.05 mg/kg
Thiofanox sulfone	<0.01 mg/kg
Thiofanox sulfoxide	<0.01 mg/kg
Thionazin (Zinophos)	<0.01 mg/kg
Thiophanate-methyl	<0.01 mg/kg
Tolclofos-methyl	<0.01 mg/kg
Tolfenpyrad	<0.01 mg/kg
Tolylfluanid	<0.01 mg/kg
Tralkoxydim	<0.01 mg/kg
Triadimefon	<0.01 mg/kg
Triadimenol	<0.01 mg/kg
Triasulfuron	<0.01 mg/kg
Triazophos	<0.01 mg/kg
Tribenuron-methyl	<0.01 mg/kg
Tribufos (DEF)	<0.01 mg/kg
Trichlorfon (Metrifonate)	<0.01 mg/kg
Trichloroanisole, 2,4,6-	<0.01 mg/kg
Tricyclazole	<0.01 mg/kg
Trietazine	<0.01 mg/kg
Trifloxystrobin	<0.01 mg/kg
Trifloxysulfuron	<0.01 mg/kg
Triflumizole	<0.01 mg/kg
Triflumuron	<0.01 mg/kg
Trifluralin	<0.01 mg/kg

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 1902183	Eurofins Sample:	9618761
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	1902183	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Result
Multi-Residue Analysis (500+ Compounds)	
Triforine	<0.01 mg/kg
Trimethacarb	<0.01 mg/kg
Triticonazole	<0.01 mg/kg
Uniconazole	<0.01 mg/kg
Vamidothion	<0.01 mg/kg
Vinclozolin	<0.01 mg/kg
Zoxamide	<0.01 mg/kg
Polycyclic Aromatic Hydrocarbons-Low Level	
Benz(a)anthracene	<0.250 ppb
Benzo(a)pyrene	<0.250 ppb
Benzo(b)fluoranthene	<0.250 ppb
Benzo(g,h,i)perylene	<0.250 ppb
Benzo(k)fluoranthene	<0.250 ppb
Chrysene	<0.250 ppb
Dibenz(a,h)anthracene	<0.250 ppb
Indeno(1,2,3-c,d)pyrene	<0.250 ppb
Pyrene	0.414 ppb

Analysis	Limit	Result	Pass/Fail
Mycotoxins in Raw Materials			
Aflatoxin B1		<0.300 ppb	
Aflatoxin B2		<0.300 ppb	
Aflatoxin G1		<0.300 ppb	
Aflatoxin G2		<0.300 ppb	
Aflatoxin M1		<0.300 ppb	
Aflatoxin M2		<0.300 ppb	
Deoxynivalenol		<56.0 ppb	
T-2 Toxin		<5.60 ppb	
HT-2 Toxin		<56.0 ppb	
Fumonisin B1		<14.3 ppb	

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited

8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 1902183	Eurofins Sample:	9618761
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	1902183	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	Limit	Result	Pass/Fail
Mycotoxins in Raw Materials			
Fumonisin B2		<14.0 ppb	
Ochratoxin A		<1.00 ppb	
Zearalenone		<16.7 ppb	

Analysis	LOQ	Limit	Result	Pass/Fail
Residual Solvents - Class 1, 2a and 2b				
1,1,1-Trichloroethane	10 ppm	10 ppm	<10 ppm	Pass
1,1-Dichloroethene	8 ppm	8 ppm	<8 ppm	Pass
1,2-Dichloroethane	5 ppm	5 ppm	<5 ppm	Pass
Benzene	2 ppm	2 ppm	<2 ppm	Pass
Carbon Tetrachloride	4 ppm	4 ppm	<4 ppm	Pass
1,2-Dimethoxyethane	100 ppm	100 ppm	<100 ppm	Pass
1,4-Dioxane	380 ppm	380 ppm	<380 ppm	Pass
Acetonitrile	410 ppm	410 ppm	<410 ppm	Pass
Chlorobenzene	360 ppm	360 ppm	<360 ppm	Pass
Chloroform	60 ppm	60 ppm	<60 ppm	Pass
1,2-Dichloroethene	1870 ppm	1870 ppm	<1870 ppm	Pass
Cumene	70 ppm	70 ppm	<70.0 ppm	Pass
Cyclohexane	3880 ppm	3880 ppm	<3880 ppm	Pass
Methanol	3000 ppm	3000 ppm	<3000 ppm	Pass
Methylbutylketone	50 ppm	50 ppm	<50 ppm	Pass
Methylcyclohexane	1180 ppm	1180 ppm	<1180 ppm	Pass
Methylene Chloride	600 ppm	600 ppm	<600 ppm	Pass
n-Hexane	290 ppm	290 ppm	<290 ppm	Pass
Nitromethane	50 ppm	50 ppm	<50 ppm	Pass
Pyridine	200 ppm	200 ppm	<200 ppm	Pass
Tetrahydrofuran	720 ppm	720 ppm	<720 ppm	Pass
Tetralin	96 ppm	96 ppm	<96.0 ppm	Pass

*** This analysis or component is not ISO accredited.**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Sample Name:	RBW 224P 1902183	Eurofins Sample:	9618761
Project ID	MCCAIN_FDS-20200620-0001	Receipt Date	20-Jun-2020
PO Number	CVD	Receipt Condition	Ambient temperature
Lot Number	1902183	Login Date	20-Jun-2020
Sample Serving Size		Date Started	22-Jun-2020
Description	Rice Bran Wax	Sampled	Sample results apply as received
		Online Order	16725-13A6324A

Analysis	LOQ	Limit	Result	Pass/Fail
Residual Solvents - Class 1, 2a and 2b				
Toluene	890 ppm	890 ppm	<890 ppm	Pass
Trichloroethylene	80 ppm	80 ppm	<80 ppm	Pass
Xylenes(O,M,P + EB)	2170 ppm	2170 ppm	<2170 ppm	Pass

Method References — **Testing Location**

Dioxin/Furans (DIOXIN_S) — **Eurofins Lancaster Laboratories Environmental LLC**
2425 New Holland Pike Lancaster, Pennsylvania 17601-443 USA

Dioxin-like PCBs (PCB_S) — **Eurofins Lancaster Laboratories Environmental LLC**
2425 New Holland Pike Lancaster, Pennsylvania 17601-443 USA

Elements by ICP Mass Spectrometry (ICP_MS_S) — **Food Integrity Innovation-Madison**
3301 Kinsman Blvd Madison, WI 53704 USA

Official Methods of Analysis, Method 2011.19 and 993.14, AOAC INTERNATIONAL, (Modified).
Paquette, L.H., Szabo, A., Thompson, J.J., "Simultaneous Determination of Chromium, Selenium, and Molybdenum in Nutritional Products by Inductively Coupled Plasma/Mass Spectrometry: Single-Laboratory Validation," Journal of AOAC International, 94(4): 1240 - 1252 (2011).

Multi-Residue Analysis (500+ Compounds) (PS05_S) — **Food Integrity Innovation-Madison**
3301 Kinsman Blvd Madison, WI 53704 USA

Official Methods of Analysis, AOAC Official Method 2007.01, Pesticide Residues in Foods by Acetonitrile Extraction and Partitioning with Magnesium Sulfate, AOAC INTERNATIONAL (modified).

CEN Standard Method EN 15662: Food of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE - QuEChERS method.

List of the tested pesticides and their limits of quantification (LOQs) are available upon request.

*** This analysis or component is not ISO accredited.**

eurofins | Food Integrity & Innovation

Report Number:	**2929308-0**
Report Date:	**10-Jul-2020**
Report Status:	**Final**
Supercedes :	**2927045-0**

Certificate of Analysis

McCain Foods Limited
8800 Main Street
Florenceville-Bristol NB E7L1B2

Method References — **Testing Location**

Mycotoxins in Raw Materials (MYCO_REG_S) — **Food Integrity Innovation-Madison**
3301 Kinsman Blvd Madison, WI 53704 USA

Varga, E., Glauner, T., Koppen, R., Mayer, K., Sulyok, M., Schumacher, R., Krska, R. and Berthiller, F., "Stable isotope dilution assay for the accurate determination of mycotoxins in maize by UHPLC-MS/MS," Analytical and BioAnalytical Chemistry, 402:2675-2686 (2012).

Polycyclic Aromatic Hydrocarbons-Low Level (LLPAH_S) — **Food Integrity Innovation-Madison**
3301 Kinsman Blvd Madison, WI 53704 USA

Internally Developed Method

Residual Solvents - Class 1, 2a and 2b (USPR_S) — **Food Integrity Innovation-Madison**
3301 Kinsman Blvd Madison, WI 53704 USA

United States Pharmacopeia, 38nd Rev. - National Formulary 33th Ed., Method <467>, USP Convention, Inc., Rockville, MD (2015). (Modified).

Testing Location(s) — **Released on Behalf of Eurofins by**

Food Integrity Innovation-Madison — **Edward Ladwig - Director**

Eurofins Food Chemistry Testing Madison, Inc.
3301 Kinsman Blvd
Madison WI 53704
800-675-8375

ilac-MRA A2LA ACCREDITED
2918.01

*** This analysis or component is not ISO accredited.**

EXHIBIT 1

Report of the GRAS Panel

OPINION OF A GRAS PANEL ON THE SAFETY AND GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF RICE BRAN WAX FOR USE IN FRYING OIL OF POTATO PRODUCTS

Introduction

An independent panel of experts (the GRAS Panel), qualified by scientific training and experience to evaluate the safety of food and food ingredients, was requested by McCain Foods Ltd. (McCain), to determine the safety and Generally Recognized as Safe (GRAS) status of the use of rice bran wax in frying oil of potato products for human consumption. McCain proposes to use rice bran wax in oil(s) used in frying operations at a maximum concentration of 0.15% to improve rheological and thermal properties of the oils used with selected fried potato products. 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 May 2020) on the safety of rice bran wax was conducted by ToxStrategies, Inc. (ToxStrategies) and is summarized in the attached dossier. The GRAS Panel members independently reviewed the dossier prepared by ToxStrategies and other pertinent information and convened on July 24, 2020 via teleconference. Based on their independent, critical evaluation of all of the available information and discussions during the July 24, 2020 teleconference, the GRAS Panel unanimously concluded that the intended uses described herein for McCain'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 the Frying Oil of Potato Products**) and manufactured according to cGMP, is safe, suitable, and GRAS based on scientific procedures. A summary of the basis for the GRAS Panel's conclusion is provided below.

Summary and Basis for GRAS Determination

Description

Rice bran wax (CAS No. 8016-60-2) is a crystalline vegetable wax obtained from rice husks. It consists primarily 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 (see Table 1 in GRAS dossier) 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 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, when stored under proper conditions. Furthermore, rice bran wax is considered to be stable by the supplier Koster Kuenen at the proposed par-frying temperatures. If there were to be any breakdown of the rice bran wax component, it would form free fatty alcohols and free fatty acids of molecular weight >C-24.

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) because 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, 2012c) applied a similar approach for beeswax and candelilla wax, bridging safety data from main constituents and other similar waxes. FDA has also issued a letter of no objection for the use of RBW in food (GRN 720; FDA, 2018) which applied a similar approach with the bridging of safety data on other waxes.

As part of the GRAS determination, 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 thus were also considered by the GRAS 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. 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. 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 both the physio-chemical behavior of waxes and oils, as well as 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 fractions (comparable to jojoba) and thus would be the least bioavailable, therefore possessing the least potential for toxicity. For these reasons, 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 and rice-derived products have a long history of human consumption (Burlando and Cornara, 2014). Currently, rice is produced worldwide and is a dietary staple for many populations around the world (Burlando and Cornara, 2014; Henderson et al., 2012). Once harvested, rice is hulled and the resulting brown rice processed further to generate derivatives such as rice bran oil, rice bran extract, and hydrolyzed rice protein. As reviewed in the manufacturing process section, rice bran wax comes from the bran, which is the part between the husk and endosperm of rice and is a by-product 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; coating for confectioneries, chocolates, cakes, and tablets; treatment of vegetables and fruits; and as a plasticizing material for chewing gum base. Rice bran wax has been approved for use in the following food applications in the U.S.; 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). As an indirect food additive as Type VIII in Table 1 of 176.170(c), at a maximum level of 1.0 percent by weight of the polymer. Rice bran wax also received a letter of no objection from FDA for use as a texturizing agent in peanut butter used in bar-form products (GRN 720; FDA, 2018). In addition, while not a food use, a 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), as described in their safety assessment (Andersen, 2006).

Intended Use and Intake Assessment

McCain is proposing to use rice bran wax in oil(s) used in frying operations at a maximum concentration of 0.15% to improve rheological and thermal properties of the oil(s) used with selected fried potato products. The final frozen commercial forms of the fried food products include the following: French fries, hash browns, home chips/steak-cut fries, waffle fries, crinkle cut fries, julienne/skinny fries, smiles, potato wedges, and curly/spiral fries (excluding sweet potatoes).

The potato products are par- fried in oil at a temperature of 170–185°C and then frozen before packaging. For each potato category, the amount of oil present was identified as per average fat levels. The residual levels of rice bran wax in the potato products were then estimated by multiplying the estimated residual oil in various potato products by 0.15%. The resultant residual levels of rice bran wax in frozen par-fried potatoes ranged from 0.006% to 0.015%. In order to define the 'average' RBW level present in potatoes across all categories required for the RBW dietary intake assessment, a weighted average based on product sales in the US was employed. This is a more robust approach that reflects the varying patterns of consumer potato consumption for each category based on product sales (e.g., higher dietary intake of French fries than hash browns) rather than applying a straight average across categories. A weighted average value of 0.009103% was calculated using this approach and then used in the RBW dietary intake assessment as per NPD's data on reported potato intake by American consumers.

McCain has performed a dietary exposure estimate of rice bran wax intake from total frozen fried potato products that were fried in oil(s) containing rice bran wax. To do so, 7-day dietary recall data from the NPD Group, Inc.'s, National Eating Trends Database (NET) were used. NET captures the food and beverage consumption habits of U.S. consumers both adults and children. Respondents report for all meals and snacks both in and away from home for up to seven consecutive days. The time period covered was from March 2019 to February 2020. NET respondents report the amount consumed for each "end dish" food and beverage they consumed. NPD's application displays the standard serving size (e.g., 22 pieces) and then the respondent inputs the quantity they consumed. The analyzed potato items included frozen potato products: French fries, hash browns, home chips/steak-cut fries, waffle fries, crinkle cut fries, julienne/skinny fries, smiles, potato wedges, and curly/spiral fries (excluding sweet potatoes).

As summarized in GRN 720, "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) 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."

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.

In addition, GRN 720 estimated the daily mean and 90_{th} percentile dietary intakes of rice bran wax to be 0.003 and 0.005 g/kg bw/day, respectively, for the 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). The dietary exposure analysis in GRN 720 included any and all bars (not just peanut butter bars), and therefore, was very conservative, and clearly resulted in an overestimate of the actual consumption.

Because the estimated intakes cannot be added together for statistical/methodological reasons, the cumulative estimated daily intake (CEDI) is certainly less than an estimated intake derived from addition of the intakes from GRN 720 and the proposed use in oil(s). If added together, the very conservative mean and 90_{th} percentile CEDI would certainly be less than 6.5 and 11.4 mg/kg bw/day, respectively, for the total U.S. population, ages 2+years. For the 2- to 5-year-old population, the CEDIs of rice bran wax would be less than 20.6 and 33.5 mg/kg bw/day, respectively.

Safety Data

Brown rice and its derivatives, such as rice bran wax, have a long history of human consumption (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 and GRN 720).

The safety 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 GRAS 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 10,200 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). Rice bran wax also received a letter of no objection from FDA for use as a texturizing agent in peanut butter used in bar-form products (GRN 720; FDA, 2018). 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, the proposed use of rice bran wax is in oil(s) used in frying operations to improve rheological and thermal properties of the oils used with selected fried potato products. McCain has performed a dietary exposure estimate of rice bran wax intake from selected fried potato products that were fried in oil(s) containing rice bran wax. To do so, 7-day dietary recall data from the NPD Group, Inc.'s, National Eating Trends Database (NET) were used. NET captures the food and beverage consumption habits of U.S. consumers, both adults and children. Respondents report for all meals and snacks, both in and away from home, for up to seven consecutive days. Using the 7-day survey data, the estimated daily mean and 90_{th} percentile dietary intakes of rice bran wax from total frozen potatoes were 3.5 and 6.4 mg/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 13.6 and 19.5 mg/kg bw/day, respectively.

GRN 720 estimated the daily mean and 90_{th} percentile dietary intakes of rice bran wax to be 0.003 and 0.005 g/kg bw/day, respectively, for the 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. The dietary exposure analysis in GRN 720 included any and all candy bars (not just peanut butter bars), and therefore, was very conservative, and clearly resulted in an overestimate of the actual consumption. Peanut butter bars containing rice bran wax are a niche product and represent only a small percentage of all candy bars as employed in the GRN 720 intake assessment.

MOEs for rice bran wax for its intended use in potato products were calculated based on the EDIs summarized in Table 7. As presented in the Dietary Exposure section, estimated mean and 90_{th} percentile intakes of rice bran wax of 3.5 mg/kg bw/day and 6.4 mg/kg bw/day, respectively, were calculated (assuming a 0.009103% residual level of RBW) for the U.S. population ages 2 and over. This provides MOEs of approximately 191× and 105×, respectively, for mean and 90_{th} percentile intakes when compared to the lowest NOAEL (670 mg/kg bw/day) 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 90_{th} percentile intakes of rice bran wax were 13.6 mg/kg bw/day and 19.5 mg/kg bw/day, respectively. This provides MOEs of approximately 49× and 35×, respectively, for the mean and 90_{th} percentile.

The estimated intakes from GRN 720 and the proposed new use cannot be added together for statistical/methodological reasons and would result in an overestimate of a cumulative estimated daily intake (CEDI); however, the CEDI is certainly less than the CEDI derived from addition of the intakes from GRN 720 and the proposed use in oil(s). When added together, the mean and 90_{th} percentile CEDIs are 6.5 and 11.4 mg/kg bw/day respectively, for the total U.S. population, ages 2+years. For the 2- to 5-year-old population, the CEDIs of rice bran wax are 20.6 and 33.5 mg/kg bw/day, respectively. Incremental exposure to rice bran wax from its expanded use in frying oils for frozen potato products is expected to be minimal and would be less than the intake values as added above. Even so, the MOEs, if calculated from these intake values, would be approximately 103× and 59× for the total U.S. population, ages 2+ years, and 33× and 20× for the 2- to 5-year-old population.

It should be noted that the MOEs presented are based on comparison to the lowest published NOAEL of 670 mg/kg bw/day, the highest dose tested (Parent et al., 1983). There are additional published studies with NOAELs up to 10,200 mg/kg bw/day, also based on the highest dose level tested. Therefore, the calculated MOEs based on the study by Parent et al. (1983) are very conservative and represent minimum MOEs. The MOEs clearly would be more than 10× higher if compared to the highest NOAEL of 10,200 mg/kg bw/day (Rowland et al., 1982) (i.e., CEDI MOEs of greater than 200×–330× for the 2- to 5-year-old population).

Lambe et al. (2000) have stated that the overestimations of shorter-term surveys may be of more significance when comparing to standards, such as ADIs. It is possible that use of longer-term survey data (e.g., 30 days, as opposed to 7 days) would further reduce the within-person variability and result in even lower EDIs relative to an ADI or NOAEL. An ADI or NOAEL is not a threshold above which the risk of health effects will suddenly be of concern. The above EDIs for the age group 2–5 years represent a transient time period that has limited relevance to a lifetime of exposure.

Therefore, we believe that the extremely conservative MOEs presented above for the age group 2–5 years are sufficient to support the safe use of rice bran wax in the proposed potato products. Furthermore, we believe that the supporting published safety data, along with the additional publicly 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 wax obtained from rice husks. The rice bran wax product is manufactured in a manner consistent with current cGMP for food (21 CFR Part 110), and 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 its derivatives have a long history of human consumption. 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; GRN 720) is supportive of its safe use in food.
- 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, 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 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. The reviewed safety studies have been conducted and are publicly available and/or have been previously reviewed and/or 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 10,200 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 male and female rats, respectively) administered in the diet for 90 days. Chronic studies with candelilla wax were also identified, and the NOAELs in these studies were up to 2,400 mg/kg bw/day, the highest dose tested.
- The dietary intake analysis resulted in EDIs (potato products only, as well as cumulative estimated daily intakes) with very conservative MOEs that are deemed sufficient to support the proposed use of rice bran wax in oil(s) used with selected fried potato products.
- Because rice bran wax contains little to no protein, rice bran wax is not likely to pose an allergenic risk.
- The addition of rice bran wax in the oils will improve heat transfer and stability and would further reduce the current par-fry oil temperature during potato processing as well as any minimal acrylamide formation.

- 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 intended use of rice bran wax product.

Conclusions of the GRAS Panel

We, the undersigned members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of McCain's rice bran wax product as described in the safety dossier titled **GRAS Determination of Rice Bran Wax for Use in the Frying Oil of Potato 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 in oil(s) used in frying operations at a maximum concentration of 0.15% to improve rheological and thermal properties of the oils used with selected fried potato products, 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.

____________________________ ____________

Michael Carakostas, DVM, PhD — Date
Consultant
MC Scientific Consulting LLC

____________________________ ____________

Stanley M. Tarka, Jr., PhD, F.A.T.S. — Date
Consultant
Tarka Group, Inc.

____________________________ ____________

Thomas Vollmuth, PhD — Date
Consultant
Vollmuth and Associates, LLC

Conclusions of the GRAS Panel

We, the undersigned members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of McCain's rice bran wax product as described in the safety dossier titled **GRAS Determination of Rice Bran Wax for Use in the Frying Oil of Potato 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 in oil(s) used in frying operations at a maximum concentration of 0.15% to improve rheological and thermal properties of the oils used with selected fried potato products, 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.

[redacted]

Michael Carakostas, DVM, PhD
Consultant
MC Scientific Consulting LLC

21- July 2020
Date

Stanley M. Tarka, Jr., PhD, F.A.T.S.
Consultant
Tarka Group, Inc.

Date

Thomas Vollmuth, PhD
Consultant
Vollmuth and Associates, LLC

Date

Conclusions of the GRAS Panel

We, the undersigned members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of McCain's rice bran wax product as described in the safety dossier titled **GRAS Determination of Rice Bran Wax for Use in the Frying Oil of Potato 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 in oil(s) used in frying operations at a maximum concentration of 0.15% to improve rheological and thermal properties of the oils used with selected fried potato products, 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.

______________________________ ______________

Michael Carakostas, DVM, PhD — Date
Consultant
MC Scientific Consulting LLC

26 July 2016

______________________________ ______________

Stanley M. Tarka, Jr., PhD, F.A.T.S. — Date
Consultant
Tarka Group, Inc.

______________________________ ______________

Thomas Vollmuth, PhD — Date
Consultant
Vollmuth and Associates, LLC

Conclusions of the GRAS Panel

We, the undersigned members of the GRAS Panel, have individually and collectively critically reviewed the published and ancillary information pertinent to the identification, use, and safety of McCain's rice bran wax product as described in the safety dossier titled **GRAS Determination of Rice Bran Wax for Use in the Frying Oil of Potato 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 in oil(s) used in frying operations at a maximum concentration of 0.15% to improve rheological and thermal properties of the oils used with selected fried potato products, 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.

Michael Carakostas, DVM, PhD
Consultant
MC Scientific Consulting LLC

Date

Stanley M. Tarka, Jr., PhD, F.A.T.S.
Consultant
[redacted]

27 July 2020
Date

Thomas Vollmuth, PhD
Consultant
Vollmuth and Associates, LLC

References

Andersen, FA. 2006. Amended final report on the safety assessment of oryza sativa (rice) bran oil, oryza sativa (rice) germ oil, rice bran acid, oryza sativa (rice) bran wax, hydrogenated rice bran wax, oryza sativa (rice) bran extract, oryza sativa (rice) extract, oryza sativa (rice) germ powder, oryza sativa (rice) starch, oryza sativa (rice) bran, hydrolyzed rice bran extract, hydrolyzed rice bran protein, hydrolyzed rice extract, and hydrolyzed rice protein. International Journal of Toxicology, 25(Suppl 2), 91-120.

Burlando, B, Cornara, L. 2014. Therapeutic properties of rice constituents and derivatives (Oryza sativa L.): a review update. Trends in Food Science & Technology, 40(1), 82-98.

Cook, R. 2011. Tracking demographics and US fruit and vegetable consumption patterns. Department of Agricultural and Resource Economics, University of California, Davis.

European Food Safety Authority (EFSA). 2007. Beeswax (E 901) as a glazing agent and as carrier for flavours. Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC). The EFSA Journal (2007) 615, 1-28.

European Food Safety Authority (EFSA). 2012a. Scientific Opinion on the evaluation of the substances currently on the list in the Annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils – Part III of III. EFSA Journal 2012;10(12):2984.

European Food Safety Authority (EFSA). 2012b. Scientific Opinion on the re-evaluation of carnauba wax (E 903) as a food additive. EFSA Journal 2012;10(10):2880.

European Food Safety Authority (EFSA). 2012c. Scientific opinion on the re-evaluation of candelilla wax (E 902) as a food additive. EFSA Journal 10(11):2946.

Food and Drug Administration (US FDA). 2018. GRN No. 720, GRAS notification for Rice bran wax. Prepared by The J.M. Smucker Co.

Hargrove, JL, Greenspan, P, Hartle, DK. 2004. Nutritional significance and metabolism of very long chain fatty alcohols and acids from dietary waxes. Experimental Biology and Medicine, 229(3), 215-226.

Henderson AJ, Ollila CA, Kumar A, Borresen EC, Raina K, Agarwal R, Ryan EP. 2012. Chemopreventive properties of dietary rice bran: current status and future prospects. Adv Nutr 3(5):643–53.

Loretz LJ, Api AM, Barraj LM, Burdick J, Dressler WE, Gettings SD, et al. 2005. Exposure data for cosmetic products: Lipstick, body lotion, and face cream. Food Chem Toxicol 43(2):279–291.

Maru, AD, Surawase, RK, Bodhe, PV. 2012. Studies on Physico-Chemical Properties of Rice Bran Wax and its Comparison with Carnauba Wax. International Journal of

Pharmaceutical an hytopharmacological Research. 1(4), 203-207.

Orlich, MJ, Jaceldo-Siegl, K, Sabaté, J, Fan, J, Singh, PN, Fraser, GE. 2014. Patterns of food consumption among vegetarians and non-vegetarians. British Journal of Nutrition, 112(10), pp.1644-1653.

Oser, BL, Ford, RA. 1977. Recent progress in the consideration of flavoring ingredients under the food additives amendment. 10. GRAS substances. Food Technol. 31(1):65–74.

Parent, RA, Re, TA, Babish, JG, Cox, GE, Voss, KA, Becci PJ. 1983. Reproduction and subchronic feeding study of carnauba wax in rats. Food and Chemical Toxicology 21:89-93.

Revolymer Limited. 2011. GRN No. 374; Maleated isoprenyl polymer with methoxy-polyethylene glycol (MIP-MPEG). http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm269568.pdf

Rowland, IR, Butterworth, KR, Gaunt, IF, Grasso, P, Gangolli, SD. 1982. Short-term toxicity study of carnauba wax in rats. Food and Chemical Toxicology 20, 467-471.

Sabale, V, Sabale, PM, Lakhotiya, CL. 2007. In vitro studies on rice bran wax as skin moisturizer. Indian J Pharmaceut Sci. 69(2):215.

Shumow L, Barraj LM, Murphy MM, Bi X, Bodor AR. 2012. Candy consumption in the United States. FASEB Journal 26:1005.3 (abstract).

Smith, JH, Mallett, AK, Priston, RA, Brantom, PG, Worrell, NR, Sexsmith, C, Simpson, BJ. 1996. Ninety-day feeding study in Fischer-344 rats of highly refined petroleum-derived food-grade white oils and waxes. Toxicol Pathol. 24(2):214–230.

Questions for GRN 962 (Rice bran wax)

<u>Dietary Exposure Questions</u>

In our review of your GRAS notice, we identified deficiencies regarding your dietary exposure estimates. In the Part 3 (Dietary Exposure) of the notice you estimate the mean and 90th percentile dietary exposure to be 3.5 mg/kg bw/d and 6.4 mg/kg bw/d, respectively, for the US population ages 2 years and older. You also estimate the mean and 90th percentile dietary exposure for the subpopulation ages 2 to 5 years to be 13.6 and 19.5 mg/kg bw/d, respectively. We have the following comments:

1. **Beginning on page 15 of your notice, you provide information regarding your dietary exposure estimate for the intended use of rice bran wax in oils used for par-frying frozen fried potato products. To estimate the dietary exposure for the intended use, you state that you use a weighted residual level (i.e., 0.009103%) based on market sales data and NPD/NET potato consumption data.**

    a. **Please provide the estimated dietary exposure with the assumption that the ingredient is present at the highest use level and in all the proposed food categories irrespective of market share.**

Response: As a point of clarification, rice bran wax (RBW) would be used only in cooking oil and at a maximum level of 0.15%. Below are the maximum residual RBW levels in potato products per category based on fat absorption.

Total Frozen Potatoes	Max RBW residual levels (%)
Total Fries including French Fries, Spirals/Curly Fries, Waffle Fries, Steak/Thick Cut Fries, Crinkle Cut Fries, Julienne/Skinny Fries, Smiles (formed mashed potato), all kinds of Fries; Hash Browns, Home Chips, Potato Wedges	0.01455
Frozen Fries	
Total Fries including French Fries, Spirals/Curly Fries, Waffle Fries, Steak/Thick Cut Fries, Crinkle Cut Fries, Julienne/Skinny Fries, all kinds of Fries	0.01455
Frozen Hash Browns	
Hash Browns	0.0087
Frozen French Fries	
Frozen French Fries	0.01455

The estimated dietary exposure to RBW employing the highest maximum residual level (0.015%) is presented below. Further dietary exposure calculations for moisture loss following baking or deep frying are presented in response to FDA Question no. 3.

Category: Frozen Potatoes			Average Daily Intake per Week in Grams				
	Age Group	No. of Eatings (n)	Median	Mean	90th Percentile	Mean mg/kg/day RBW	90th %tile mg/kg/day RBW
Total Frozen Potatoes (0.015% RBW)	2+	1,733	16.7	22.8	42.0	5.7	10.5
	2-5	153	15.0	23.9	34.2	22.4	32.1
	6-18	358	16.7	23.0	42.0	7.8	14.3
	18+	1,222	16.7	22.5	43.2	4.8	9.3

b. Please provide details on how you derived the weighted residual level and provide an example calculation using the maximum use level for a specific food category.

Response: In the absence of an available analytical methodology to detect RBW residual levels in potato products, McCain estimated the residual levels in the following manner:

1. RBW would be used at maximum level of 0.15% in the par-fry oil.
2. Fat present in the potato products is coming from the par-fry oil, and the fat levels present in potato products are known. Hence, the oil percentage in potato products is known and their corresponding residual RBW levels (fat x 0.15%). There is slight overestimation of oil levels as the potato could contain some very low levels of fat.
3. McCain has identified all the relevant potato products and their individual average fat values as per nutrient information (e.g., French fries at different cut sizes, potato wedges, potato lattice, potato formed products, etc.). McCain reviewed its volume sales for each product and identified the percentage contribution from each of them to the total volume sales in the U.S. (e.g., French fries x % of total sales volume)
4. The RBW residual levels had already been estimated for each of these products, so rather than calculating a straight average, we applied a weighted average based on individual volume sales. This average would be more representative of the products most sold/consumed within each relevant category. This approach was applied to Total Frozen Potatoes, Total Frozen Fries and Total Frozen French Fries.

- Example calculation using maximum RBW residual level for a specific category:

  Frozen French Fries: Highest fat value was 9.7%; at 0.15% RBW use in oil, the maximum residual level would be 0.01455% (0.15%).

2. **On page 15 you list the frozen food products in which rice bran wax is intended for use as the following: French fries, hash browns, home chips/steak-cut fries, waffle fries, crinkle cut fries, julienne/skinny fries, smiles, potato wedges, and curly/spiral fries (excluding sweet potatoes). We note that the food products listed are broad and request that you provide the specific NHANES food codes for the foods in which rice bran wax is intended for use, and their corresponding use levels.**

Response: RBW is not intended for use in potatoes but in the cooking oil. The maximum RBW residual levels are as follows:

Product	Average Total Fat (%)	RBW (%)
French Fries - 1/2 INCH cut	5.2	0.0078
French Fries - 1/4 INCH cut	6.6	0.0099
French Fries - 3/16 INCH cut	9.7	0.01455
French Fries - 3/8 INCH cut	5.4	0.0081
French Fries - 3/4 INCH cut	4	0.006
French Fries - 5/16 INCH cut	6.8	0.0102
French Fries - 7/16 INCH cut	5.5	0.00825
French Fries – Spirals	7.2	0.0108
Potato Lattice	9.7	0.01455
Potato Formed Product – Smiles	6.7	0.01005
Hash Browns	5.8	0.0087
Potato Wedges	5.6	0.0084

The relevant NHANES food codes are as follows:

Food code	Short description
71401020	POTATO, FRENCH FRIES, FROM FROZEN, BAKED
71401020	WHITE POTATO, FRENCH FRIES, FROM FROZEN, OVEN-BAKED
71401030	POTATO, FRENCH FRIES, FAST FOOD
71401030	WHITE POTATO, FRENCH FRIES, FRM FRZ, DEEP FRD, FF/REST
71401030	WHITE POTATO, FRENCH FRIES, FROM FAST FOOD / RESTAURANT
71401030	WHITE POTATO, FRENCH FRIES, FROM FROZEN, DEEP-FRIED
71401031	POTATO, FRENCH FRIES, RESTAURANT
71401032	POTATO, FRENCH FRIES, FROM FROZEN, FRIED
71401032	WHITE POTATO, FR FRIES, FR FROZ, DEEP FRIED, FR HOME/STORE
71401033	POTATO, FRENCH FRIES, SCHOOL

71401035 WHITE POTATO, FRENCH FRIES, FR FRZN, NS AS TO FRIED OR BKD
71401039 POTATO, FRENCH FRIES, WITH CHEESE, FAST FOOD / RESTAURANT
71401041 POTATO, FRENCH FRIES, WITH CHEESE, SCHOOL
71401045 POTATO, FRENCH FRIES, WITH CHILI, FAST FOOD / RESTAURANT
71401050 POTATO, FRENCH FRIES, WITH CHILI AND CHEESE, FAST FOOD / RES
71403030 POTATO, HOME FRIES, FROM RESTAURANT / FAST FOOD
71404010 POTATO, HASH BROWN, FROM FAST FOOD
71404020 POTATO, HASH BROWN, FROM FAST FOOD, WITH CHEESE
71404030 POTATO, HASH BROWN, FROM RESTAURANT
71404040 POTATO, HASH BROWN, FROM RESTAURANT, WITH CHEESE
71404050 POTATO, HASH BROWN, FROM SCHOOL LUNCH
71405020 WHITE POTATO, HASH BROWN, FROM FROZEN

3. **In addition to the dietary exposures related to the maximum and residual use levels, we request that you address the estimated dietary exposure to rice bran wax from the final cooked food product. In doing that, please account for potential increases in the rice bran wax concentration due to moisture loss and/or fat absorption during the final cooking method of the specified products.**

Response:

RBW residual values from oven preparation:

McCain does not have actual data from U.S. products (e.g., fat or moisture levels after oven preparation), but McCain does have data for the same products manufactured in other countries. McCain has analyzed this information and identified % fat increases that were then applied to the fat levels reported in the U.S. The maximum RBW residual levels after moisture loss from oven preparation (baking) are as follows:

Total Frozen Potatoes	Max RBW residual levels after moisture loss (%)
Total Fries including French Fries, Spirals/Curly Fries, Waffle Fries, Steak/Thick Cut Fries, Crinkle Cut Fries, Julienne/Skinny Fries, Smiles (formed mashed potato), all kinds of Fries; Hash Browns, Home Chips, Potato Wedges	0.01618

Frozen Fries	
Total Fries including French Fries, Spirals/Curly Fries, Waffle Fries, Steak/Thick Cut Fries, Crinkle Cut Fries, Julienne/Skinny Fries, all kinds of Fries	0.01618

Frozen Hash Browns	
Hash Browns	0.01

Frozen French Fries	
Frozen French Fries	0.01618

Category: Frozen Potatoes			Average Daily Intake per Week in Grams				
	Age Group	No. of Eatings (n)	Median	Mean	90th Percentile	Mean mg/kg/day RBW	90th %tile mg/lg/day RBW
Total Frozen Potatoes (0.016% RBW)	2+	1,733	16.7	22.8	42.0	6.1	11.2
	2-5	153	15.0	23.9	34.2	23.9	34.2
	6-18	358	16.7	23.0	42.0	8.3	15.3
	18+	1,222	16.7	22.5	43.2	5.1	9.9

RBW residual values from deep frying:

Again, McCain does not have actual data from U.S. products (e.g., fat or moisture levels after deep fry preparation), but does have data for the same products manufactured in other countries. McCain analyzed this information and then identified % increases that were then applied to the fat levels reported in the U.S.

Two different approaches were conducted, each yielding approximately the same values:

- The first approach involved calculating solids before and after cooking and then recalculating the value for RBW (0.01873 g/100 g).
- The second approach involved identifying % moisture loss during deep frying, identifying the extra added fat, and then recalculating RBW (0.01855 g/100 g). The higher of the two values can be found in the following table.

Total Frozen Potatoes	Max RBW residual levels after moisture loss (%)
Total Fries including French Fries, Spirals/Curly Fries, Waffle Fries, Steak/Thick Cut Fries, Crinkle Cut Fries, Julienne/Skinny Fries, Smiles (formed mashed potato), all kinds of Fries; Hash Browns, Home Chips, Potato Wedges	0.01873

Frozen Fries	
Total Fries including French Fries, Spirals/Curly Fries, Waffle Fries, Steak/Thick Cut Fries, Crinkle Cut Fries, Julienne/Skinny Fries, all kinds of Fries	0.01873

Frozen French Fries	
Frozen French Fries	0.01873

Category: Frozen Potatoes			Average Daily Intake per Week in Grams				
	Age Group	No. of Eatings (n)	Median	Mean	90th Percentile	Mean mg/kg/day RBW	90th %tile mg/kg/day RBW
Total Frozen Potatoes (0.019% RBW)	2+	1,733	16.7	22.8	42.0	7.2	13.3
	2-5	153	15.0	23.9	34.2	26.6	40.6
	6-18	358	16.7	23.0	42.0	9.9	18.1
	18+	1,222	16.7	22.5	43.2	6.1	11.7

4. **Please also address the potential dietary exposure from degradation products that may result from the intended use.**

Response:

Rice bran wax (RBW) consists predominantly of wax monoesters accounting for up to 98% (wt%) of the total wax. These molecules, the esters of saturated long chain fatty acids linked to fatty alcohols, are chemically stable and can withstand thermal stresses. McCain has conducted analyses that demonstrate that RBW degradation does not occur under the conditions encountered upon par frying or conventional industrial food frying (see Attachment 1 for full report). The findings also strongly suggest that very high temperatures (above 400°C) or an extremely high number of fry-up cycles (above 280) are necessary to begin to induce RBW degradation. Since these conditions are never encountered upon industrial, retail, or domestic food manufacturing practices, it can be concluded that RBW stability is maintained. The different analytical techniques employed in the studies provided insight into the stability of RBW at different length-scales: from macroscopic behavior (RBW preserved ability to form gels after 280 fry-ups), to the molecular packing (comparable melting and TGA profile between fresh and fried samples), to molecular composition as determined through gas chromatography and high-performance thin layer chromatography.

5. **In the safety section we note that you rely on safety data for carnauba wax for information relevant to rice bran wax. Please provide a cumulative dietary exposure estimate that includes the uses of rice bran and carnauba wax, as you have stated that rice bran wax is not substitutional for carnauba wax.**

Response:

As noted in GRN 962, a conservative estimate of background dietary exposure to rice bran wax from current approved uses is approximately 0.1 g/day and the dietary exposure to RBW from the proposed peanut butter bar in GRN 720 was estimated to be 0.1 – 0.2 g/day at the 90th percentile. As for carnauba wax dietary exposure, EFSA (2012) re-evaluated the safety of carnauba wax as permitted in food and summarized the total dietary exposure to carnauba wax as follows:

> "Refined estimates reported for carnauba wax, when considering Maximum Permitted Levels (MPLs), resulted in a mean dietary exposure of European toddlers (aged 12-35 months and weighing an average of 15 kg) ranged from 2.6-4.6 mg/kg bw/day, and from 3.1-8.1 mg/kg bw/day at the 95th percentile. The mean dietary exposure of European children (aged 3-9 years and weighing an average of 30 kg) ranged from 1.6-4.5 mg/kg bw/day, and from 3.2-7.6 mg/kg bw/day at the 95th percentile. The main contributors to the total anticipated mean exposure to carnauba wax for these populations were fruits and confectionary.
>
> The mean dietary exposure of European adolescents (aged 10-17 years and weighing an average of 50 kg) ranged from 0.9-2.1 mg/kg bw/day, and from 1.9-3.8 mg/kg bw/day at the 95th percentile. The main contributors to the total anticipated mean exposure to carnauba wax for this population were fruits and confectionary. Whereas the mean dietary exposure of the European adult population gave a mean dietary exposure in the range of 0.7-1.7 mg/kg bw/day and 1.5-3.0 mg/kg bw/day for high level consumers. The main contributors to the total anticipated mean exposure to carnauba wax for this population were fruits. For the elderly, mean exposure to carnauba wax was in the range of 0.8-1.5 mg/kg bw/day and in the range of 1.9-2.7 mg/kg bw/day at the 95th percentile. Main contributors for these populations were fruits. From the highest consumers of these populations (95th percentile) these exposures estimates would result in margins of safety from 83 to 447 when compared to the NOAEL of 670 mg/kg bw/day identified in a reproductive toxicity study with rats by Parent (Parent et al., 1983), from 31 to 67 when compared to the NOAEL of 250 mg/kg bw/day identified in a subchronic toxicity study with dogs by Parent (Parent et al., 1983b), from 185 to 1000 when compared to the NOAEL of 1500 mg/kg bw/day identified in a subchronic toxicity study with rats by Edwards (Edwards et al., 1998), and from 1086 to 5867 when compared to the NOAEL of 8800 mg/kg bw/day identified in a subchronic toxicity study with rats by Rowland (Rowland et al., 1982). These margins of safety are considered sufficient by the Panel taking into consideration that the NOAEL's identified are the highest dose tested not

> showing any effect in their respective studies, and that the exposure estimates to carnauba wax carried out in this opinion are very conservative."

It must be noted that the EFSA estimate of dietary exposure is very conservative as it assumes that all processed foods contain carnauba wax added at the MPLs. Given the worst-case dietary exposure to residual rice bran wax from frying (0.019%), the 90th percentile exposure to RBW ranges from 11.7 – 40.6 mg/kg bw/day, significantly higher than the EFSA exposure estimates to carnauba wax (i.e., 0.7 – 8.1 mg/kg bw/day at the 95th percentile) summarized above. Therefore, the overall contribution of carnauba wax to a cumulative dietary exposure estimate is small and a fraction of the very conservative estimates of RBW dietary exposure from its proposed use in cooking oil for frozen potato products. The cumulative dietary exposure from both waxes would certainly be less than 50 mg/kg bw/day at the 90th percentile. As noted in GRN 962, the highest consumption of RBW from the proposed use is in the 2 – 5-year age group which is the same for carnauba wax. Similarly large margins of exposure can be calculated for RBW when consideration is given to the range of publicly available toxicity study NOAEL values cited by EFSA and reviewed in GRN 962. Margins of exposure are further discussed in response to Toxicology Question No. 2 below.

Reference*:* EFSA. 2012. Scientific opinion on the re-evaluation of carnauba wax (E 903) as a food additive. EFSA Journal 10(10):2880.

<u>Additional Comments</u>

6. **On page 11 of the notice, you state that the total arsenic levels in analyzed lots were below 10 ppb (µg/kg). Please provide a specification for total arsenic that is reflective of measured analytical values.**

Response: McCain sets a specification of 10 ppb for arsenic.

7. **We note that there are several errors in your notice regarding incorrect references in the text to data listed in the provided tables. For example, you state "Table 6 below converts the g/day intake in Table 5 to mg/kg bw/day based on default body weights". However, Table 5 is not included in your submission. Further, Table 6 in the notice provides information on the "NET consumer portion size report". Please make sure that references to all tabular data are accurate.**

Response: The first sentence on page 18 of GRN 962 should read, "Table 7 below converts the g/day intake in Table 6 to mg/kg bw/day based on default body weights, as follows: 2+ years, 60 kg; 2–5 years, 16 kg; 6–18 years, 44 kg, 19+ years, 70 kg."

<u>Toxicology Questions</u>

It appears that the notifier's safety narrative is based on absorption, distribution, metabolism, and excretion (ADME) and toxicological properties of other similar waxes such as carnauba wax and other hard waxes. Given these waxes are not typically used at elevated temperatures such as during par-frying and thus involves novel uses, it is not clear how the intended use would or would not be expected to alter the ADME and/or toxicological properties. We note the following:

The notifier states on pg. 24:

"Smith et al. (1996) demonstrated that the toxicity of waxes decreases with increasing chain length … As the molecular weight of the various waxes increased, a decrease in incidence and severity of adverse effects was observed. Systemic exposure to lower weight waxes resulted in effects such as increased organ weights and inflammatory changes of the liver and mesenteric lymph nodes."

On pg. 14, the notifier states:

"Rice bran wax is considered to be stable by the supplier Koster Kuenen at the proposed par-frying temperatures. If there were to be any breakdown of the rice bran wax component, it would form free fatty alcohols and free fatty acids of molecular weight >C24 (see Table 9)."

On pg. 26, the notifier states:

"… the rate of uptake is thought to decrease as chain length and hydrophobicity increase … Therefore, the long-chain fatty acid esters present in plant-based waxes such as rice bran wax and the other waxes referenced here are thought to be poorly absorbed in the GI tract …"

1. **Please provide a more detailed narrative, including publicly available data and information used, discussing evidence to support the conclusion that the constituents of rice bran wax are not expected to generate smaller degradation products under the condition of intended use that would have toxicological consequences.**

Response: As noted in response to Question 4 above and Attachment 1, McCain has demonstrated that RBW (and its constituents) does not degrade under the high temperature conditions of use (par-frying), as well as subsequent retail or home use of the frozen potato products (deep-frying or baking). Therefore, the use of other waxes such as carnauba wax to support the safe use of rice bran wax in cooking oil is justified. 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 (GI) tract (EFSA, 2012a,b), because uptake of wax esters decreases as chain length and hydrophobicity increase (Hargrove et al., 2004; Krendlinger et al., 2002.) No adverse or biological effects have been observed following exposure to the highest molecular weight waxes, including carnauba wax and rice bran wax. 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 fractions 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. Given that RBW does not degrade under the proposed conditions of use in frying oil, the safety study database considered in GRN 720 and GRN 962 is still considered directly relevant to the safety of RBW.

References:

EFSA (European Food Safety Authority). 2012a. Scientific Opinion on the evaluation of the substances currently on the list in the Annex to Commission Directive 96/3/EC as acceptable previous cargoes for edible fats and oils – Part III of III. EFSA Journal 10(12):2984.

EFSA (European Food Safety Authority). 2012b. Scientific opinion on the re-evaluation of carnauba wax (E 903) as a food additive. EFSA Journal 10(10):2880.

Hargrove, JL, Greenspan, P, Hartle, DK. 2004. Nutritional significance and metabolism of very long chain fatty alcohols and acids from dietary waxes. Exper Biol Med 229(3):215–226.

Krendlinger E, Wolfmeier U, Schmidt H, Heinrichs F, Michalczyk G, Payer W, et al. 2002. Ullmann's Encyclopedia of Industrial Chemistry. Wiley-VCH Verlag GmbH & Co. KGaA, publisher. Available from: http://onlinelibrary.wiley.com/doi/10.1002/14356007.a28_103.pub2/abstract.

2. **Given that your safety conclusions are almost entirely based on toxicological and ADME data from similar but not identical waxes, it is reasonable to consider background/cumulative exposures resulting from uses for all similar waxes currently authorized. Based on your new updated dietary exposure estimates, please provide a narrative describing how exposure from current and the intended uses of all similar waxes would not be a safety concern.**

Response:

Of the waxes evaluated in GRN 962, rice bran wax contains the longest alcohol and acid chain lengths and has one of the largest monoester fractions (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. It should also be noted that carnauba wax can be used in food per 21 CFR 184.1978 with no limitation other than current good manufacturing practices. Taken together, the available data on these various waxes provides sufficient publicly available information to assess the safety of rice bran wax and its constituents for its intended use.

As noted previously, given the worst-case dietary exposure to residual rice bran wax from at home frying (0.019%), the 90th percentile exposure to RBW ranges from 11.7 – 40.6 mg/kg bw/day, significantly higher than the EFSA exposure estimates to carnauba wax (i.e., 0.7 – 8.1 mg/kg bw/day at the 95th percentile) summarized above. Therefore, the overall contribution of carnauba wax to a cumulative dietary exposure estimate is small and a fraction of the very conservative estimates of RBW dietary exposure from its proposed use cooking oil for frozen potato products. The cumulative dietary exposure from both waxes would certainly be less than 50 mg/kg bw/day and would be considered a very conservative estimate of consumption based on multiple worst-case assumptions (i.e., use levels, 90-95th percentile intake values). As noted in GRN 962, the highest consumption of RBW from the proposed use is in the 2 – 5-year age group which is the same for carnauba wax. Similarly large margins of exposure can be calculated for RBW when consideration is given to the range of publicly available toxicity study NOAEL values cited by EFSA and reviewed in GRN 720 and GRN 962.

Worst-case MOEs for rice bran wax for its intended use in potato products were calculated based on the EDIs summarized in the table related to deep frying of potatoes, the worst-case use level of 0.019% (see Question 3 response), and body weights for 2+ years, 60 kg; 2–5 years, 16 kg; 6–18 years, 44 kg, and 18+ years, 70 kg. As presented in the referenced table, estimated mean and 90th percentile intakes of rice bran wax of 7.2 mg/kg bw/day and 13.3 mg/kg bw/day, respectively, were calculated (assuming a 0.019% residual level of RBW) for the U.S. population ages 2 and over. This provides MOEs of approximately 93x and 50x, respectively, for mean and 90th percentile intakes when compared to the lowest NOAEL (670 mg/kg bw/day) 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 26.6 mg/kg bw/day and 40.6 mg/kg bw/day, respectively. This provides MOEs of approximately 25x and 17x, respectively, for the mean and 90th percentile daily intake. The MOEs for the 6–18-year age group were 68x and 37x at the mean and 90th percentile and for the 18+ age group, the MOEs were 110x and 57x at the mean and 90th percentile daily intake.

The above MOEs are based on comparison to the lowest published NOAEL of 670 mg/kg bw/day, the highest dose tested (Parent et al., 1983b). There are additional published studies with NOAELs up to 10,200 mg/kg bw/day, all based on the highest dose level tested. Therefore, the calculated MOEs based on the study by Parent et al. (1983) are very conservative and represent minimum MOEs. The MOEs clearly would be more than 10x higher if compared to the highest NOAEL of 10,200 mg/kg bw/day. None of the published studies on carnauba wax identified an adverse effect level. EFSA drew a similar conclusion for carnauba wax and stated that "these margins of safety (83x to 5867x at the 95th percentile) are considered sufficient by the Panel taking into consideration that the NOAEL's identified are the highest dose tested not showing any effect in their respective studies, and that the exposure estimates to carnauba wax carried out in this opinion are very conservative." The same can be said for rice bran wax and an evaluation of the combined intake of rice bran wax and carnauba wax (estimated to be <50 mg/kg bw/day).

In another comparison, employing the worst-case 0.019% inclusion rate, a 2-5-year-old child would have to consume approximately ten times the 90th percentile daily intake (34.2 mg/kg bw/day) to ingest the same amount of wax in one standard 5-gram crayon (approximately 312.5 mg/kg bw/day for a 16 kg individual). Furthermore, the 90th percentile daily intake of 34.2 mg/kg/day is more than 146-fold lower than the highest dose tested in most of the acute oral toxicity studies identified for waxes (5,000 mg/kg-bw).

In conclusion, 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 used in cooking oil in the production of frozen potato products. McCain has demonstrated that RBW does not degrade under the conditions of use. Therefore, the use of other safety study data on similar waxes to support the safety of RBW is justified. 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 because uptake of wax esters decreases as chain length and hydrophobicity increase. No adverse or biological effects have been observed following exposure to the highest molecular weight waxes, including carnauba wax and rice bran wax. An ADI or NOAEL is not a threshold above which the risk of health effects will suddenly be of concern. The above EDIs for the age group 2–5 years represent a transient time period that has limited relevance to a lifetime of exposure. Therefore, we believe that the extremely conservative MOEs presented above for the age group 2–5 years are sufficient to support the safe use of rice bran wax in the proposed potato products. In addition, the dietary intake analysis resulted in EDIs (potato products only, as well as cumulative estimated daily intakes) with very conservative MOEs that are deemed sufficient to support the proposed use of rice bran wax in oil(s) used in frying operations.

ATTACHMENT 1: Assessment of RBW Degradation

From: Vincenzo di Bari, Food Sciences, The University of Nottingham (UK)

Assessment of rice bran wax stability for industrial frying applications

Executive summary

Rice bran wax (RBW) consists predominantly of wax monoesters accounting for up to 98% (wt%) of the total wax. These molecules, the esters of saturated long chain fatty acids linked to fatty alcohols, are chemically stable and can withstand thermal stresses. The experimental evidence discussed in this report suggest that RBW degradation does not occur under the conditions encountered upon conventional industrial food frying. The findings also strongly suggest that very high temperatures (above 400°C) or extremely high number of fry-up cycles (above 280) are necessary to begin to induce RBW degradation. Since these conditions are never encountered upon industrial, retail, or domestic food manufacturing practices, it can be concluded that RBW stability will be maintained.

Terminology and abbreviations:
In this report, the word wax will be used as synonym of rice bran wax. The expressions “wax-oil blends” and “wax-oil gels” will be used interchangeably. The acronym “RBW” and “SFO” will be used as abbreviations for “rice bran wax” and “sunflower oil”, respectively.

1. Rice bran wax stability upon frying: Overview and rationale of the study

RBW thermal stability at high temperatures has received little attention. This study aims at filling such knowledge gap by assessing RBW chemical evolution and functionality following prolonged exposure to frying temperatures. Two samples were tested: (1) RBW added to SFO at a concentration of 0.15% (wt%) and (2) a control, i.e., neat SFO with no RBW added. These samples were used for potato frying at 175°C for up 280 fry-up cycles. Each fry-up (FU) cycle lasted five minutes, therefore RBW was exposed to a total of over 23h of continuous frying. These processing conditions are extreme and significantly more intense than those encountered on conventional industrial frying. These conditions were implemented to assess RBW stability upon extensive thermal stress simulating the absolute “worst-case scenario”.

RBW evolution upon exposure to extensive thermal stress was evaluated using a range of analytical techniques. This enabled gaining a thorough understanding of RBW physical and chemical stability at different length scales, ranging from the molecular composition to the macroscopic behavior. Results of the performed analyses are detailed in Sections 1.2, 1.3, 1.4, 1.5, and 1.6.

1.1. Preparation of samples

RBW type 224P was provided by Koster Keunen (US). Sunflower oil (SFO) – RBW blends were manufactured according to patent “WO2021064453 - OIL-WAX COMPOSITIONS AND USES OF OIL-WAX COMPOSITIONS FOR COOKING FOOD ARTICLES”. Briefly, the blends consisted of RBW added to SFO at a concentration of 0% (control) and 0.15% (wt%).

1.2. Chemical profile of wax-oil blends pre- and post-frying

RBW and SFO chemical composition was determined using gas chromatography coupled with flame ionization detector (Fig. 1). The chromatographic profile (upper panel in Fig. 1) confirmed that RBW is mostly composed of long chain wax monoesters, with a chain length ranging from 44 (C-44, 0.3%, wt%)

to 66 carbon unit (C-66, 0.1%, wt%) with the C-54 being the most abundant compound (20%, wt%). The analysis of fresh SFO (lower panel in Fig. 1) confirmed that triglycerides are, as expected, the major constituent with a minor fraction represented by diglycerides.

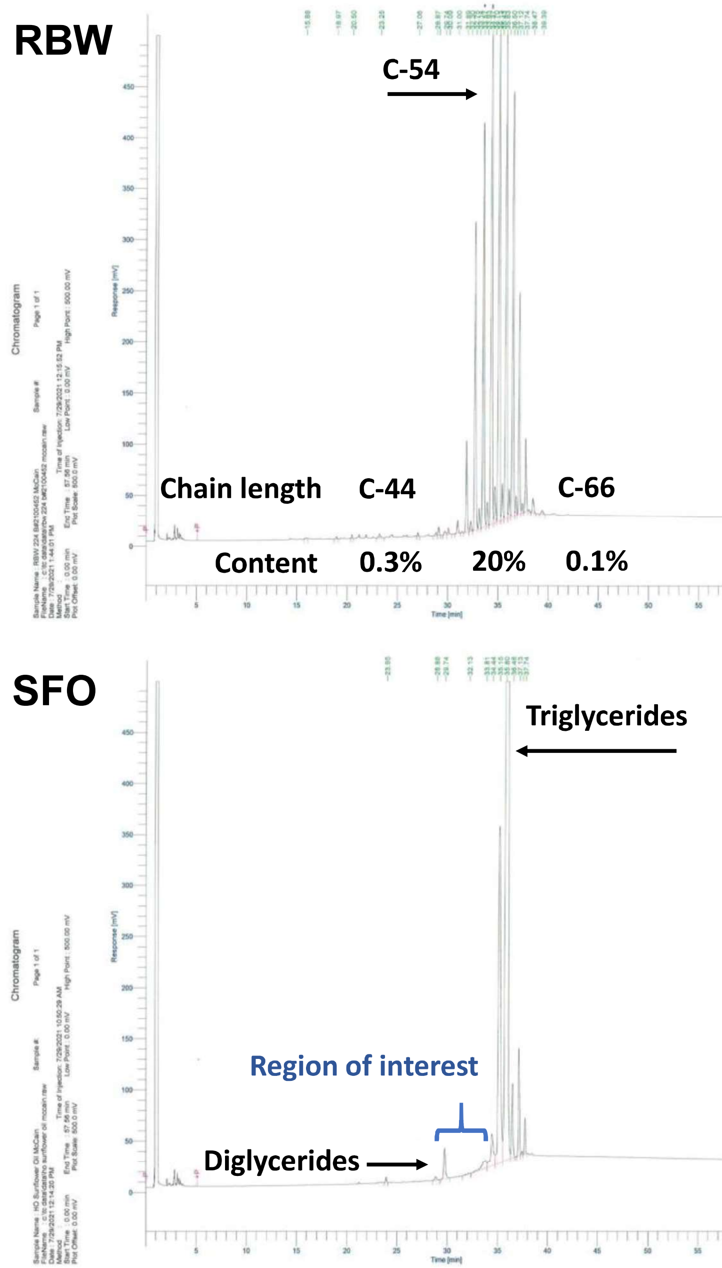

Figure 1: Chromatographic profile of RBW (upper panel) and SFO (lower panel). The main molecular components of both materials are indicated in each figure. The region of interest (in blues) is highlighted in the lower panel. Refer to text for details.

Comparison of the two chromatograms in Fig. 1 also revealed the existence of a separation region of interest where only RBW molecular constituents are present while none is observed for SFO (lower panel in Fig. 1). Since this fingerprint region accounts for molecules with shorter chain length (C48 and C50, see also Fig. 2), an increase in the size of peaks associated with these molecules would suggest degradation of RBW wax monoesters during frying.

The chromatograms in Figure 2 refer to the wax-oil blend with 0.15% RBW at 0 fry-up (i.e., no frying performed; left panel in Fig. 2) and 280 fry-ups (i.e., extensive thermal stress; right panel in Fig. 2), respectively. While the content of diglycerides significantly increased during the frying period, a negligible variation in the peaks size associated with C48 and C50 was observed, suggesting RBW remained stable.

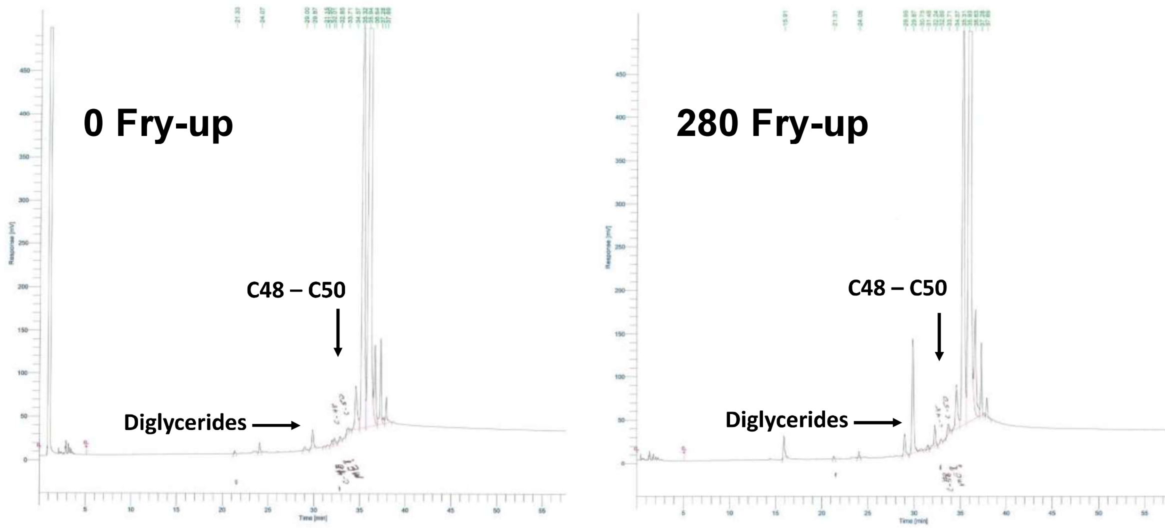

Figure 2: Chromatograms of 0.15% RBW in SFO at 0 fry-up (left hand side panel) and 280 fry-ups (right hand side panel). Only the peak associated with the diglycerides increased significantly upon prolonged frying (280 fry-ups).

1.3. RBW gel formation ability preserved on post-frying

RBW is an effective SFO gelator providing solid-like consistency and self-standing behavior to the liquid oil. This ability of RBW is due to its high wax-monoesters content (see Section 1.2). If these molecules were to degrade upon frying, a gel could no longer be formed. In this test, RBW ability to form a gel was assessed prior to and post frying. In Figure 3 two vials containing the wax-oil gels are shown. Vial "A" contains the gels produced by RBW prior to frying, while vial "B" contains the gel formed after 280 fry-ups. In both cases, a firm, self-standing gel is formed suggesting RBW molecular stability is retained upon extensive frying. The color difference between the two gels can be attributed to typical golden color formation of oils occurring upon frying and it does not affect RBW.

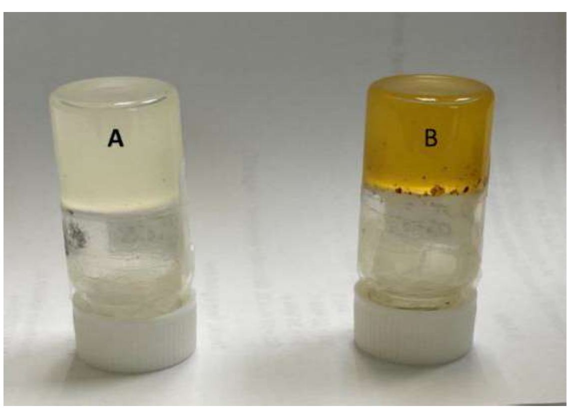

Figure 3: (A) Gel formed by RBW in SFO prior to frying. (B) Gel formed by RBW in SFO after 280 fry-up. The two gels appear comparable suggesting RBW molecular stability upon extensive frying.

1.4. Thermal gravimetric analysis of RBW and RBW-SFO blends.

Thermal gravimetric analysis (TGA) is an analytical technique which monitors the mass evolution of a sample subjected to a controlled temperature program. In this experiment, the oil-wax blends were heated at 10°C/min from 20 to 550°C in the open air, whilst monitoring the sample mass loss. This results from the volatilization of molecules within the samples with the peak temperatures representing a characteristic of constituting molecules. If upon frying the initial molecules were to degrade to form new species, the number and/or position of peaks would be expected to change.

In Figure 4a the degradation profile of pure RBW is shown. RBW displays a major peak at 445°C and a small shoulder peak at 459°C. This finding suggests that RBW begins to degrade at very high temperature. In Figure 4b the degradation profile of a 0.15% wax-oil blend at zero (black line) and 280 fry-ups (orange line) is shown. The two profiles overlay well, and both display four peaks suggesting that the sample remains stable during prolonged frying (i.e., 280 fry-ups). The values of the four peak temperatures are shown in Figure 4c.

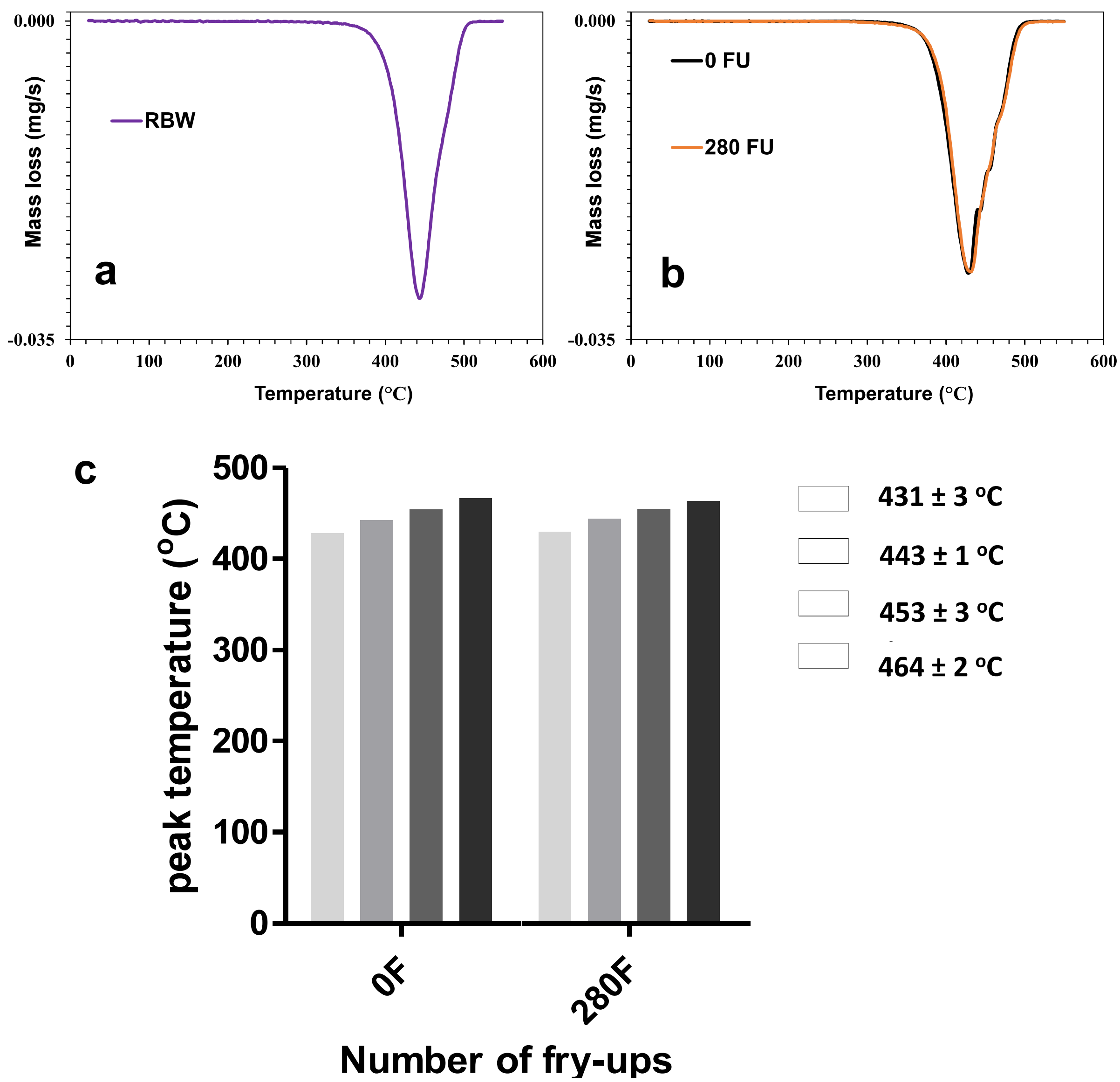

Figure 4: (a) TGA profile of RBW. (b) TGA profile of wax-oil blend after zero (0 FU) and 280 (280 FU) fry-ups. (c) Peak temperatures of the four main degradation peaks visible in panel b for both samples.

1.5. Differential scanning calorimetry analysis of RBW-SFO blends

Differential scanning calorimetry (DSC) is an analytical technique that measures the energy and temperature associated with the solid-to-melt phase transition of materials. Such transition depends on and reflects the molecular composition and interaction. In this study, DSC analysis was implemented to evaluate RBW temperature and enthalpy of melting. RBW is solid at ambient temperature; this is the property enabling the gel formation ability observed when blended in SFO (see Fig. 3). If any change in the RBW molecular composition would occur upon prolonged frying, this would determine a variation in the melting profile of the wax-oil blend. The melting behavior of samples was recorded at 10°C/min from 20 to 90°C. The melting profiles of a 0.15% wax-oil blend following 0 (black line) and 280 (orange line) fry-ups (FU) is shown in Figure 5, with the values of enthalpy, onset, and peak of melting compiled in Table 1.

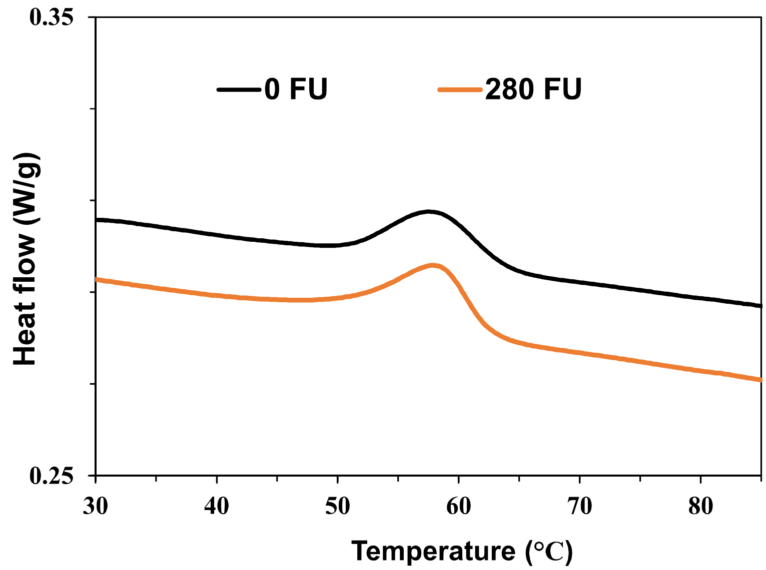

Figure 5: DSC melting profile of RBW-oil blend at 0 (black line) and 280 (orange line) fry-ups (FU).

The profiles in Figure 5 and the values in Table 1 are comparable for both samples suggesting RBW molecular degradation has not occurred during frying. These findings are consistent with those shown in Fig. 3, where RBW ability to form gels is retained after 280 fry-ups, and those shown in Fig. 4 where the TGA mass loss profile remains unchanged following frying.

Table 1: Values of enthalpy, onset, and peak of melting for wax-oil blends following 0 and 280 fry-ups (FU).

Sample	0 FU	280 FU
Enthalpy (J/g)	0.54	0.56
Onset temperature (°C)	50.78	49.44
Peak temperature (°C)	58.08	58.25

1.6. High-performance thin layer chromatographic analysis of wax-oil blends

To gain a deeper insight on the chemical profile evolution of wax-oil blends upon frying, thin layer chromatographic analysis of samples was implemented. Thin layer chromatography (TLC) is a chromatographic technique to separate the components of a chemical mixture using a thin solid stationary phase and a mobile liquid phase. The separation results from the relative affinity of each component for the stationary and the mobile phase, which affects extent and rate of migration. In this study high-performance thin layer chromatography (HP-TLC) was used. This technique allows to reproducibly deposit the desired volume of sample and to analyze the compounds migration and band intensity using the software operating the device (details on the preparation of materials, procedure, and device in Appendix 1). This enables to obtain semiquantitative data of wax-monoester content.

In Figure 6 the molecular bands obtained after the TLC separation for the samples are shown. The analyzed samples were (from left to right): (1) lipid standard, (2) RBW, RBW-oil blend at 0.15% concentration and after (3) zero, (4) 60, (5) 100, (6) 160, (7), 280 fry-ups (FU). The bands associated with each molecular class are clearly labelled in Fig. 6. Furthermore, for this analysis the samples obtained at intermediate number of fry-ups (i.e., 60, 100, 160 FU) were investigated to gain a deeper insight on wax-monoesters evolution upon frying.

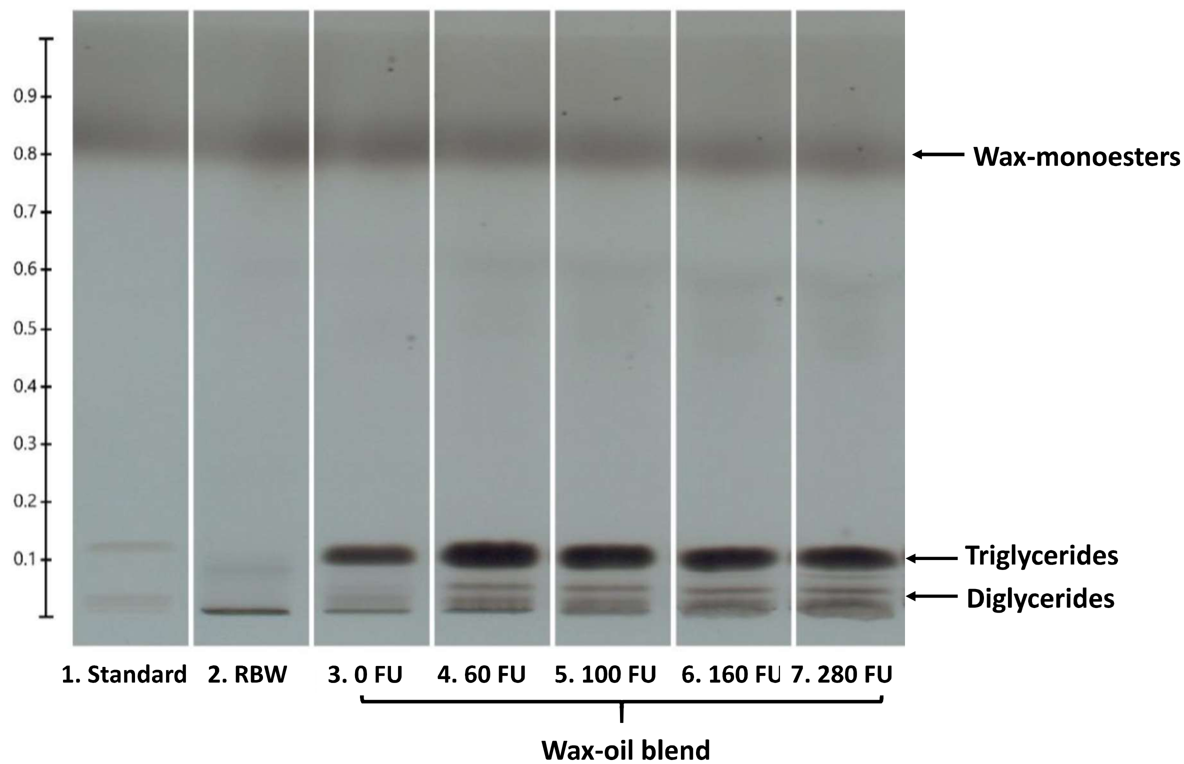

Figure 6: HP-TLC separation profile of molecular constituents displaying clearly separated bands. The name tags are used to highlight the di- and triglycerides and the wax-monoester bands, respectively. Peak intensity profile was analysed for samples of (from top to bottom): (1) Lipid standard, (2) RBW, wax-oil blend after (3) zero, (4) 60, (5) 100, (6) 160, (7), 280 fry-ups (FU).

The separated bands were digitally analyzed using the device software to obtain the profile shown in Figure 7. The dotted and dashed lines are used to highlight the di- and triglycerides and the wax-monoester bands, respectively. From these profiles it is possible to integrate the peaks to quantify the wax-monoesters content as a result of number fry-ups.

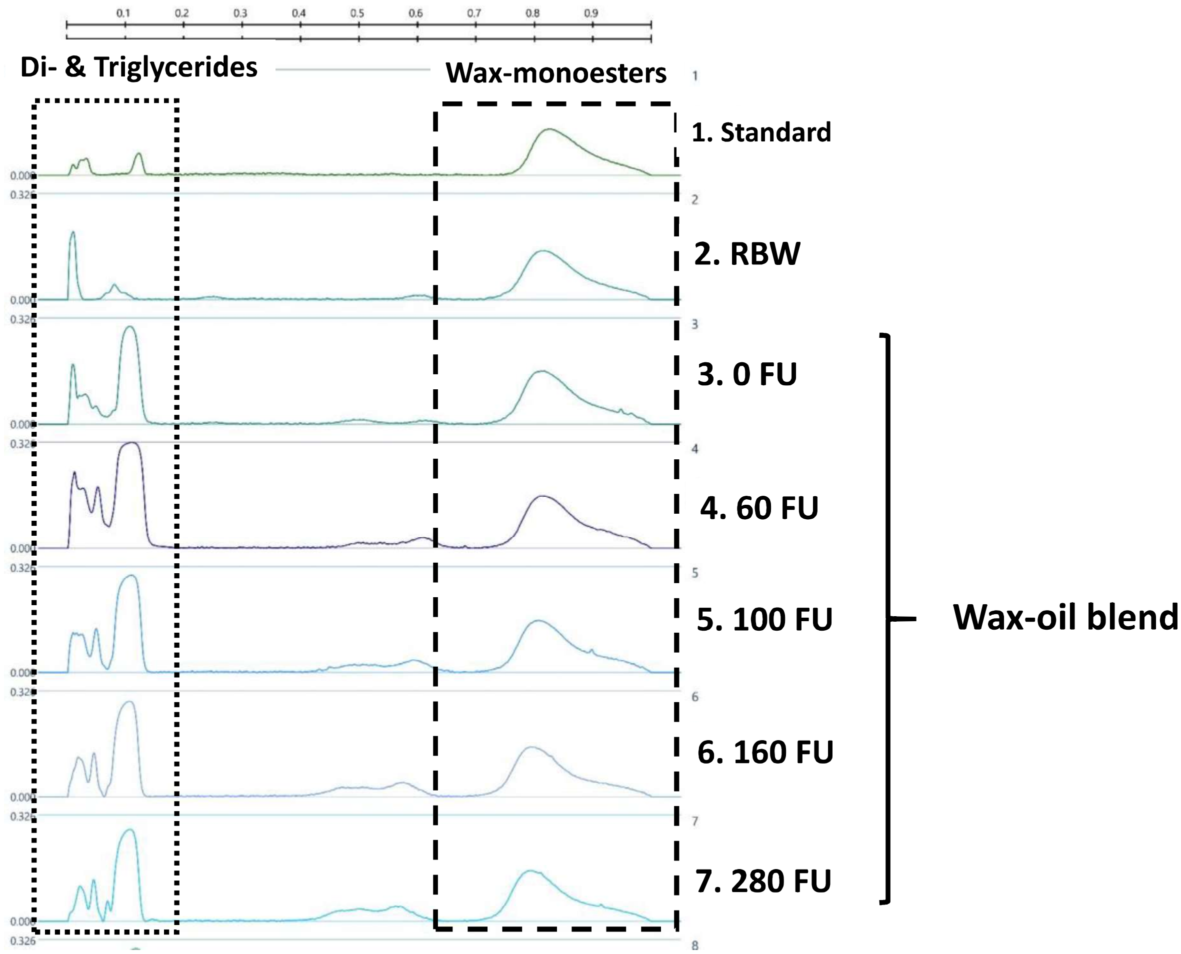

Figure 7: Peak intensity profile of bands separated using HP-TLC. The dotted and dashed lines are used to highlight the di- and triglycerides and the wax-monoester bands, respectively. Peak intensity profile was analysed for samples of (from top to bottom): (1) Lipid standard, (2) RBW, wax-oil blend after (3) zero, (4) 60, (5) 100, (6) 160, (7), 280 fry-ups (FU).

The concentration of the wax-monoesters for each sample were calculated using Equation 1 and expressed as percentage relative values:

$$\text{Wax-monoester (\%)} = \frac{Area\ of\ the\ peak\ at\ any\ FU}{Area\ of\ the\ peak\ at\ 0\ FU} \text{ x } 100\% \qquad \text{(Eq. 1),}$$

Where "area of the peak at any FU" is the area of the wax-monoester peak at any fry-up (FU) number while the "area of the peak at 0 FU" is the area of the wax-monoester peak at zero fry-up (FU). The wax-monoesters concentration at 60, 100, 160, 280 FU was equivalent to 97%, 94%, 93%, 96% of the concentration initially, i.e., at zero fry up. These data strongly suggest that wax monoesters remain stable upon prolonged frying and extensive thermal stress.

2. Conclusions

In this study. the stability of RBW added to SFO to form a wax-oil blend was assessed under prolonged and extensive thermal stress upon frying. The findings of this work suggest that RBW is able to withstand thermal stresses without undergoing molecular degradation with subsequent formation of new molecular species. The different analytical techniques implemented to complete this study allowed to gain a good insight of such stability at different length-scales: from macroscopic behavior (RBW preserved ability to form gels after 280 fry-ups) to the molecular packing (comparable melting and TGA profile between fresh and fried samples), to the molecular composition as determined through gas chromatography and high-performance thin layer chromatography.

Appendix 1

High-Performance Thin Layer Chromatography (HPTLC)

Due the low RBW content (0.15, wt%) in the studied wax-oil blend, it was necessary to implement an intermediate step prior to the analysis. This was to separate the wax from the oil allowing to visualize the bands associated with the RBW components. The separation was performed by refluxing the wax-oil blends with hexane at 55°C to disrupt the gel structure and separate the wax from the oil. After the refluxing (30 minutes), the sample wax allowed to rest for two hours at 4 °C prior to centrifugation. This procedure was repeated twice per each sample at all fry-up times.

To separate compounds using TLC, thin layer silica gel 60 F254 glass TLC plates (20x20 cm) from Merck were used. The lipid standard mix (consisting of Monoolein (MAG), 1,2-Dioleoyl-rac-glycerol (1,2-DAG), 1,3-Diolein (1,3-DAG) and TAG), wax and oil samples were diluted in chloroform and applied on a TLC plate using a Linomat V (Camag, Switzerland) sample applicator. Based on an optimization pre-study, a volume equal to 10 μL was applied on the plate for all samples. To ensure complete dispersion, all wax samples were heated in sealed containers for 1 min at 40°C before applying to the TLC plate. Chromatograms were developed to 100 mm in a glass chamber (Camag, Switzerland) saturated with a mobile phase, which consisted of hexane: diethyl ether: glacial acetic acid (90:10:1, v/v/v). To identify wax esters, plates were immersed in 10 g cupric sulphate in 100 mL 8% phosphoric acid solution for 2 minutes. When dried, plates were charred in the oven for up to 5 min at 150˚C, until dark brown ester spots were visible. Developed plates were scanned under white light and UV light at 366 nm using TLC Visualizer 2 (Camag, Switzerland) and analyzed with VisionCATS version 2.5 software (Camag, Switzerland). Wax ester spots were identified, comparing retention factor (Rf) to results from literature (Holloway & Challen, 1966; Hwang, Cuppett, Weller, Hanna, & Shoemaker, 2002; Sarkisyan et al., 2021; Vali, Ju, Kaimal, & Chern, 2005).

The retention factor (Rf) is equal to the distance a compound migrated on the plate over the total distance covered by the solvent. Rf is unique for each compound. Therefore, when comparing two or more samples under the same condition, the same compound in different samples will have the same Rf value.

HPTLC References

Holloway, P. J., & Challen, S. B. (1966). Thin layer chromatography in the study of natural waxes and their constituents. Journal of Chromatography A, 25(C), 336–346. https://doi.org/10.1016/S0021-9673(01)98251-2

Hwang, K. T., Cuppett, S. L., Weller, C. L., Hanna, M. A., & Shoemaker, R. K. (2002). Aldehydes in grain sorghum wax. Journal of the American Oil Chemists' Society, 79(6), 529–533. https://doi.org/10.1007/S11746-002-0516-4

Sarkisyan, V., Sobolev, R., Frolova, Y., Malinkin, A., Makarenko, M., & Kochetkova, A. (2021). Beeswax Fractions Used as Potential Oil Gelling Agents. Journal of the American Oil Chemists' Society, 98(3), 281–296. https://doi.org/10.1002/AOCS.12451

Vali, S. R., Ju, Y. H., Kaimal, T. N. B., & Chern, Y. T. (2005). A process for the preparation of food-grade rice bran wax and the determination of its composition. JAOCS, Journal of the American Oil Chemists' Society, 82(1), 57–64. https://doi.org/10.1007/s11746-005-1043-z.