Safety for the environment of sorbitan monolaurate as a feed additive for all animal species

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Kos Durjava, Maryline Koub, Marta López-Alonso, Secundino Lopez Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Georges Bories, Antonio Finizio, Andreas Focks, Ivana Teodorovic, Paola Manini and Jordi Tarrés-Call

Abstract

The additive sorbitan monolaurate consists of sorbitol (and its anhydrides) esterified with fatty acids derived from coconut oil. It is currently authorised in the European Union and it is intended to be used as a technological additive (functional group of emulsifiers), in feedingstuffs for all animal species, at a maximum concentration of 85 mg/kg complete feed. In 2019, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued an opinion on the safety and efficacy of sorbitan monolaurate. Owing the lack of data, the FEEDAP Panel could not conclude on the safety of the additive for the environment. The applicant submitted new data (fate and degradation as well as ecotoxicity data) that were evaluated in the present opinion. The absorption, distribution, metabolism and excretion of structurally related compounds (sorbitan monostearate and sorbitan trioleate) indicate that the additive is expected to be partially metabolised. In addition, sorbitan monolaurate and some related compounds are readily biodegradable. The limited available data on the effects of sorbitan monolaurate in marine crustaceans and in marine sediment indicate that the ecotoxicity of the additive is low, in consistency with the very low acute toxicity of sorbitan esters. Overall, the FEEDAP Panel concludes that a risk of sorbitan monolaurate to terrestrial and aquatic environment is unlikely. Therefore, no safety concerns for the environment are expected from the use of the additive under assessment according to the established conditions of use.

© 2020 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: sorbitan monolaurate, technological additives, emulsifiers, safety, environment

Requestor: European Commission
Question number: EFSA-Q-2019-00595
Correspondence: feedap@efsacMembrainec.eu
Panel members: Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Kos Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Kos Durjava M, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Bories G, Finizio A, Focks A, Teodorovic I, Manini P and Tarrés-Call J, 2020. Scientific Opinion on the safety for the environment of sorbitan monolaurate as a feed additive for all animal species. EFSA Journal 2020;18(6):6162, 12 pp. https://doi.org/10.2903/j.efsa.2020.6162

ISSN: 1831-4732

© 2020 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Table of contents

Abstract................................................................................................................................................... 1
1. Introduction................................................................................................................................... 4
  1.1. Background and Terms of Reference as provided by the requestor..................................................... 4
  1.2. Additional information..................................................................................................................... 4
2. Data and methodologies................................................................................................................. 4
  2.1. Data.............................................................................................................................................. 4
  2.2. Methodologies................................................................................................................................5
3. Assessment.................................................................................................................................... 5
  3.1. Safety for the environment ............................................................................................................. 5
  3.1.1. Literature review on sorbitan esters................................................................................................. 6
  3.1.2. ADME of structurally related compounds – metabolism of sorbitan esters ........................................... 7
  3.1.3. Ready biodegradability of sorbitan monolaurate and sorbitan esters................................................... 7
  3.1.4. Ecotoxicity data.............................................................................................................................. 8
  3.1.5. Conclusions on the safety for the environment ................................................................................. 8
4. Conclusions.................................................................................................................................... 9
5. Documentation as provided to EFSA/Chronology............................................................................... 9
References............................................................................................................................................... 9
Abbreviations ........................................................................................................................................... 11
Appendix A – Chemical structure of the compounds of the additive and similar compounds relevant for the assessment.................................................................................................................. 12
1. Introduction

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

Regulation (EC) No 1831/2003\(^1\) establishes rule governing the Community authorisation of additives for animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, Kemin Europa N.V, is seeking a Community authorisation of Sorbitan Monolaurate as feed additive to be used as an emulsifier for all animal species (Table 1).

Table 1: Description of the substances

| Category of additive | Technological additive |
|----------------------|------------------------|
| Functional group of additive | Emulsifier |
| Description | Sorbitan monolaurate (Kemin) |
| Target animal category | All animal species |
| Applicant | Kemin Europa N.V. |
| Type of request | New opinion |

On 27 February 2019, the Panel on Additives an Products or Substances used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on the safety of the product, could not conclude on the safety of Sorbitan monolaurate in all animal species, under the conditions of use as posed by the applicant. Owing the lack of data, the FEEDAP Panel could not conclude on the safety of the additive for the environment. It was suggested to check for the possibility to demonstrate the safety of the additive.

The Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment and to allow a revision of Authority’s opinion. The new data have been received on 2 April 2019.

In view of the above, the Commission asks the Authority to deliver a new opinion on Sorbitan monolaurate as feed additive for all animal species based on the additional data submitted by the applicant.

1.2. Additional information

The re-evaluation of the safety of sorbitan monolaurate for the environment is the object of the current risk assessment. It is currently authorised as a technological additive, functional group (c) emulsifier, for all animal species.

Sorbitan monolaurate (E 493) is approved as a food additive (Commission Regulation (EU) No 1129/2011) in a wide range of commonly consumed foods (up to 10 g/kg), including dietary food supplements (quantum satis). Sorbitan stearate (E 491), sorbitan tristearate (E 492), sorbitan oleate (E 494), sorbitan palmitate (E 495) and sorbitol (E 420) are authorised as food additives in the EU.

The European Food Safety Authority (EFSA) FEEDAP Panel adopted, in 2019, an opinion on the safety and efficacy of sorbitan monolaurate as a feed additive for all animal species. In that opinion, owing the lack of data, the FEEDAP Panel could not conclude on the safety of the additive for the environment.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of additional information\(^2\) to a previous application on the same product.\(^3\)

---

\(^1\) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
\(^2\) FEED dossier reference: FAD-2019-0060.
\(^3\) FEED dossier reference: FAD-2010-0333.
2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of sorbitan monolaurate is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance for assessing the safety of feed additives for the environment (EFSA, 2008).

3. Assessment

The additive under assessment, sorbitan monolaurate, is intended to be used as a technological additive (functional group: emulsifiers) in feedingstuffs for all animal species.

The additive was characterised in a previous opinion (EFSA FEEDAP Panel, 2019). It consists of sorbitol (and its anhydrides) esterified with fatty acids derived from coconut oil. The additive is an oily liquid, insoluble in water, and has a density of about 1,030 kg/m³.

The typical fatty acid profile of the additive sorbitan monolaurate reflects the fatty acid composition of coconut oil and according to the applicant, it is specified to contain a number of compounds reported in Table 2.

Table 2: Typical fatty acid profile of the additive sorbitan monolaurate

| Compound (chemical name and linear formula) | Content (%) |
|---------------------------------------------|-------------|
| Lauric acid (dodecanoic acid, CH₃(CH₂)₁₀COOH) | 40-60       |
| Myristic acid (1-tetradecanoic acid, CH₃(CH₂)₁₂COOH) | 14-25       |
| Palmitic acid (hexadecenoic acid, CH₃(CH₂)₁₄COOH) | 7-15        |
| Oleic acid ((9Z)-octadec-9-enoic acid, CH₃(CH₂)₁₇CH=CH(CH₂)₇COOH) | < 11        |
| Caprylic acid (octanoic acid, CH₃(CH₂)₇COOH) | < 10        |
| Capric acid (decanoic acid, CH₃(CH₂)₉COOH) | < 10        |
| Stearic acid (octadecanoic acid, CH₃(CH₂)₁₈COOH) | < 7         |
| Linoleic acid ((9Z,12Z)-octadeca-9,12-dienoic acid, CH₃(CH₂)₉CH=CHCH₂CH=CH(CH₂)₇COOH) | < 3         |

In the previous opinion, the FEEDAP Panel could not conclude on the safety of the additive for the environment due to lack of data and inherent uncertainties. The applicant has submitted additional information in support to the safety for the environment.

Sorbitan monolaurate is intended to be used as emulsifier in feed materials and compound feed quantum satis but with a maximum content of 85 mg sorbitan monolaurate/kg complete feed.

3.1. Safety for the environment

In the previous opinion, the FEEDAP Panel performed a Phase I environmental risk assessment and noted that the predicted environmental concentrations (PECs) for soil, groundwater and surface water were exceeded. Since the PEC surface water for the aquatic compartment was around the trigger value, no further assessment was considered required for this environmental compartment (EFSA FEEDAP Panel, 2019).

In the same opinion, it was not possible to refine the above PECs in Phase II, due to the absence of quantitative data and it was noted the following: Degradation studies indicate that sorbitan monolaurate is readily degradable (US EPA, 2010), and with an estimated log Kow of 3.15 (US EPA, 2005) is not expected to bioaccumulate. Limited data are available on the ecotoxicity of sorbitan monolaurate. Studies in rats indicate that approximately 90% of sorbitan monostearate is hydrolysed to its fatty acid moiety and the corresponding anhydrides of sorbitol. Assuming similar metabolism of sorbitan monolaurate, a limited proportion of the additive will be excreted to the environment.

Based on the above, in 2019, the FEEDAP Panel concluded that the lack of data and the inherent uncertainties do not allow the environmental risk assessment to be completed.

In order to fulfil the lack of data identify in the previous assessment, the applicant submitted one study on degradation in marine water of sorbitan monolaurate, on one toxicity in marine sediment.
testing sorbitan monolaurate,\(^6\) and one on toxicity in marine water testing sorbitan monolaurate and sorbitan monooleate.\(^7\) In addition, a review of the literature on the safety of sorbitan esters for the environment was performed.\(^8\)

The FEEDAP Panel assessed the new information available and considered in particular the following: (i) the outcome of the literature review on sorbitan esters, (ii) the available data on the Absorption, distribution, metabolism and excretion (ADME) of structurally related compounds (sorbitan esters), (ii) the study on the aerobic degradability of sorbitan monolaurate in seawater and (iii) the ecotoxicity data on marine crustaceans and in marine sediment organisms.

In performing the assessment, the FEEDAP Panel considered the additive as a mixture of different derivates of sorbitol and fatty acids, naturally present in plants/animal products used as food or feed (Table 3).

### Table 3: Natural occurrence of the compounds of the additive

| Compound     | CAS number                  | Naturally present in                                                                 |
|--------------|-----------------------------|---------------------------------------------------------------------------------------|
| Lauric acid  | 143-07-7 (1338-39-2)        | Laurel oil, palm kernel oil, watermelon seed, pumpkin seed [E 493]                    |
| Myristic acid| 544-63-8 (56645-05-7)       | Palm kernel oil, coconut oil, nutmeg                                                  |
| Palmitic acid| 57-10-3 (26266-57-9)        | Palm tree (Mediterranean coast), canola oil (EU), linseed oil (EU) [E 495]            |
| Oleic acid   | 112-80-1 (1338-43-8)        | Olive oil, canola oil (EU), linseed oil, sunflower oil [E 494]                        |
| Caprylic acid| 124-07-2 (60177-36-8)       | Palm kernel oil, coconut oil.                                                         |
| Capric acid  | 334-48-5                   | Palm kernel oil, coconut oil.                                                         |
| Stearic acid | 57-11-4 (1338-41-6)         | Canola oil, linseed oil, cotton oil, sunflower oil, rapeseed, palm kernel oil [E491]|
| Linoleic acid| 60-33-3                    | Linseed oil, poppyseed oil, sunflower oil, maize oil.                                  |
| Sorbitol     | 50-70-4                    | Sugar alcohol present in stone fruits, and in trees of the genus Surbus, present in Europe [E420] |

#### 3.1.1. Literature review on sorbitan esters

The applicant has reviewed the scientific literature in two database platforms (Science direct and Livivo). Search strategies used included ‘sorbitan AND toxicity AND availability’, ‘sorbitan AND environment AND earthworm’, ‘sorbitan AND environment’. The search was restricted to reports published within the period 1992-2020 and written in the English language. Those not publicly available were excluded.\(^9\) After screening for relevance, 11 papers were selected from a total of 179 hits for closer attention: Alwadani and Fatehi (2018), Chen et al. (2001), Franzetti et al. (2006), Harvey et al. (2011), Kim and Weber (2005), Krogh et al. (2003), Li and Yang (2010), Toshima et al. (1992), Wirz et al. (2015), Xi et al. (2016) and Zheng et al. (2012).

The FEEDAP Panel noted that ecotoxicity studies reviewed in the scientific literature submitted by the applicant tested sorbitan monolaurate and similar substances (e.g. sorbitan monooleate, sorbitol polyoxyethylene) that are still considered relevant as supportive evidence. The chemical structure of these substances is available in Appendix A.

The scientific papers of Toshima et al. (1992), Harvey et al. (2011); Krogh et al. (2003); Li and Yang (2010), Zheng et al. (2012), and Xi et al. (2016), were considered not relevant for the hazard characterisation of the additive because the endpoints measured or because they were designed for different purposes. The remaining scientific papers are described in the following sections.

---

\(^6\) Technical dossier/Annex SIn 1.

\(^7\) Technical dossier/Annex SIn 2.

\(^8\) Technical dossier/Annex SIn 4.

\(^9\) Technical dossier/Supplementary information February 2020/FAD-2019-0333 supplementary information, table 18.
3.1.2. ADME of structurally related compounds – metabolism of sorbitan esters

The metabolic fate of sorbitan monostearate has been studied in the rat. After administration of a single dose of $^{14}$C-sorbitan monostearate (labelled on the polyol moiety), 90% and 50% (oily and water emulsion form, respectively) of the emulsifier were hydrolysed to stearic acid and anhydrides of sorbitol that were extensively excreted (44% and 66%) in the urine; only a fraction of sorbitol anhydrides was oxidised to $^{14}$CO$_2$ (14–24% of the administered radioactivity); very low amounts of radioactivity (< 0.1%) were measured in tissues; continuous administration (28 days) of the same labelled compound showed no accumulation of the additive in the fat (Wick and Joseph, 1952, 1953).

Similar studies performed with sorbitan $^{14}$C-monostearate (labelled on the fatty acid) showed that the stearate moiety had a coefficient of digestibility of 53.3%; fractionation of carcass fat showed that $^{14}$C was incorporated into fatty acids, glycerol and non-identified residues (Wick and Joseph, 1953; Oser and Oser, 1957).

The metabolic fate of sorbitan trioleate has been studied in the rat. After administration of a single oral dose of sorbitan $^{14}$C-trioleate (labelled in the oleate moiety), 42% was found in the faeces and gastrointestinal tract, indicating that the compound was incompletely absorbed; $^{14}$CO$_2$ excretion amounted to 30–35%, urinary excretion to 3%; the liver contained about 3% and the carcass about 22%. After administration of the $^{14}$C-sorbitan-trioleate (labelled in the polyol moiety), less than 2% of the label was recovered as $^{14}$CO$_2$; the proportions not absorbed were 24% when administrated in a water emulsion but 37% from an oily solution; urinary excretion amounted 88%; the liver contained about 1% and the carcass about 6% of the administered radioactivity (Treon et al., 1967).

It was shown that the bioavailability of mono-, di- and tri-esters of sorbitan was similar (Mattson and Nolen, 1972).

The ANS Panel, in its opinion of 2017, considered that the different sorbitan esters will follow the same metabolic and excretion pathways as sorbitan monostearate (E491). The FEEDAP Panel assumes that the above-mentioned results would qualitatively/semiquantitatively apply to the homologous fatty esters of sorbitan constitutive of the additive under assessment.

The pancreas is considered to be the major source of digestive carboxylic ester hydrolases in fish as it is in mammals (review from Tocher, 2003). The same has been shown to occur in birds (review from Krogdahl, 1985). Consequently, the sorbitan moiety of sorbitan monolaurate should be released in the same way in the digestive tract of these species and undergo a similar metabolic fate as in the rat.

Based on the data from structurally related compounds, the Panel considers that the additive (esters of fatty acids and sorbitol (and its anhydrides) is partially absorbed and metabolised and metabolites of sorbitan are excreted by urine. The exact amount of the additive that is metabolised cannot be determined from the data available. The data available on structurally related compounds allow to estimate that about 20% of the absorbed fraction is exhaled in the form of CO$_2$, and that about 20–50% (when administrated in a water vehicle or in an oily vehicle, respectively) of the absorbed fraction is excreted in urine as sorbitan or metabolites.

3.1.3. Ready biodegradability of sorbitan monolaurate and sorbitan esters

The aerobic degradability (biochemical oxygen demand of insoluble substances [BODIS test]) of sorbitan monolaurate in seawater was tested. The test substance was biodegraded by 54% over 28 days and showed only a slight inhibition of 8% to seawater bacteria. The test was extended for an additional 7 days to establish whether degradation was continuous after the test period. Sorbitan monolaurate achieved a plateau by day 35 in the 7 days extended test.

Chen et al. (2001), investigating the biodegradability of surfactants in activated sludge, found that sorbitan monooleate was readily degraded (90%) by activated sludge within 100 h.

Kim and Weber (2005) reported about the degradation of a number of poly cyclic aromatic hydrocarbons with and without polyoxyethylene-sorbitan-monolaurate. Its biodegradation in a soil-free liquid bacteria culture was limited to 17.8% of the initial dose, degradation in soil systems was not tested. The degradation potential for polyoxyethylene-sorbitan-monolaurate in soil-free systems is limited.

Franzetti et al. (2006) reported about sorption and biodegradation of polyoxyethylene-sorbitan-monolaurate. The compound showed moderate sorption (sorption/desorption coefficient [Kd] of 37 L/kg), but at higher concentrations, it showed non-linear ‘cooperative sorption’ behaviour. Biodegradation was

---

10 Technical dossier/Supplementary information February 2020/Annex Sin3 Degradability.
assessed indirectly by liquid respirometry with the conclusion that the compound is extremely degradable and is completely mineralised.

Sorbitan monolaurate is readily biodegradable (US EPA, 2010), achieving 57% of its theoretical biochemical oxygen demand over a 14-day period.

Wirz et al. (2015) assessed the environmental risk posed by excipients from a galenic pharmaceutical production (including sorbitol (CAS: 50-70-4) and polyoxyethylene-sorbitan-monolaurate (CAS: 9005-64-5)) to receiving water bodies upon wastewater treatment process. From the results, it can be seen that compounds similar to sorbitan monolaurate (e.g. polyoxyethylene-sorbitan-monolaurate, stearic acid, sorbitol) are highly biodegradable and the risk for aquatic biota is highly unlikely.

These studies indicate that sorbitan monooleate as well as chemically similar molecules are readily degradable in activated sludge.

3.1.4. Ecotoxicity data

Franzetti et al. (2006) reported about microbial toxicity of polyoxyethylene-sorbitan-monolaurate. The compound showed very low toxicity in the MICROTOX® bioassay (EC50 7.0 g/L).

A limited set of relevant ecotoxicological information is mentioned in only one paper, Wirz et al. (2015) where some PEC and Predicted no effect concentration (PNEC) values are reported.11

The applicant submitted the following studies on aquatic organisms in which sorbitan monolaurate and/or sorbitan monooleate were used as test items.

Marine water toxicity

The toxicity of sorbitan monolaurate and sorbitan monooleate was tested in a study following good laboratory practices (GLPs) performed according to ISO 14669:1999 with the marine crustacean Acartia tonsa.12 Sorbitan monolaurate exhibited a 48-h LC50 value of 452.8 mg/L and sorbitan monooleate a 48-h LC50 > 10,000 mg/L.

Marine sediment toxicity

Sorbitan monolaurate was tested in a sediment toxicity test with the intertidal amphipod Corophium volutator.13 According to the method, test duration was 10 days. Sorbitan monolaurate was characterised as poorly soluble and therefore was added to the test system via dried sediment. Well-defined information was provided on the source of test species and sediment (Bay of Suckquoy, Scotland), acclimation period (4 days) and test conditions. Tests were conducted (under controlled illumination and temperature) in 1 L capacity glass beakers each containing 2 cm depth of amended sediment and 850 mL of overlying seawater. Three replicates were prepared for each test concentration; controls were replicated five times. In total, 60 organisms were exposed per concentration of the test item and 100 for control. The target wet weight nominal concentrations ranged from 10 to 10,000 mg/kg (10, 100, 320, 1,000, 10,000). The validity criteria were fulfilled. Based on the obtained results, sorbitan monolaurate exhibited a 10-day LC50 value of 1,141 mg/kg (dry weight) to the marine amphipod Corophium volutator in the sediment phase.

The ecotoxicity of sorbitan monolaurate to marine sediment organisms is very low as well as to marine water species.

3.1.5. Conclusions on the safety for the environment

The additive is a mixture of different compounds. Biodegradation studies and ADME data are available only for a few compounds of the additive. Few ecotoxicity data on sorbitan esters are available, mainly related to marine environment.

| Sorbitan ester of | Content (%) | ADME | Biodegradability | Ecotoxicity | Literature review |
|------------------|-------------|------|------------------|-------------|------------------|
| Lauric acid      | 40–60       | X    | X (marine water) | X (biodegradability) |
### Sorbitan ester of

| Content (%) | ADME | Biodegradability | Ecotoxicity | Literature review |
|-------------|------|------------------|-------------|------------------|
| Myristic acid | 14-25 | X (trioleate) | X (marine sediment) | X (biodegradability) |
| Palmitic acid | 7-15 | | | |
| Oleic acid | < 11 | | X (marine water) | |
| Caprylic acid | < 10 | | | |
| Capric acid | < 10 | | | |
| Stearic acid | < 7 | | X | |
| Linoleic acid | < 3 | | | |

A complete ecotoxicological data set is not available. Nevertheless, the FEEDAP Panel considers that even with a limited amount of studies, some conclusions on the safety for the environment of sorbitan monolaurate can be drawn through a weight of evidence assessment (EFSA Scientific Committee, 2017). Information from different lines of evidence was integrated including:

i) the available data on the ADME of structurally related compounds, sorbitan monostearate and sorbitan trioleate, which indicate that the additive is expected to be metabolised at least in part, as about 20% of the absorbed fraction is exhaled in the form of CO₂, and that about 20–50% of the absorbed fraction is excreted in urine as sorbitan or metabolites,

ii) the readily aerobic degradability of sorbitan monolaurate in water and seawater, supported by evidence available from the literature on structurally related compounds, sorbitan monooleate and polyoxyethylene-sorbitan-monolaurate,

iii) the limited available ecotoxicity data for sorbitan monolaurate and marine crustaceans and in marine sediment organisms, which indicate that the ecotoxicity of the additive is low, in consistency with the very low acute toxicity of sorbitan esters.

Overall, the FEEDAP Panel concludes that an environmental risk of sorbitan monolaurate to terrestrial and aquatic organisms is unlikely. Therefore, no safety concerns for the environment are expected from the use of the additive under assessment according to the proposed conditions of use.

### 4. Conclusions

No safety concerns for the environment are expected from the use of the additive under assessment according to the established conditions of use.

### 5. Documentation as provided to EFSA/Chronology

| Date       | Event                                                                 |
|------------|----------------------------------------------------------------------|
| 02/04/2019 | Dossier received by EFSA. Sorbitan monolaurate for all animal species. Submitted by Kemin Europa N.V |
| 10/07/2019 | Reception mandate from the European Commission                       |
| 19/09/2019 | Application validated by EFSA – Start of the scientific assessment    |
| 04/12/2019 | Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: safety for the environment |
| 19/02/2020 | Reception of supplementary information from the applicant - Scientific assessment re-started |
| 25/05/2020 | Opinion adopted by the FEEDAP Panel. End of the Scientific assessment |

### References

Alwadani N and Fatehi P, 2018. Synthetic and lignin-based surfactants: challenges and opportunities. Carbon Resources Conversion, 1, 126–138.

Chen G, Strevett KA and Vanegas BA, 2001. Naphthalene, phenanthrene and surfactant biodegradation. Biodegradation, 12, 433–442.

Clariant, 2011. Material Safety Data Sheet for Polyglycol 6000PF, 10/22/2011. Clariant Co., Charlotte, NC, USA. Available online: [http://www.hbchemical.com/wp-content/uploads/2014/04/PEG-6000-PF.pdf](http://www.hbchemical.com/wp-content/uploads/2014/04/PEG-6000-PF.pdf) [Accessed: 3 March 2015].
Tocher DR, 2003. Metabolism and functions of lipids and fatty acids in teleost.

Oser BL and Oser M, 1957. Nutritional studies on rats on diets containing high levels of partial ester emulsi.

Toshima Y, Moriya T and Yoshimura K, 1992. Effects of polyoxyethylene (20) sorbitan monooleate on the acute.

Straub JO, Shearer R and Studer M, 2014. Rational selection of alternative, environmentally compatible surfactants.

Li Q and Yang GP, 2010. In.

Krogh KA, Halling-Sørensen B, Mogensen BB and Vejrup KV, 2003. Environmental properties and effects of.

Kim HS and Weber WJ, 2005. Polycyclic aromatic hydrocarbon behavior in bioactive soil slurry reactors amended.

EFSA (European Food Safety Authority), 2008. Technical Guidance of the Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) for assessing the safety of feed additives for the environment. EFSA Journal 2008;6(10):842, 28 pp. https://doi.org/10.2903/j.efsa.2008.842

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Koubá M, Kos Durjava M, Lopez-Alonso M, Lopez Puente S, Marcon F, Mayo B, Pechova A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Aquilina G, Bories G, Chesson A, Nebbia C, Renshaw D, Innocenti ML and Gropp J, 2019. Scientific Opinion on the safety and efficacy of sorbitan monolaurate as a feed additive for all animal species. EFSA Journal 2019;17(3):5651, 15 pp. https://doi.org/10.2903/j.efsa.2019.5651

EFSA Scientific Committee, Hardy A, Benford D, Halldorsson T, Jeger MJ, Knutsen HK, More S, Naegeli H, Noteborn H, Ockleford C, Ricci A, Rychen G, Schlatter JR, Silano V, Solecki R, Turck D, Benfenati E, Chaudhry QM, Craig P, Frampton G, Greiner M, Hart A, Hogstrand C, Lambre C, Luttik R, Makowski D, Siani A, Wahlstroem H, Aguilera J, Dorme J-L, Fernandez Dumont A, Hempen M, Valtuena Martinez S, Martino L, Smeraldi C, Terron A, Georgiadis N and Younes M, 2017. Scientific Opinion on the use of the weight of evidence approach in scientific assessments. EFSA Journal 2017;15(8):4971, 69 pp. https://doi.org/10.2903/j.efsa.2017.49712017

Franzetti A, Di Gennaro P, Bevilacqua A, Papacchini M and Bestetti G, 2006. Environmental features of two commercial surfactants widely used in soil remediation. Chemosphere, 62, 1474–1480.

Gonzalez CF, Taber WA and Zeitoun MA, 1972. Biodegradation of ethyleneglycol by a salt-requiring bacterium. -

ECHA (European Chemicals Agency), 2015. Review of Annex IV of Regulation (EC) no.1907/ 2006 (REACH), Evaluation of existing entries in Annex IV, Prepared by DHI, Milieu Ltd. and Protection Through Knowledge (PKT) Ltd., pp. 1–159. Available online: http://ec.europa.eu/environment/chemicals/reach/pdf/6b_appendix_2.pdf (Accessed: 2 March 2015).

US EPA (United States Environmental Protection Agency), 2005. Action Memo [Inert Reassessment -

Frazer AN and Joseph L, 1952. The metabolism of sorbitan monostearate. Food Research, 18, 79–84.

Wick AN and Joseph L, 1953. Sorbitan monostearate metabolism. Lack of deposition upon chronic feeding. Agricultural and Food Chemistry, 1, 398–399.

Wirs KC, Studer M and Straub JO, 2015. Environmental risk assessment for excipients from galenic pharmaceutical production in wastewater and receiving water. Sustainable Chemistry and Pharmacy, 1, 28–35.

Xi Y, Seyoum H and Liu MC, 2016. Role of SULT-mediated sulfation in the biotransformation of 2-butoxyethanol and sorbitan monolaurate: a study using zebrafish SULTs. Aquatic Toxicology, 177, 19–21.

www.efsa.europa.eu/efsajournal 10 EFSA Journal 2020;18(6):6162
Zheng G, Selvam A and Wong JWC, 2012. Enhanced solubilization and desorption of organochlorine pesticides (OCPs) from soil by oil-swollen micelles formed with a nonionic surfactant. Environmental Science & Technology, 46, 12062–12068.

**Abbreviations**

| Abbreviation | Definition |
|--------------|------------|
| ADME         | Absorption, distribution, metabolism and excretion |
| CAS          | Chemical Abstracts Service |
| BODIS test   | Test of biochemical oxygen demand of insoluble substances |
| DM           | Dry matter |
| EC50         | The concentration of a test substance which results in 50% of the test organisms being adversely affected, i.e. both mortality and sublethal effects |
| GLP          | Good laboratory practice |
| Kd           | Sorption/desorption coefficient |
| LC50         | The concentration of a test substance which results in a 50% mortality of the test species |
| Log Kow      | Logarithm of octanol-water partition coefficient |
| MW           | Molecular weight |
| PEC          | Predicted environmental concentration |
| PNEC         | Predicted no effect concentration |
| US EPA       | United States environmental protection agency |
Appendix A — Chemical structure of the compounds of the additive and similar compounds relevant for the assessment

Chemical structure of the different compounds of the additive and similar compounds considered relevant for the assessment, retrieved from the literature review.

| Compound                        | Chemical Structure                                                                 |
|---------------------------------|------------------------------------------------------------------------------------|
| Sorbitol                        | ![Sorbitol structure](image)                                                        |
| Sorbitan caprylate              | ![Sorbitan caprylate structure](image)                                             |
| Sorbitan caprate                | ![Sorbitan caprate structure](image)                                               |
| Sorbitan monolaurate            | ![Sorbitan monolaurate structure](image)                                           |
| Sorbitan myristate              | ![Sorbitan myristate structure](image)                                             |
| Sorbitan monopalmitate          | ![Sorbitan monopalmitate structure](image)                                         |
| Sorbitan monostearate           | ![Sorbitan monostearate structure](image)                                          |
| Sorbitan monooleate             | ![Sorbitan monooleate structure](image)                                            |
| Sorbitan linoleate              | ![Sorbitan linoleate structure](image)                                             |
| Sorbitan trioleate              | ![Sorbitan trioleate structure](image)                                             |
| Polyoxethylene-sorbitan-monolaurate | ![Polyoxethylene-sorbitan-monolaurate structure](image)                         |