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SCIENTIFIC OPINION

Safety assessment of the substances 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt' for use in food contact materials

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Abstract

The EFSA Panel on Food Contact Materials (FCM) assessed the safety of the substances 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt', used as additives up to 0.3% in polyethylene terephthalate (PET), polyamide (PA), thermoplastic polyurethane (TPU), polylactic acid (PLA) and poly(vinyl chloride) (PVC) in contact with all food types for long-term storage at room temperature and below, after hot-fill and/or heating. The substances consist of the chemical classes wax esters, carboxylic acids, alcohols and calcium salts of acids, along with an unidentified organic fraction up to [redacted] w/w. Migration into 10% ethanol and 4% acetic acid was below 0.012 mg/kg for each chemical class, and about 0.001 mg/kg for the unidentified fraction. In isooctane, migration was up to 0.297 mg/kg food for wax esters, below 0.01 mg/kg food for the other chemical classes and about 0.02 mg/kg food for the unidentified fraction. The contact with dry food and food simulated by 20% ethanol were considered covered by the migration tests with aqueous simulants. Based on genotoxicity assays and compositional analyses, the constituents of the chemical classes did not raise a concern for genotoxicity. The potential migration of individual constituents or groups of chemically-related compounds of the unidentified fraction would result in exposures below (for aqueous food) and above (for fatty food) the threshold of toxicological concern for genotoxic carcinogens. Therefore, the FCM Panel concluded that the substances are not of safety concern for the consumer, if used as additives up to 0.3% w/w in PET, PLA and rigid PVC materials and articles intended for contact with all food types except for fatty foods, for long-term storage at room temperature and below, including hot-fill and/or heating up to 100°C for up to 2 h.

KEYWORDS

additive, CAS no. 1883583–80-9 and 1850357–57-1, FCM substance no. 1093, food contact materials, safety assessment, 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt'

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1 | INTRODUCTION

1.1 | Background and Terms of Reference

Before a substance is authorised to be used in food contact materials (FCM) and is included in a positive list EFSA's opinion on its safety is required. This procedure has been established in Articles 8, 9 and 10 of Regulation (EC) No 1935/2004[1] of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States' competent authorities which transmit the applications to the European Food Safety Authority (EFSA) for their evaluation.

In this case, EFSA received an application from the German competent authority (Federal Office of Consumer Protection and Food Safety), requesting the evaluation of the substance 'Wax, rice bran, oxidized' and 'Wax, rice bran, oxidized, partially saponified', with the CAS numbers 1883583-80-9 and 1850357-57-1, respectively, and FCM number 1093. The dossier was submitted on behalf of Clariant Produkte GmbH, Germany.

According to Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food, EFSA is asked to carry out an assessment of the risks related to the intended use of the substance and to deliver a scientific opinion.

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant has submitted a confidential and a non-confidential version of the dossier in support of their application for the authorisation of 'Wax, rice bran, oxidised' and 'Wax, rice bran, oxidised, partially saponified' to be used in plastic FCM.

Additional information was provided by the applicant during the assessment process in response to requests from EFSA sent on 16 February 2023 (see 'Section 5').

In accordance with Art. 38 of the Commission Regulation (EC) No 178/2002[2] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation and of the Decision of the EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[3] the non-confidential version of the dossier is published on Open.EFSA.[4]

According to Art. 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,[5] EFSA carried out a public consultation on the non-confidential version of the application from 6 to 27 June 2024, for which no comments were received.

Data submitted and used for the evaluation are:

Non-toxicological data and information

- Chemical identity
- Description of manufacturing process of the substances
- Physical and chemical properties
- Intended uses
- Migration of the substance
- Residual content of the substance
- Identification, quantification and migration of impurities

Toxicological data

- Bacterial gene mutation test
- In vitro mammalian cell gene mutation test
- In vitro mammalian chromosome aberration tests
- In vivo mammalian erythrocyte micronucleus tests
- In vitro chromosome aberration test
- 90-day oral toxicity studies in rats
- Reproduction/developmental toxicity screening test in rats
- Reasoning on accumulation potential

[1]Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

[2]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

[3]Decision https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

[4]The non-confidential version of the dossier, following EFSA's assessment of the applicant's confidentiality requests, is published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/FCM-2022-4638.

[5]Decision https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf.

2.2 | Methodologies

The assessment was conducted in line with the principles laid down in Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. This Regulation underlines that applicants may consult the Guidelines of the Scientific Committee on Food (SCF) for the presentation of an application for safety assessment of a substance to be used in FCM prior to its authorisation (European Commission, 2001), including the corresponding data requirements. The dossier that the applicant submitted for evaluation was in line with the SCF guidelines (European Commission, 2001).

The methodology is based on the characterisation of the substances that is/are the subject of the request for safety assessment prior to authorisation, its impurities and reaction and degradation products, the evaluation of the exposure to those substances through migration and the definition of minimum sets of toxicity data required for safety assessment.

To establish the safety from ingestion of migrating substances, the toxicological data indicating the potential hazard and the likely human exposure data need to be combined. Exposure is estimated from studies on migration into food or food simulants and considering that a person may consume daily up to 1 kg of food in contact with the relevant FCM.

As a general rule, the greater the exposure through migration, the more toxicological data is required for the safety assessment of a substance. Currently there are three tiers with different thresholds triggering the need for more toxicological information as follows:

a. In case of high migration (i.e. 5–60 mg/kg food), an extensive data set is needed.
b. In case of migration between 0.05 and 5 mg/kg food, a reduced data set may suffice.
c. In case of low migration (i.e. < 0.05 mg/kg food), only a limited data set is needed.

More detailed information on the required data is available in the SCF guidelines (European Commission, 2001).

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3 | ASSESSMENT

According to the applicant, the substances 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, partially saponified' are intended to be used as additives at a maximum use level of 0.3% w/w in polyethylene terephthalate (PET), polyamides (PA), thermoplastic polyurethane (TPU), polylactic acid (PLA) and poly(vinyl chloride) (PVC). The final articles are intended for contact with all types of food for long term storage at room temperature, including hot-fill. The contact with infant formulae and human milk was not specified as intended application of the substances.

According to the applicant, the substances are used as processing aids, lubricants, release agents or slip additives. Their main function is to improve the ease of flow of the melt during processing of plastics by preventing internal friction between particles of the polymer.

The Panel noted that the name 'wax, rice bran, oxidised, partially saponified' may be misunderstood. Based on the information provided by the applicant and on the available compositional data (Section 3.1.1), the Panel noted that the treatment with calcium hydroxide primarily forms the calcium salts of the carboxylic acids, but can additionally result in ester cleavage (i.e. saponification) at the high temperature of the manufacturing process. Furthermore, the name proposed by the applicant did not indicate the corresponding cation. Therefore, the Panel recommended the alternative names 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt'.

The substances have not been evaluated in the past by the SCF or EFSA.

3.1 | Non-toxicological data[6]

3.1.1 | Identity of the substance

3.1.1.1 | *Manufacturing process*

'Wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt' are non-defined mixtures which, according to the applicant, are produced from crude rice bran wax (RBW) obtained by 'crystallisation' (actually a precipitation) from rice bran oil that is also being sold for human consumption. The applicant specified crude RBW as having a melting point of 70–80°C and a remaining oil content < 20%, but did not report its composition. Based on literature, the composition of crude RBW may vary greatly depending, e.g. on the production process used to prepare it from rice bran oil. Crude RBW is reported to largely consist of linear wax esters with minor proportions of fatty alcohols, acids and hydrocarbons. Indicatively, Yoon and Rhee (1982) reported wax esters with a carbon number in the range C40–C64, with the most abundant ones being saturated and in the range C46–C56. A minor proportion of wax esters was reported to be unsaturated. The fraction of

[6]Technical report, section 'Identity of Substance'.

branched acids and alcohols is expected to be negligible due to the composition of the rice brain oil from which the wax is obtained and due to the crystallisation process, which favours the incorporation of linear over branched species.

To manufacture 'wax, rice bran, oxidised', the crude RBW is oxidised [redacted]. To obtain 'wax, rice bran, oxidised, calcium salt', the process includes an additional step [redacted].

3.1.1.2 | *Method used for the compositional analysis*

The applicant submitted detailed composition data of commercial products representing 'wax, rice bran, oxidised' (Licocare RBW 101, 102 and 106) and 'wax, rice bran, oxidised, calcium salt' (Licocare RBW 300, 330 and 360) (Table 1).

The composition was determined by gas chromatography-flame ionisation detection (GC-FID) after derivatisation with *N*-methyl-*N*-(trimethylsilyl)trifluoroacetamide (silylation) or diazomethane (esterification). The applicant quantified and identified the individual constituents by carbon number range and main functional groups (i.e. esters, carboxylic acids, alcohols, calcium salts).

Based on mass balance calculations, a fraction of the analysed samples could not be detected by the applied method [redacted]. This was attributed by the applicant to high molecular weight (MW) wax esters that were not amenable to the GC–FID method used. The Panel considered this explanation reasonable and supported by the raw data of the analysis, which showed that for some samples only esters up to C59 were detected, while for other samples esters up to C66 were detected.

To determine the whole fraction of wax esters, the applicant performed an additional analysis adapting the method described above by treating the samples with [redacted] prior to derivatisation, resulting in the complete hydrolysis of the wax esters to the corresponding shorter chain carboxylic acids and alcohols, which were all amenable to GC-FID after derivatisation. For this second analysis, the applicant reported the fraction of the various chemical classes. The difference between the quantity of carboxylic acids and alcohols determined in the two analyses was used to calculate the total quantity of wax esters. The difference between this total quantity of wax esters and the wax esters amenable to the direct GC–FID analysis was used in turn to quantify the high MW wax esters that were not measured in the direct analysis. The Panel considered the approach used to measure the composition appropriate.

3.1.1.3 | *Composition of the substances*

The composition varies depending on the manufacturing process (i.e. the extent of oxidation, neutralisation/saponification, bleaching; see Section 3.1.1.1). Based on the two analyses, the products consist of wax esters (in proportions from 39.8% to 90.9% w/w), carboxylic acids (from 4.6% to 56.4% w/w), alcohols (from 0.4% to 4.7% w/w) and calcium salts of carboxylic acids (from 13% to 46% w/w) (Table 1). For the chemical class of carboxylic acids, the applicant additionally reported the fraction of mono-, di- and hydroxy carboxylic acids.

The oxidation of crude RBW cleaves wax esters to alcohols and carboxylic acids, and oxidises alcohols to carboxylic acids. It additionally cleaves double bonds, generating shorter chain mono- and dicarboxylic acids as well as low amounts of hydroxy carboxylic acids. [redacted], the acid content increases and the wax ester content decreases from Licocare RBW 101 to 102 to 106 and from Licocare RBW 300 to 330 to 360. Similarly, the fraction of calcium salts increases from Licocare RBW 300 to 330 to 360 [redacted].

The substances detected but not identified in the first GC-FID analysis were reported as 0.66 to 2.9% w/w. The applicant identified chromium (up to 5 mg/kg) and 'ashes' (from [redacted] to [redacted] w/w) as impurities. The calcium fraction in the 'wax, rice bran, oxidised, calcium salt' products was reported to be from 1.4% to 4.0% w/w.

Additionally, the applicant provided the ranges of composition specified for each chemical class (Table 2).

TABLE 1 Composition of the 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt' products by chemical class, based on GC-FID analysis (provided by the applicant).

Chemical class			'Wax, rice bran, oxidised'			'Wax, rice bran, oxidised, calcium salts'		
			Licocare RBW 101	Licocare RBW 102	Licocare RBW 106	Licocare RBW 300	Licocare RBW 330	Licocare RBW 360
Wax esters (% w/w)			**90.91**	**72.95**	**39.77**	**70.3**	**65.3**	**41.8**
Calcium salts of carboxylic acids (% w/w)			–	–	–	**13.03**	**18.6**	**46**
Carboxylic acids (% w/w)	**Short chain (≤ C_{11})**	Carboxylic	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
		Dicarboxylic	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
		Hydroxy carboxylic	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
		Total	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Medium chain (C_{12}–C_{18})	Carboxylic	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
		Dicarboxylic	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
		Hydroxy carboxylic	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
		Total	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Long chain (≥ C_{19})	Carboxylic	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
		Dicarboxylic	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
		Hydroxy carboxylic	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
		Total	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	Total carboxylic acids (% w/w)		**8.03**	**25.14**	**56.41**	**12.51**	**10.2**	**4.6**
Alcohols (% w/w)			**0.4**	**1.22**	**0.85**	**1.92**	**4.0**	**4.7**
Unknown organic compounds (% w/w)			0.66	0.69	2.6	2.24	1.9	2.9
Total chromium (mg/kg)			1	< 2	3	5	< 1	< 1
Chromium (VI) (µg/kg)			< 10	< 10	< 10	< 10	< 10	< 10

Note: The fractions corresponding to each chemical class are reported with bold text.
Abbreviation: n.d., not detected.

TABLE 2 Ranges of composition of 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt' by chemical class (provided by the applicant).

Chemical class			'Wax, rice bran, oxidised'	'Wax, rice bran, oxidised, calcium salt'
Wax esters (% w/w)			[redacted]	[redacted]
Calcium salts of carboxylic acids (% w/w)			[redacted]	[redacted]
Carboxylic acids (% w/w)	**Short chain (≤ C_{11})**	Carboxylic	[redacted]	[redacted]
		Dicarboxylic	[redacted]	[redacted]
		Hydroxy carboxylic	[redacted]	[redacted]
		Total	[redacted]	[redacted]
	Medium chain (C_{12}–C_{18})	Carboxylic	[redacted]	[redacted]
		Dicarboxylic	[redacted]	[redacted]
		Hydroxy carboxylic	[redacted]	[redacted]
		Total	[redacted]	[redacted]
	Long chain (≥ C_{19})	Carboxylic	[redacted]	[redacted]
		Dicarboxylic	[redacted]	[redacted]
		Hydroxy carboxylic	[redacted]	[redacted]
		Total	[redacted]	[redacted]
Alcohols (% w/w)			[redacted]	[redacted]
Unknown organic compounds (% w/w)			[redacted]	[redacted]
Total chromium (mg/kg)			[redacted]	[redacted]

Note: The fractions corresponding to each chemical class are reported with bold text.

3.1.1.4 | *Identity of the individual constituents*

The individual constituents of the substances were identified from the first GC–FID analysis (i.e. without the hydrolysis step). Wax esters were in the carbon number range [redacted] (depending on the analysed product, see Section 3.1.1.2),

with the most abundant ones being [redacted] (up to about [redacted] w/w [redacted] in Licocare RBW 101). The most abundant carboxylic acids were in the carbon number range [redacted], with the most abundant one typically being [redacted] (up to about [redacted] w/w in Licocare RBW 106). Finally, the most abundant alcohol was [redacted] (up to about [redacted] w/w in Licocare RBW 360). The MW of the large majority of the individual constituents was below 1000 Da.

The applicant did not identify the structure of the individual constituents in terms of unsaturation and additional functional groups (i.e. other than those defining the chemical classes). Only for the class of carboxylic acids, the fractions of mono-, di- and hydroxy carboxylic acids were identified. The Panel expected that wax esters containing double bonds, which are present in minor proportion in the crude RBW (Section 3.1.1), are largely cleaved during the oxidation treatment applied to manufacture 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt'.

3.1.1.5 | *Unidentified fraction and impurities*

The applicant did not elaborate on the composition and the potential identity of the constituents of the unidentified fraction, which could be potentially up to [redacted] w/w (Table 2) and was found to be from 0.66 to 2.9% w/w in the analysis of the tested samples (Table 1). The content of this fraction in the substances was determined by considering the unassigned peaks that were eluted before the C40 ester in the chromatograms of the first GC–FID analysis (Section 3.1.1.3). The Panel assumed that the unidentified fraction consisted of hydrocarbons, reported to be about 1.0% w/w, and other minor natural compounds from the rice bran oil, such as squalene, partially hydrolysed triglycerides, sterols, sterenes and their oxidation products. The unidentified compounds that were eluted after the C40 ester were not included in the unidentified fraction because they were attributed to the chemical class of wax esters, which was considered a reasonable assumption by the Panel.

The applicant reported a level of total chromium up to 5 mg/kg and of hexavalent chromium Cr(VI) below 10 µg/kg. Considering the maximum use level of 0.3% of the substances in plastics, the levels of total chromium and Cr(VI) in PET would be up to 15 µg/kg and below 30 ng/kg, respectively. Therefore, the expected migration of chromium into food is expected to be well below 10 µg/kg food, which is the level used for showing compliance as required by Reg. (EU) 10/2011.[7]

The purity of the analysed samples (Table 1) was reported as > 99.6%, which was calculated by subtracting the ash fraction from 100%.

3.1.2 | Physical and chemical properties[8]

The melting points, determined by differential scanning calorimetry (DSC) under nitrogen, were ca. 75°C for Licocare RBW 106 and ca. 79°C for Licocare RBW 300.

A significant decomposition or evaporation occurred at 471°C for Licocare RBW 106 and at 391°C for Licocare RBW 300. Therefore, the substances are expected to be thermally stable at the maximum processing temperature of PET (320°C), i.e. the plastic used in migration testing (Section 3.1.3). The substances are also expected to be thermally stable in PA, TPU, PLA and PVC, which are generally processed at similar or lower temperatures than PET.

The solubility in water was reported to vary between 2 and 21 mg/L for Licocare RBW 300, however, the Panel noted that the overall solubility of a multi-component mixture has little meaning as the substances are made of various constituents of very different polarity.

3.1.3 | Specific migration[9]

3.1.3.1 | *Tested samples and testing conditions*

Migration tests were conducted using Licocare RBW 102 and Licocare RBW 300 as representative products. The Panel considered Licocare RBW 102 as sufficiently representative of 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt' with respect to the overall composition, because the proportions of the main chemical classes (i.e. wax esters, carboxylic acids and alcohols) are roughly the middle value in the overall range of composition (please compare Table 1 with Table 2). Licocare RBW 300 is the calcium salt with the closest composition to Licocare RBW 102 and was considered suitable to determine whether the presence of calcium salts influences migration.

The specific migration was determined using 250-µm thick PET sheets manufactured at the maximum use level of 0.3% w/w. The test samples were found to contain slightly less than the added level (0.26 and 0.27% w/w for Licocare RBW 102 and Licocare RBW 300, respectively). The Panel considered the samples suitable.

[7]European Commission. Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. Official Journal of European Union, 14.1.2011, 12, pp. 1–89.

[8]Technical report, section 'Physical and Chemical Properties of Substance'.

[9]Technical report, section 'Data on Migration of Substance'.

Migration tests were conducted with the food simulants 10% ethanol, 4% acetic acid (for 2 h at 70°C followed by 10 days at 60°C), 95% ethanol (for 2 h at 70°C followed by 10 days at 40°C) and isooctane (for 4 h at 70°C followed by 10 days at 60°C). The migration was determined with a GC–FID method like the one used for the determination of the composition (without the hydrolysis step, see Section 3.1.1) and reported for each chemical class. The method was able to measure the migration of the fraction of the substance below 1000 Da.

The applicant did not provide migration data for the other polymers in which the substance is intended to be used (PA, TPU, PLA, PVC).

3.1.3.2 | *Migration of the various chemical classes*

For the aqueous simulants (10% ethanol and 4% acetic acid), the applicant reported a migration of the individual constituents of each class below the limit of quantification (LoQ) of 10 μg/kg, which corresponded to the lowest standard used in the calibration curve. The Panel noted that the constituents of each class were not detected. The analysis of the food simulants was validated by the analysis of a mixture of surrogate substances that were available as analytical standards and were considered to be representative of the different chemical classes of the additives.

Based on the concentration of the lowest standard for the wax ester surrogate (i.e. 10 μg/kg for the C56 ester) and on the raw data on calibration and migration analysis provided, the Panel estimated that the limit of detection (LoD) of the individual wax esters was in the region of 2 μg/kg for the analysis in the aqueous food simulants. Considering that the migration of wax esters into isooctane is essentially due to seven wax esters (C46–C58) having a similar migration and that a similar pattern is expected for the other simulants, the LoD was estimated to be around 12 μg/kg for the sum of the wax esters. Therefore, the migration of the sum of the wax esters in the aqueous food simulants was estimated to be below 12 μg/kg. The migration of the other chemical classes was estimated to be below the migration of the wax esters based on the raw data provided.

For fatty food simulants, the migration test into isooctane was considered more representative than that into 95% ethanol, as 95% ethanol is known to swell PET and to lead to an overestimation of migration potential. The migration of the wax esters class into isooctane was 297 and 257 μg/kg for Licocare RBW 102 and Licocare RBW 300, respectively. Regarding the other classes (carboxylic acids and alcohols), the migration of the sum of constituents of each class was below the LoD of 10 μg/kg (recalculated by the Panel as for the tests with aqueous simulants).

3.1.3.3 | *Migration of unidentified organic compounds*

The migration of the sum of the unidentified organic compounds into isooctane was estimated by the Panel to be around 20 μg/kg, assuming a pro-rata migration to the wax ester class (i.e. the chemical class the highest specific migration, 297 μg/kg) and considering the relative proportions of unidentified organic compounds (up to [redacted] w/w) and wax esters (72.95% w/w) in the substance. Similarly, the migration of the sum of the unidentified organic compounds into aqueous simulants was estimated by the Panel to be around 1 μg/kg based pro-rata on the migration of the wax esters class below the LoD of ca. 12 μg/kg food.

3.2 | Toxicological data[10]

As the specific migration of the substance in fatty food simulants exceeded 0.05 mg/kg food, in accordance with the EFSA Note for Guidance for Food Contact Materials (EFSA, 2008), the applicant provided a battery of genotoxicity studies, 90-day oral toxicity studies, data to demonstrate the absence of potential for accumulation in humans and reproduction/developmental toxicity screening tests.

Licocare RBW 106 and Licocare RBW 300 were selected by the applicant as representative substances for 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt', respectively, and were used as test items in the toxicity studies. The Panel considered that Licocare RBW 106 and Licocare RBW 300 are acceptable choices as representative test items as the proportions of the various chemical classes reasonably cover the ranges of composition. For Licocare RBW 106 and 300, the content of wax esters was 39.4 and 70.3% w/w, respectively (range: [redacted] w/w); for acids: 56.4 and 12.51% w/w, respectively (range: [redacted] w/w for long-chain acids); for alcohols: 0.85 and 1.92% w/w, respectively (range: [redacted] w/w); for calcium salts: 0% and 13.03% w/w, respectively (range: [redacted] w/w); unidentified organic compounds: 2.6 and 2.24% w/w, respectively (range: [redacted] w/w). The test items were also acceptably representative of the composition of the migrate from the tested plastics: in isooctane the migration was up to 297 μg/kg for wax esters and below the LoD of 10 μg/kg for carboxylic acids and alcohols (Section 3.1.3).

[10]Technical report, section 'Toxicological data'.

3.2.1 | Genotoxicity

3.2.1.1 | *Licocare RBW 106*

3.2.1.1.1 | *Bacterial reverse mutation test*

Licocare RBW 106 ([redacted], purity 99.63%) was tested in a bacterial reverse mutation test (Ames test) according to the Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 471 (OECD, 1997a) and following Good Laboratory Practice (GLP). Four strains of Salmonella Typhimurium (TA98, TA100, TA1535 and TA1537) and *Escherichia coli* WP2*uvrA* pKM101 were used. Two separate experiments in triplicate were performed: a plate incorporation method followed by a pre-incubation method both in the absence and presence of S9-mix. The test item was homogeneously suspended in dimethyl sulfoxide (DMSO). Based on the results of the dose range-finding study, Licocare RBW 106 was tested up to the limit of solubility at the concentrations of 17, 52, 164, 512 and 1600 µg/plate. The test item precipitated on the plates at the top dose of 1600 µg/plate in both experiments. In the first experiment, no toxicity was reported. In the second experiment, toxicity was observed in *S.* Typhimurium strains at the highest concentration tested in the absence of S9-mix with an extreme reduction of the number of revertants in strains TA100 and TA1537 (only microcolonies were present) and a moderate reduction in strains TA98 and TA1535. No biologically relevant increase in the number of revertant colonies above the control values was observed, in any strain tested both with or without S9-mix. The study was considered reliable without restrictions and the negative results were considered of high relevance.

3.2.1.1.2 | *In vitro mammalian cell gene mutation test*

Licocare RBW 106 ([redacted], purity 99.63%) was evaluated for gene mutation test in CHO AA8 cells using the Hprt assay, according to OECD TG 476 (OECD, 1997b) and following GLP. The test item was suspended in acetone. The precipitation was tested up to 2 mg/mL. After 4 h of incubation, heavy precipitation was observed at 2 mg/mL. A cytotoxicity test was conducted at the concentrations of 0.03125, 0.0625, 0.125, 0.25 and 0.5 mg/mL for 3 h in the presence and absence of metabolic activation. The results of the cytotoxicity test indicated that the relative survival rate at 0.5 mg/mL was greater than 20% when compared with the respective vehicle control, both in the presence and absence of S9-mix. Based on the results of a range-finding study, the gene mutation test was conducted at the concentrations of 0.0625, 0.125, 0.25 and 0.50 mg/mL for 4 h in the presence and absence of S9-mix. No statistically significant increase in mutant frequencies was observed at any of the concentrations tested when compared with the vehicle control. The test item was considered as non-mutagenic up to the concentration of 0.5 mg/mL, both in the presence and absence of metabolic activation under the tested laboratory conditions. The study was considered reliable without restrictions and the negative results were considered of high relevance.

3.2.1.1.3 | *In vitro mammalian chromosomal aberration test*

Licocare RBW 106 ([redacted], purity 99.63%) was evaluated for chromosomal aberrations in human lymphocytes according to OECD TG 473 (OECD, 2016a) and following GLP. The test item was suspended in acetone. Precipitation and pH test were conducted up to 2 mg/mL. After 24 h of incubation, mild and heavy precipitation was observed at 1 and 2 mg/mL, respectively. Based on these results, a cytotoxicity test was conducted at the concentrations of 0.125, 0.25, 0.5 and 1 mg/mL in a short-term treatment (4 h) in the presence and absence of metabolic activation (S9-mix) and in a long-term treatment (22 h) in the absence of S9-mix. The percentage of reduction in mitotic index was not higher than 45 ± 5% at the concentration of 1 mg/mL. Based on the results from the main study, the cell cultures were treated in duplicate cultures with the test item at the concentrations of 0.25, 0.5 and 1 mg/mL for short- and long-term treatment. A reduction in mitotic index was observed reaching the maximum values at 1 mg/mL (41.20%, 42.88%, 40.85% in short-term treatment and in long-term treatment, respectively). There was no statistically significant increase in cells with structural chromosomal aberrations in treated cultures when compared with vehicle control at any concentration of the test item. Based on the results obtained, the test item was considered as non-clastogenic up to the concentration of 1 mg/mL, both in the presence and absence of metabolic activation under the conditions of the study. The study was considered reliable without restrictions and the negative results on structural chromosomal aberrations were considered of high relevance. However, the Panel noted that data on polyploidy, as a hallmark of potential aneugenicity, were not recorded.

3.2.1.1.4 | *In vivo mammalian erythrocyte micronucleus test*

Licocare RBW 106 ([redacted], purity 99.63%) was evaluated in the mammalian erythrocyte micronucleus test according to OECD TG 474 (OECD, 2016b) and following GLP. Licocare RBW 106 was tested for its ability to induce micronuclei in the polychromatic erythrocytes (PCEs) of the bone marrow in treated Swiss Albino mice. The test item was dissolved in 0.5% carboxymethyl cellulose. In a range-finding study, groups of 3 males and 3 female mice were treated by gavage at 500, 1000 and 2000 mg/kg bw per day for two consecutive days. No mortality, no clinical signs, no body weight changes, and no gross pathological findings were observed in any of the animals dosed with the test item. Based on these results in the main study, three groups of mice consisting of five males and five females were administered with the vehicle, with the

positive control (cyclophosphamide monohydrate at 100 mg/kg bw) and with Licocare RBW 106 at 2000 mg/kg bw per day (considered as the limit dose) for two consecutive days. No statistically significant decrease in the PCE/total erythrocyte ratio with respect to the vehicle control was reported at any dose of the test item either in the range-finding study or in the main study. Mice treated with the test item exhibited mean frequencies of micronucleated PCE (MNPCE) that were not statistically different from those seen in the concurrent vehicle control. However, no evidence of bone marrow exposure was available and, therefore, the results were considered inconclusive.

Considering that the substance is a mixture, the maximum applied dose of 2000 mg/kg bw cannot be classified as the limit dose (as recommended by OECD TG 474; OECD, 2016b). If no toxicity is observed in a designed range-finding study, it would be appropriate to test higher doses than the maximum limits, in order to increase the dose of each of the individual components. The highest dose to be applied is limited by the maximum volume that should be given to rodents. The study was considered not reliable and the results were considered of low relevance.

3.2.1.2 | *Licocare RBW 300*

3.2.1.2.1 | *Bacterial reverse mutation test*

Licocare RBW 300 ([redacted], purity 99.75%) was tested in a bacterial reverse mutation test (Ames test) according to the OECD TG 471 (OECD, 1997a) and following GLP. Four strains of *S.* Typhimurium (TA98, TA100, TA1535 and TA1537) and *E. coli* WP2*uvrA* pKM101 were used. Two separate experiments in triplicate were performed: a plate incorporation method followed by a pre-incubation method both in the absence and presence of S9-mix. The test item was suspended in DMSO. In the dose range-finding study, Licocare RBW 300 was tested at eight concentrations up to 5000 μg/plate in the strains TA100 with the plate incorporation assay. The test item did not precipitate on the plates and did not show toxicity to the strain TA100 at any of the tested concentrations. Based on the results of the dose range-finding study in the first and in the second mutation experiment, Licocare RBW 300 was tested at 50, 158, 500, 1581 and 5000 μg/plate in the strains TA98, TA100, TA1535, TA1537 and *E. coli* WP2*uvrA* pKM101. The test item did not precipitate at any of the tested concentrations and did not show toxicity to any of the tester strains up to the top concentration of 5000 μg/plate.

The results of the study from both the initial and confirmatory mutation assay showed that Licocare RBW 300 VITA did not induce any increase in the mean number of revertant colony number for any of the tester strains when compared to the respective vehicle control plates. The study was considered reliable without restrictions and the negative results were considered of high relevance.

3.2.1.2.2 | *In vitro mammalian cell gene mutation test*

Licocare RBW 300 VITA ([redacted], purity 99.75%) was evaluated for gene mutation test in CHO AA8 cells using the Hprt gene, according to OECD TG 476 (OECD, 1997b) and following GLP. The test item was suspended in DMSO. Precipitation test was conducted at 0.0625, 0.125, 0.25, 0.50, 1 and 2 mg/mL. Post 3 h of incubation, no change in pH and no precipitation was observed at 2 mg/mL. On the basis of these results, a cytotoxicity test was conducted at the concentrations of 0.125, 0.25, 0.5, 1 and 2 mg/mL for 3 h in the presence and absence of metabolic activation (S9-mix). The results indicated that the relative survival at 2 mg/mL was greater than 20% when compared with the respective vehicle control, both in the presence and absence of S9-mix. Based on the results, the gene mutation test was conducted at concentrations of 0.25, 0.5, 1 and 2 mg/mL for 3 h in the presence and absence of S9-mix. There was no statistically significant increase in mutant frequency at any of the concentrations tested when compared with the vehicle control.

Based on the results obtained, the test item Licocare RBW 300 was considered as non-mutagenic up to concentration of 2 mg/mL, both in presence and absence of metabolic activation under the tested laboratory conditions. The study was considered reliable without restrictions and the negative results were considered of high relevance.

3.2.1.2.3 | *In vitro mammalian chromosomal aberration test*

Licocare RBW 300 ([redacted], purity 99.75%) was evaluated for chromosomal aberrations in human lymphocytes according to OECD TG 473 (OECD, 2016a) and following GLP. The test item was suspended in DMSO. Precipitation test was conducted at 0.03125, 0.0625, 0.125, 0.25, 0.5, 1 and 2 mg/mL. After 24 h of incubation, moderate and mild precipitation was observed at 2 and 1 mg/mL, respectively. On the basis of these results, a cytotoxicity test was conducted at the concentrations of 0.125, 0.25, 0.5, 1 and 2 mg/mL of the test item in duplicate in a short-term treatment (3 h) in the presence and absence of metabolic activation (S9-mix) and in a long term treatment (21 h) in the absence of S9-mix. The reduction in mitotic index reached the maximum (11.85%) at 2 mg/mL. Based on these results, in the main study the cell cultures were treated in duplicate with the test item at the concentrations of 0.5, 1 and 2 mg/mL for short- and long-term treatment. There was no statistically significant increase in the number of cells with structural chromosomal aberrations when compared with vehicle control at any of the concentrations tested.

Based on the results obtained, the test item, Licocare RBW 300 was considered as non-clastogenic up to the concentration of 2 mg/mL both in the presence and absence of metabolic activation under the conditions of the study. The study was considered reliable without restrictions and the negative results on structural chromosomal aberrations were considered of high relevance. However, the Panel noted that data on polyploidy, as a hallmark of potential aneugenicity, were not recorded.

3.2.1.2.4 | *In vivo mammalian erythrocyte micronucleus test*

Licocare RBW 300 ([redacted], purity 99.75%) was evaluated in the mammalian erythrocyte micronucleus test according to OECD TG 474 (OECD, 2016b) and following GLP. The test item was suspended in corn oil. In a range-finding study, groups of 3 male and 3 female mice were treated by gavage at three doses of the test item: 500, 1000 and 2000 mg/kg bw per day for two consecutive days. No mortality and no clinical sign were observed in any of the animals dosed with the test item. Based on these results, in the main study three groups of mice consisting of five males and five females were administered with the vehicle, with the positive control (cyclophosphamide monohydrate at 100 mg/kg bw) and with the test item at 2000 mg/kg bw per day (considered as the limit dose) for two consecutive days. A decrease in the PCE/total erythrocytes ratio with respect to the vehicle control was reported at 2000 mg/kg of test item, which reached the statistical significance in the main study (7.84% and 9.80% in the range-finding study and 9.80% and 10% in the main study in males and females, respectively). The observed decrease of PCE was not considered sufficient to demonstrate bone marrow exposure. The micronuclei were scored only in the main study. The mean frequencies of MNPCE in mice treated at 2000 mg/kg bw of Licocare RBW 300 VITA were similar to and not statistically different from those seen in the concurrent vehicle control. However, no sufficient evidence of bone marrow exposure was reported, and therefore, the study was considered inconclusive.

Considering that the substance is a mixture, the maximum applied dose of 2000 mg/kg bw cannot be classified as the limit dose (as recommended by OECD TG 474; OECD, 2016b). If no toxicity is observed in a designed range-finding study, the highest dose to be applied is limited by the maximum volume that should be given to rodents. The study was considered not reliable and the results were considered of low relevance.

3.2.1.3 | *Discussion and conclusions on genotoxicity*

Licocare RBW 106 and Licocare RBW 300 were tested in a battery of three in vitro and one in vivo genotoxicity studies. The substances, tested up to the limit of solubility, did not induce gene mutations in bacteria and in mammalian cells. In in vitro chromosomal aberration tests in human peripheral lymphocytes, the substances did not induce the increase of structural chromosomal aberrations. The available in vivo micronucleus assays were considered not reliable. The data available were therefore not adequate to evaluate the potential aneugenicity of the substances. However, the compositional analysis (Table 1) showed that the test items essentially consist of chemical classes known to be non-genotoxic (i.e. wax esters, carboxylic acids, alcohols and calcium salts of acids). The content of the individual unidentified organic compounds may be too low to elicit a response in experimental studies with the substances. Therefore, on one hand it was considered that further experimental studies to evaluate the aneugenic activity of the constituents of the chemical classes were not needed. On the other hand, the genotoxicity potential of the unidentified organic fraction was considered not addressed.

Regarding the migration into fatty food simulants, the potential migration of the sum of the unidentified organic compounds was estimated by the Panel to be in the range of 20 μg/kg food (Section 3.1.3). Therefore, the migration of genotoxic substances at concentrations that would result in an exposure of the consumers exceeding the threshold of toxicological concern (TTC) for genotoxic carcinogens[11] (EFSA Scientific Committee, 2019) could not be ruled out for fatty food contact.

Regarding the migration into aqueous simulants, the potential migration of the sum of the unidentified organic compounds was estimated to be about 1 μg/kg (Section 3.1.3). The Panel noted that the unidentified fraction consists of a large number of different individual compounds (as up to 100 peaks were attributed to unknown compounds in the GC-FID analyses) and that these compounds are expected to belong to various groups with similar structure or functionality (Section 3.1.1). Based on these considerations, the potential migration of unidentified compounds, either individually or as a group of chemically-related compounds, is expected to result in an exposure of the consumers that would be below the TTC for genotoxic carcinogens, hence expected not to be of safety concern.

3.2.2 | Other toxicity studies

Based on the considerations reported above, the Panel considered only the contact with aqueous food. In this case, the migration of the sum of constituents for each chemical class was below 12 μg/kg food (hence below 0.05 mg/kg food). Therefore, according to the 'EFSA Note for Guidance for the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials' (EFSA, 2008), only the genotoxicity potential of the substances needs to be addressed.

The Panel reviewed the provided 90-day repeated-dose oral toxicity and the reproduction/developmental toxicity screening studies and did not identify any concern that could affect the outcome of the assessment. Therefore, these studies were not reported in this opinion.

[11] 0.0025 μg/kg bw or 0.15 μg/kg food under the SCF food consumption scenario (EFSA Scientific Committee, 2019; European Commission, 2001).

3.3 | Discussion

'Wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt' are non-defined mixtures consisting of substances belonging to the chemical classes of wax esters, carboxylic acids, alcohols and calcium salts of acids, along with a fraction of unidentified organic compounds. The specific migration of the wax esters from PET in isooctane was up to 297 μg/kg, with migration of the other classes below the LoD of 10 μg/kg. The specific migration into acetic acid 4% and ethanol 10% was estimated to be below 12 μg/kg for all the chemical classes.

The Panel concluded that the substances were adequately represented by the test items used in toxicity tests. Based on the results of the genotoxicity assays and the compositional analysis, the constituents of the chemical classes of wax esters, acids, alcohols and calcium salts chemical did not raise concern for genotoxicity. The Panel considered that the migration of potentially genotoxic compounds belonging to the unidentified fraction of the substances cannot be ruled out into fatty food. By excluding contact with fatty foods, the migration potential of the unidentified constituents is expected to result in an exposure of the consumers that would be below the TTC for genotoxic carcinogens.

The Panel noted that the chemical class 'carboxylic acids' and calcium salts of authorised acids are covered by generic authorisations for use in plastic FCM.[12] Fatty acids are also authorised food additives (E570) in accordance with Reg. (EC) No 1333/2008.[13]

The substances are intended to be used in PET, PA, TPU, PLA and PVC, but only migration tests using PET were provided. The Panel concluded that the data provided also covered the potential migration from PLA and rigid PVC, as the diffusion properties of these plastics for migrating organic substances are comparably low as those of PET. The migration from PA, TPU and plasticised PVC may be higher than that from PET, as aqueous food may swell PA and as the rubbery elastomer TPU and plasticised PVC are known to have higher diffusivity. Therefore, the Panel concluded that the data provided did not cover the potential migration from PA, TPU and plasticised PVC.

The Panel considered that due to the high lipophilic character of the identified individual constituents of the substances, largely consisting of compounds with a carbon number > C24, the potential migration into 20% ethanol (i.e. simulant C in Reg. (EU) 10/2011) is expected to be comparable to that into 10% ethanol and 4% acetic acid. The Panel considered that the potential migration into solid foods would not be higher than the migration reported into aqueous simulants, hence contact with solid foods is covered by the assessment made for contact with aqueous simulants.

The contact with infant formula and human milk was not specified as intended application of the substance. However, PET is largely used to pack water, which in turn is also used to reconstitute infant formula. Considering that the proposed restriction in use (i.e. limited to contact to non-fatty food) ensure a potential migration of the individual constituents of the chemical classes (wax esters, carboxylic acids, alcohols and calcium salts of acids) to be in the region of 2 μg/kg food or below, and a potential exposure of the consumer to the individual unknown compounds below the TTC for genotoxic carcinogens, the Panel concluded that the contact with water used to reconstitute infant formula is covered.

4 | CONCLUSIONS

Based on the above-mentioned data, the Panel concluded that the substances 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt' are not of safety concern for the consumer if they are used as additives up to 0.3% w/w in PET, PLA and rigid PVC materials and articles intended for contact with all food types except for fatty foods, for long-term storage at room temperature and below, including hot-fill and/or heating up to 100°C for up to 2 h.

5 | DOCUMENTATION PROVIDED TO EFSA

Dossier "wax, rice bran, oxidized and wax, rice bran, partially saponified", July 2022. Submitted on behalf of Clariant Produkte.

Additional data, March 2024. Submitted on behalf of Clariant Produkte.

ABBREVIATIONS

bw	body weight
CAS	Chemical Abstracts Service
CEF Panel	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP Panel	EFSA Panel on Food Contact Materials, Enzymes and Processing Aids
DMSO	dimethyl sulfoxide
DSC	differential scanning calorimetry
FCM	food contact materials

[12]Reg. (EU) 10/2011 authorises FCM no. 12 ('acids, fatty, from animal or vegetable food fats and oil') and several individual fatty acids (e.g. FCM no. 67, 105, 106, 272, 345, 348, 350) without a specific migration limit (SML). Salts of authorised acids are authorised as per Article 6.

[13]Consolidated text: Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (Text with EEA relevance). OJ L 354, 31.12.2008.

GC–FID	gas chromatography – flame ionisation detection
GLP	good laboratory practice
LoD	limit of detection
LoQ	limit of quantification
MNPCE	mean frequencies of micronucleated polychromatic erythrocytes
OECD	Organisation for Economic Co-operation and Development
PA	polyamide
PCE	polychromatic erythrocytes
PET	polyethylene terephthalate
PLA	polylactic acid
PVC	poly(vinyl chloride)
RBW	rice bran wax
SCF	Scientific Committee on Food
SML	specific migration limit
TG	test guideline
TPU	thermoplastic polyurethane
TTC	threshold of toxicological concern

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

German competent authority (Federal Office of Consumer Protection and Food Safety).

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