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## Safety assessment of the mixture of methyl-branched and linear C<sub>14</sub>–C<sub>18</sub> alkanamides, derived from fatty acids, for use in food contact materials

Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), Vittorio Silano, Claudia Bolognesi, Jean-Pierre Cravedi, Karl-Heinz Engel, Paul Fowler, Roland Franz, Konrad Grob, Rainer Gürtler, Trine Husøy, Sirpa Kärenlampi, Wim Mennes, Maria Rosaria Milana, André Penninks, Andrew Smith, Maria de Fátima Tavares Poças, Christina Tlustos, Detlef Wölfle, Holger Zorn, Corina-Aurelia Zugravu, Martine Kolf-Clauw, Eugenia Lampi, Kettil Svensson, Eric Barthélémy and Laurence Castle

### Abstract

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) deals with the safety assessment of the mixture of methyl-branched and linear C<sub>14</sub>–C<sub>18</sub> alkanamides, derived from fatty acids, for use in food contact materials as a slip or release agent at up to 1% w/w in polyolefins. The final materials are intended for contact with foodstuffs other than fatty foods for long-term storage at room temperature including short heating. No thermal degradation of the substance is expected under manufacturing process conditions of polyolefins. Specific migration from low-density polyethylene (LDPE) made with 0.37% of the substance into 3% acetic acid and 10% ethanol was up to 0.68 mg/kg. Based on negative results in a bacterial mutation test and in an *in vivo* micronucleus test, there was no evidence of a genotoxic potential of the substance. Impurities were determined and the main ones were tested in a bacterial mutation test giving negative results. Along with the negative results from the *in vivo* micronucleus test on the substance containing the impurities, there was no evidence of a genotoxic potential of the impurities. Based on a 28-day study on the substance, the Panel noted that there is sufficient margin of safety between the no observed adverse effect level (NOAEL) and the maximum exposure of consumers that could occur at a migration level of 5 mg/kg food, to cover uncertainties about toxic effects due to potential accumulation of slowly hydrolysed branched amide species of the substance during chronic exposure. The CEF Panel concluded that the substance is not of safety concern for consumers if it is used in the manufacture of polyolefin articles intended for contact with all foodstuffs other than fatty foods and the migration does not exceed 5 mg/kg food. The 5 mg/kg food migration should not apply to *n*-stearamide.

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**Keywords:** mixture of methyl-branched and linear C<sub>14</sub>–C<sub>18</sub> alkanamides, derived from fatty acids, isooctadecanamide, additive, FCM substance No. 1065, food contact materials, polyolefins, safety assessment

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**Question number:** EFSA-Q-2014-00651

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**Note:** The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality, in line with Article 20(3) of the Regulation, will be received from the European Commission. The following information has been provided under the confidentiality framework and has been redacted awaiting the decision of the Commission: the level of the components in the applied substance; the identity and level of impurities in the applied substance; and results of the *in vitro* hydrolysis studies on the applied substance.

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## 1. Introduction

### 1.1. Background and Terms of Reference as provided by the requestor

Before a substance is authorised to be used in food contact materials (FCM) and 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 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 Food Standards Agency, United Kingdom, requesting the evaluation of the substance called 'isooctadecanamide' then renamed by the CEF Panel "mixture of methyl-branched and linear C<sub>14</sub>–C<sub>18</sub> alkanamides derived from fatty acids", with the food contact material (FCM) substance No 1065. The dossier was submitted on behalf of Croda Europe Ltd.

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 dossier in support of its application for the authorisation of the substance 'isooctadecanamide' to be used in FCM. Data submitted and used for the evaluation are:

#### Non-toxicological data and information

- Chemical identity
- Description of manufacturing process of the substance
- Physical and chemical properties including *in vitro* hydrolysis tests
- Intended use
- Existing authorisation(s)
- Migration of the substance
- Impurities
- Thermostability

#### Toxicological data

- Bacterial gene mutation tests on the mixture of methyl-branched and linear C<sub>14</sub>–C<sub>18</sub> alkanamides, derived from fatty acids and on two of the main impurities [REDACTED]
- *In vivo* mouse bone marrow micronucleus test on the mixture of methyl-branched and linear C<sub>14</sub>–C<sub>18</sub> alkanamides, derived from fatty acids
- 28-day oral toxicity study in Wistar rats on the mixture of methyl-branched and linear C<sub>14</sub>–C<sub>18</sub> alkanamides, derived from fatty acids

### 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 substance that is 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:

- In case of high migration (i.e. 5–60 mg/kg food), an extensive data set is needed.
- In case of migration between 0.05 and 5 mg/kg food, a reduced data set may suffice.
- 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, 2009a) and considering the relevant existing Guidance from the EFSA Scientific Committee.

### 3. Assessment

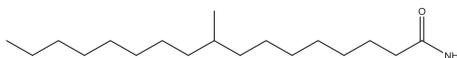
The substance applied and called 'isooctadecanamide' is a mixture of methyl-branched and linear C<sub>14</sub>–C<sub>18</sub> alkanamides derived from fatty acids. It is intended to be used as a slip or release agent in polyolefins, such as high- and low-density polyethylene (HDPE and LDPE), to manufacture sheets and films (up to 0.2% w/w), closures (up to 0.5% w/w), compression-moulded articles (up to 0.9% w/w) and injection-moulded articles (up to 1% w/w). Finished articles are intended for contact with non-fatty foods for up to long-term storage (greater than 6 months) at room temperature and below, including heating up to 70°C for up to 2 h, or heating up to 100°C for up to 15 min.

The substance was not evaluated by SCF and EFSA in the past.

#### 3.1. Non-toxicological data

Chemical formula of the main component, isooctadecanamide: C<sub>18</sub>H<sub>37</sub>N<sub>1</sub>O<sub>1</sub>

Molecular mass: 283.5 Da



**Figure 1:** Chemical structure of one of the isomers of isooctadecanamide

A description of the production process was supplied in confidence. As a consequence of the method of synthesis, the alkyl chains are fully saturated. The substance tested for potential migration and toxicity was a mixture composed of isooctadecanamide (predominantly methyl branched) and *n*-octadecanamide (also called stearamide), along with minor amounts of hexadecanamide (also called palmitamide), polybranched isooctadecanamide, tetradecanamide (also called myristamide) and the amides of eicosanoic (also called arachidic acid) and docosanoic acid (also called behenic acid). According to the applicant, branching is predominantly mono-methyl with some di-methyl and ethyl. The main area of branching is in the centre of the chain between C<sub>8</sub> and C<sub>11</sub> (branching at C<sub>9</sub> is shown as an example in Figure 1), but branching also occurs on C<sub>7</sub> downwards and on C<sub>12</sub>–C<sub>16</sub>. By-products and impurities may be up to in total.

The Panel noted that stearamide, one of the main components, is authorised and listed in the 'plastic' Regulation (EU) 10/2011<sup>1</sup> under the FCM number No 306 without specific restriction. Behenamide is also authorised and listed under the FCM number No 458 without specific restriction.

The substance is a solid with a melting point at around 70°C. It is lipophilic and essentially insoluble in water, but is soluble in alcohol. The log *P*<sub>o/w</sub> was not measured, but is expected to be similar to that of stearamide, which was measured to be above 6.5 (calculated to be 6.7). Solubility of stearamide in water was measured to be < 0.1 mg/L.

The substance was stable up to at least 260°C. Therefore, no thermal degradation is expected under manufacturing process conditions of polyolefins.

Hydrolysis to innocuous products was considered, with particular regard to branching. *In vivo*, linear fatty acid amides are rapidly hydrolysed into ammonia and their corresponding acid, which are all

<sup>1</sup> Regulation (EU) No 10/2011 of the Commission of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1–89.

authorised and listed in the Regulation (EU) 10/2011 without restriction (stearic acid: FCM No 106, palmitic acid: FCM No 105, myristic acid: FCM No 348, arachidic acid: FCM No 345 and behenic acid: FCM No 272). Branching of the alkyl moiety may decrease the enzymatic hydrolysis rate, especially when close to the amide function, e.g. at carbon 2 position. Hydrolysis studies on the substance were performed in simulated intestinal fluid. Gas chromatography–mass spectrometry analysis (GC–MS) was used to measure the disappearance of the amide and the formation of the acids. [REDACTED]

[REDACTED] No conclusion on the hydrolysis rate of amides branched close to the amide function could be drawn.

The maximum intended use of the substance is 1% w/w. Specific migration from low-density polyethylene (LDPE) plaques made with 0.37% of the substance was determined in 3% acetic acid and 10% ethanol for 10 days at 60°C. Migration was 0.11 and 0.68 mg/kg, respectively. The food simulants used for testing do not cover all applications foreseen (i.e. all non-fatty foods), but are indicative.

Main impurities were determined [REDACTED]

[REDACTED]. If anyone impurity constituted 1% of the substance and had the same migration behaviour as the substance itself migrating at a maximum of 5 mg/kg food, then a migration of impurity around 50 µg/kg food would occur.

### 3.2. Toxicological data

#### Genotoxicity potential of the substance

A bacterial mutation assay was performed with the substance according to OECD 471 (1997) with and without a metabolising system (S9 mix) using *Salmonella* Typhimurium strains TA1535, TA1537, TA98 and TA100 and the *Escherichia coli* strain WP2uvrA. The concentration ranges were from 1.5 to 5,000 µg/plate. Based on the absence of toxicologically significant increases in revertant colonies, it is concluded that there is no indication of a mutagenic potential.

A micronucleus test was performed with the substance administered to male mice (7 animals/group) at 100, 200 or 400 mg/kg body weight (bw) via intraperitoneal injection. Based on a reduction in the polychromatic erythrocytes (PCE) to normochromatic erythrocytes (NCE) ratio, it is concluded that the substance reached the bone marrow. No toxicological relevant increase in micronucleated PCE was observed.

Based on negative results in the adequately performed bacterial mutation test and *in vivo* micronucleus test, the Panel considered that there is no evidence of a genotoxic potential of the substance.

#### Genotoxicity potential of the impurities

Bacterial mutation assays were performed with the two main impurities, [REDACTED] according to OECD 471 (1997) with and without S9 mix using *Salmonella* Typhimurium strains TA1535, TA1537, TA98 and TA100 and the *E. coli* strain WP2uvrA. The concentration ranges were from 1.5 to 5,000 µg/plate. Based on the absence of toxicologically significant increases in revertant colonies, it is concluded that there is no indication of a mutagenic potential.

Regarding a chromosomal damaging potential of the impurities [REDACTED], the Panel considered that they are covered by the *in vivo* micronucleus test with the substance, with negative results. Based on those negative results along with the negative results in the bacterial mutation tests performed with the two main impurities, the Panel considered that there is no evidence of a genotoxic potential of the impurities.

#### Toxicokinetics of the substance

Linear fatty acid amides are rapidly hydrolysed into ammonia and their corresponding acid (see Section 3.1), hence only branched fatty acid amides are discussed. Based on *in vitro* hydrolysis tests on the substance (see Section 3.1), most of the branched components of the substance are expected to readily hydrolyse, resulting in the corresponding acid. However, as the substance was not fully hydrolysed *in vitro* within 4 h, it is not possible to rule out that certain branched amide species are only slowly hydrolysed. Consequently, the results may raise uncertainty about a potential accumulation of a slowly metabolised fraction of the substance (e.g. C<sub>2</sub> branched amides) *in vivo*. For the major part of the substance, which can be hydrolysed, the resulting fatty acids are expected to be metabolised

via oxidation using normal biochemical processes that exist for similar branched fatty acids. The EFSA CEF Panel opinion on FGE.01 (Rev2) (EFSA CEF Panel, 2010) reviewed the toxicokinetics of short- and medium-length branched chain carboxylic acids and concluded that these substances are rapidly absorbed from the gastrointestinal tract and can be expected to be extensively metabolised. Additional information on branched chain fatty acids (BCFA, C<sub>14</sub>–C<sub>20</sub>) indicates that they are absorbed intestinally in experiments using weanling rats. BCFA are a major component of the infant gut. BCFA are present in meconium and high exposure occurs during infancy. Based on data reported by Ran-Ressler et al. (2013), the estimated BCFA consumption is 23 mg/kg bw per day for 1- to 3-month-old males and approximately 415 mg/person for adults. In addition to the mitochondrial beta oxidation, BCFA, e.g. phytanic acid (3,7,11,15-tetramethylhexadecanoic acid) are reported to be metabolised in the human body by peroxysomal alpha-oxidation and omega-oxidation (Verhoeven et al., 1998). By analogy, therefore, even if amide hydrolysis is not rapid, accumulation of a slowly metabolised fraction of the substance (e.g. C<sub>2</sub> branched amides) is not likely to be of relevance.

### General toxicity potential of the substance

A repeated dose 28-day oral toxicity study on the substance was performed in Wistar rats (5/sex per dose) at dose levels of 0, 100, 300 or 1,000 mg/kg bw per day according OECD TG 407. At 1,000 mg/kg bw per day, a reduction in spleen weight in both sexes (16% for males and 25% for females) was associated with alterations in haematology parameters (increase in haematocrit and a statistically significant reduction in mean corpuscular haemoglobin concentration in males) and microscopic changes (decrease in the amount of haematopoiesis in the spleen in females). In addition, several changes in blood chemistry and a reduction in absolute and relative brain weight were observed in females. Based on the changes related to haematology and spleen, the no observed adverse effect level (NOAEL) in this study is 300 mg/kg bw per day.

The Panel considered that the margin of safety (MOS) of more than 3,000 between the NOAEL of 300 mg/kg bw per day from the subacute study and a maximum exposure of consumers at a level of 5 mg/kg food (equivalent to 0.08 mg/kg bw per day according to EFSA standard assumptions, see Section 2.2), along with supporting information on fatty acid amides and on BCFA, is sufficient to not require a subchronic toxicity study (90 days) on the substance and to cover the uncertainties about toxic effects due to a potential accumulation of slowly hydrolysed branched amide species during chronic exposure.

If side chains longer than methyl were to be present as impurities at a few per cent of the substance, which cannot be ruled out from the data provided, they could give rise to a migration up to approx. 200 µg/kg food if assumed to be present at 4% to illustrate the point. The Panel considered that they would have been covered by (i) the tests carried out on the substance and (ii) toxicological data from studies on 2-ethylhexanol, 2-ethylhexanoic acid and valproic acid. For 2-ethylhexanol, the EFSA CEF Panel opinion on FGE.04 derived a NOAEL of 50 mg/kg bw per day (EFSA, 2009b) in line with the acceptable daily intake (ADI) of 0.5 mg/kg bw per day established by JECFA in 1993 (WHO, 1993). In the VKM Opinion on 2-ethylhexanoic acid (VKM, 2005), the listed NOAELs range from 25 to several hundred mg/kg bw per day. For valproic acid, oral studies in mice, rats, rabbits and monkeys indicate developmental effects at or above 100 mg/kg bw per day (Hendrickx et al., 1988). Overall, this would give a MOS of approx. 7,500 between the lowest reported NOAEL of 25 mg/kg bw per day and a maximum exposure of consumers at a level of 200 µg/kg food (equivalent to 0.0033 mg/kg bw per day). Therefore, the CEF Panel considered that the potential presence of impurities with a side chain longer than methyl is not of concern under the intended conditions of use.

Therefore, based on the absence of evidence of genotoxicity, the low toxicity in the subacute (28 days) oral rat study, the hydrolysis of the linear fatty acid amides and the limited information regarding the hydrolysis/metabolism of certain branched amide species, the Panel considered appropriate that migration should not exceed 5 mg/kg food. Considering that the substance evaluated contained ████████ *n*-stearamide which is authorised and listed in the Regulation (EU) 10/2011 without specific restriction, the 5 mg/kg food migration should not apply to *n*-stearamide.

## 4. Conclusions

Having considered the above-mentioned data, the CEF Panel concluded that the mixture of methyl-branched and linear C<sub>14</sub>–C<sub>18</sub> alkanamides, derived from fatty acids, is not of safety concern for consumers if it is used in the manufacture of polyolefin articles intended for contact with all foodstuffs

other than fatty foods (as defined by simulant D2) and the migration does not exceed 5 mg/kg food. The 5 mg/kg food migration limit should not apply to *n*-stearamide.

## Documentation provided to EFSA

- 1) Initial dossier. September 2014. Submitted on behalf of Croda Europe Ltd.
- 2) Missing information. March 2015. Submitted on behalf of Croda Europe Ltd.
- 3) Additional data. September 2015. Submitted on behalf of Croda Europe Ltd.
- 4) Additional data. July 2016. Submitted on behalf of Croda Europe Ltd.
- 5) Additional data. November 2016. Submitted on behalf of Croda Europe Ltd.

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## Abbreviations

ADI	acceptable daily intake
BCFA	branched chain fatty acids
bw	body weight
CEF	Panel on food Contact Materials, Enzymes, Flavourings and Processing Aids
FAO	Food and Agriculture Organization of the United Nations
FCM	food contact materials
FGE	flavouring group evaluation
GC–MS	gas chromatography–mass spectrometry
HDPE	high-density polyethylene
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LDPE	low-density polyethylene
MOS	margin of safety
NCE	normochromatic erythrocytes
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PCE	polychromatic erythrocytes

SCF	Scientific Committee on Foods
$P_{o/w}$	octanol/water partition coefficient
VKM	Norwegian scientific committee for food safety
w/w	weight per weight
WHO	World Health Organization