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Safety Assessment: Outcome of Assessment of Wax, Rice Bran, Oxidized and Saponified as a Component of Plastic Materials and Articles Intended to Come into Contact with Food

Reference number RP1642

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Food Standards Agency (FSA) and Food
Standards Scotland (FSS)

Regulated Product Dossier Assessment

Assessment finalised: 14/05/2024

Summary

An application has been submitted to the Food Standards Agency (FSA) and Food Standards Scotland (FSS) requesting the authorisation of wax, rice bran, oxidized (CAS 1883583-80-9) and wax, rice bran, saponified (CAS 1850357-57-1) as a component of plastic materials and articles intended to come into contact with food.

The applicant stated that due to the high decomposition points of the substances no thermal decomposition is expected during manufacture or use of the food contact articles containing the additive. However, non-intentionally added substances (NIAS) testing should also assess impurities and reaction products and not just decomposition products. Therefore, additional data was requested on NIAS testing in order to assess compliance with the relevant safety criteria in accordance with assimilated Regulation 10/2011 on plastic materials and articles intended to come into contact with food. Evidence was requested on the presence or absence of organic impurities/matter in the additives as well as data on the presence or absence of other substances of potential concern, e.g. minor oxidation products.

The applicant was requested to provide this additional information in March 2023 and reminded in November 2023, however this was not provided and there has been no further communication. As such, due to deficiencies in the data, the assessment of the additive has stopped and the FSA/FSS could not conclude on the safety of the additive under its proposed conditions of use.

Abbreviations

Acronym	Definition
FCMJEG	Joint Expert Group on Food Contact Materials
FSA	Food Standards Agency
FSS	Food Standards Scotland
NIAS	Non-Intentionally Added Substances
PET	Polyethylene Terephthalate

Introduction

The company Clariant Produkte GmbH submitted an application to the Food Standards Agency (FSA) and Food Standards Scotland (FSS) regarding the use of wax, rice bran, oxidized (CAS 1883583-80-9) and wax, rice bran, saponified (CAS 1850357-57-1) as a component of plastic materials and articles intended to come into contact with food.

The Joint Expert Group on Food Contact Materials (FCMJEG), who assess and provide advice to the FSA on applications for the authorisation of new food contact materials, was requested to evaluate the information provided by the Applicant.

Identity and characterisation

The following information was provided on the substance:

- **Chemical Names:** Wax, rice bran, oxidized or saponified
- **Synonyms:** Mikronisiertes Wachs, waxes and waxy substances, rice bran, oxidized, renewable wax, waxes and waxy substances, rice bran, oxidized, saponified
- **CAS Registry Numbers:** 1883583-80-9, 1850357-57-1

The applicant stated that due to the high decomposition points of the substances no thermal decomposition is expected during manufacture or use of the food contact articles containing the products. After initially reviewing the application the FCMJEG advised that Non-Intentionally Added Substances (NIAS) data should be provided, in order to assess compliance with the relevant safety criteria in accordance with assimilated Regulation 10/2011 (paragraph 9 and 20 within the recitals of the legislation). FSA/FSS wrote to the applicant on 16th March 2023 to request additional information on NIAS and evidence was also requested on the presence or absence of organic impurities/matter in the additives as well as data on the presence or absence of other substances of potential concern, e.g. minor oxidation products. The applicant did not provide the requested additional information on NIAS and there has been no further response by the applicant since the 29th June 2023 to FSA/FSS communications.

Intended Use

The products are intended for use as a processing aid, lubricant, release agent, and/or slip agent in food-contact polymers. It is proposed for use in levels up to 0.3% in finished polyethylene terephthalate (PET) polymers. The finished polymers will be intended for use in contact with all types of food under all conditions.

Safety evaluation

The NIAS information is an integral part of the assessment, which supports the identify and characterisation of the material or article being applied for. Without this information the FSA/FSS cannot complete the safety assessment, as the impact of NIAS cannot be understood or evaluated. As such the assessment of the additive has stopped and the FSA/FSS could not conclude on the safety of the additive to consumers under its proposed conditions of use.

Conclusions

Due to a lack of NIAS data the FSA/FSS could not conclude on the safety of the additive to consumers under its proposed conditions of use. No further assessment or evaluation was undertaken.

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