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Re-evaluation of stearyl tartrate (E 483) as a food additive

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Abstract

The Panel on Food Additives and Flavourings (FAF) provided a scientific opinion re-evaluating the safety of stearyl tartrate (E 483) as a food additive. The previously evaluated toxicological studies were not available, in addition to no genotoxicity data being available. Thus, adequate toxicity data on stearyl tartrate were not available for its re-evaluation. In addition, adequate data demonstrating the complete hydrolysis of stearyl tartrate (E 483) in the gastrointestinal tract and/or presystemically, that could allow read-across from data on its constituents, were lacking. Therefore, the safety of the use of stearyl tartrate as a food additive could not be assessed and the acceptable intake established by the Scientific Committee on Food (SCF) in 1978 could not be confirmed. Exposure to stearyl tartrate (E 483) was calculated using the maximum level exposure assessment scenario as neither use levels nor analytical data were available. Mean exposure to stearyl tartrate (E 483) as a food additive ranged from 0.1 mg/kg body weight (bw) per day in infants to 82.5 mg/kg bw per day in toddlers. The 95th percentile of exposure ranged from 0 mg/kg bw per day in adults to 192.7 mg/kg bw per day in toddlers. The Panel also noted that information from the Mintel's GNPD indicates that only two products have been labelled with stearyl tartrate (E 483) since 1996. Some recommendations were proposed by the Panel.

Keywords: stearyl tartrate, E 483

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Summary

Following a request from the European Commission, the Panel on Food Additives and Flavourings (FAF) was asked to deliver a scientific opinion on the re-evaluation of the safety of stearyl tartrate (E 483) used as a food additive. The present opinion document deals with the re-evaluation of stearyl tartrate (E 483) when used as a food additive.

Stearyl tartrate (E 483) is an authorised food additive in the European Union (EU) according to Annex II of Regulation (EC) No 1333/2008 and specifications have been defined in the Commission Regulation (EU) No 231/2012 and by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2006. Stearyl tartrate (E 483) has been previously evaluated by the Scientific Committee on Food (SCF) in 1978 and by JECFA in 1965. The SCF allocated an acceptable daily intake of 1,200 mg/adult per day, corresponding to 20 mg/kg body weight (bw) per day for an adult weighing 60 kg.

Stearyl tartrate (E 483) is defined by Commission Regulation (EU) No 231/2012 as 'Product of the esterification of tartaric acid with commercial stearyl alcohol, which consists essentially of stearyl and palmityl alcohols. It consists mainly of diester, with minor amounts of monoester and of unchanged starting materials'. The Panel noted that the name 'stearyl tartrate' for E 483 does not reflect the composition of the food additive since it is a mixture of three different esters (distearyl tartrate, dipalmityl tartrate and stearylpalmityl tartrate).

Apart from the specifications given in Commission Regulation (EU) No 231/2012 and by JECFA, there was only minor information available relating to the manufacturing process of stearyl tartrate (E 483). The Panel considered that only L(+)-tartaric acid should be used in the manufacturing process of stearyl tartrate (E 483).

The limited available absorption, distribution, metabolism, excretion (ADME) data are not sufficient to confirm the extent of hydrolysis of stearyl tartrate in the gastrointestinal (GI) tract and presystemically or the extent of absorption or metabolism. In the absence of additional data, the Panel noted that kinetic fate of this food additive remains uncertain. Therefore, read-across from data on its constituents is not applicable.

No short-term toxicity, subchronic toxicity or genotoxicity data was available.

The Panel considered the information on chronic toxicity and reproduction summarised in the JECFA evaluation in 1965, inadequate for hazard identification. The toxicological studies were not available. No genotoxicity data were available to the Panel; however, no relevant structural alert for genotoxicity was found analysing distearyl L(+)-tartrate, stearylpalmityl L(+)-tartrate and dipalmityl L(+)-tartrate through the OECD QSAR toolbox (version 4.3).

Food consumption data derived from the EFSA Comprehensive European Food Consumption Database was used to estimate the dietary exposure to stearyl tartrate (E 483). In response to the call for data, no concentration data for stearyl tartrate (E 483) in foods was made available by the Member States or Industry or other interested parties. The Panel noted that the lack of reported use levels was in line with the data obtained from the Mintel's Global New Products Database (GNPD), where only two entries in total were observed for stearyl tartrate since 1996. As a result, exposure assessment to stearyl tartrate (E 483) was carried out based on maximum permitted levels, known as the *maximum level exposure assessment scenario*. Mean exposure to stearyl tartrate (E 483) ranged from 0.1 mg/kg bw per day in infants to 82.5 mg/kg bw per day in toddlers. The 95th percentile of exposure ranged from 0 mg/kg bw per day in adults to 192.7 mg/kg bw per day in toddlers. The Panel considered that the exposure to stearyl tartrate (E 483) was an overestimation, due to the assumption that the food additive is used at maximum permitted level in each authorised food category.

The Panel concluded that there was inadequate toxicity data on stearyl tartrate (E 483), in addition to a lack of adequate data demonstrating its complete hydrolysis in the GI tract and/or presystematically that could allow read-across from data on its constituents. As a result, its safety as a food additive could not be assessed and the acceptable intake of 20 mg/kg bw per day established by the SCF in 1978 could not be confirmed.

The Panel made a number of recommendations: confirmation that stearyl tartrate (E 483) is used by industry, and if confirmed, information on use and use levels should be made available in order to perform a refined exposure assessment; that data showing complete presystematic hydrolysis and/or appropriate toxicity studies be made available in order to assess the safety of stearyl tartrate (E 483); that the European Commission consider revising the EU specifications for stearyl tartrate (E 483) to specify that only L(+)-tartaric acid can be used in the manufacturing process; that the European Commission should consider setting lower maximum limits for toxic elements in the EU specifications for stearyl tartrate (E 483) to ensure that its use as a food additive will not be a significant source of exposure to these toxic elements in food; and finally that the European Commission consider revising the name of E 483 since it is a mixture of three different esters.

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1. Introduction

The present opinion document deals with the re-evaluation of stearyl tartrate (E 483) when used as a food additive.

1.1. Background and Terms of Reference as provided by the European Commission

1.1.1. Background

Regulation (EC) No 1333/2008[1] of the European Parliament and of the Council on food additives requires that food additives are subject to a safety evaluation by the European Food Safety Authority (EFSA) before they are permitted for use in the European Union. In addition, it is foreseen that food additives must be kept under continuous observation and must be re-evaluated by EFSA.

For this purpose, a programme for the re-evaluation of food additives that were already permitted in the European Union before 20 January 2009 has been set up under the Regulation (EU) No 257/2010.[2] This Regulation also foresees that food additives are re-evaluated whenever necessary in light of changing conditions of use and new scientific information. For efficiency and practical purposes, the re-evaluation should, as far as possible, be conducted by group of food additives according to the main functional class to which they belong.

The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria: the time since the last evaluation of a food additive by the Scientific Committee on Food (SCF) or by the European Food Safety Authority (EFSA), the availability of new scientific evidence, the extent of use of a food additive in food and the human exposure to the food additive taking also into account the outcome of the Report from the Commission on Dietary Food Additive Intake in the EU[3] of 2001. The report 'Food additives in Europe 2000'[4] submitted by the Nordic Council of Ministers to the Commission, provides additional information for the prioritisation of additives for re-evaluation. As colours were among the first additives to be evaluated, these food additives should be re-evaluated with a highest priority.

In 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives. However, as a result of adoption of Regulation (EU) 257/2010 the 2003 Terms of References are replaced by those below.

1.1.2. Terms of Reference

The Commission asks the European Food Safety Authority to re-evaluate the safety of food additives already permitted in the Union before 2009 and to issue scientific opinions on these additives, taking especially into account the priorities, procedures and deadlines that are enshrined in the Regulation (EU) No 257/2010 of 25 march 2010 setting up a programme for the re-evaluation of approved food additives in accordance with the Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

1.2. Information on existing authorisations and evaluations

Stearyl tartrate (E 483) is an authorised food additive in the EU according to Annex II of Regulation (EC) No 1333/2008 and specifications have been defined in the Commission Regulation (EU) No 231/2012.[5]

Stearyl tartrate (E 483) was previously evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in its ninth meeting in 1965 (JECFA, 1965). Based on the available data the Committee noted that stearyl tartrate has been extensively studied in animals. According to metabolic studies it was assumed that it is poorly absorbed under ordinary circumstances, but that if it is

[1] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008.

[2] Commission Regulation (EU) No 257/2010 of 25 march 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27.

[3] COM(2001) 542 final.

[4] Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord 2002, 560.

[5] Commission Regulation (EU) No 231/2012 of 9 march 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) no 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p 1.

absorbed it can be metabolised and does not accumulate in the tissues. Furthermore, the Committee concluded that there 'exists little doubt concerning the safety and freedom from carcinogenic hazard of stearyl tartrate'. The Committee considered up to 500 mg/kg flour as an acceptable level of treatment for bread.

In 1978, the Scientific Committee on Food (SCF) published an evaluation on stearyl tartrate (no indication of stereochemistry given), in which an acceptable intake of 1,200 mg/adult per day was allocated, corresponding to 20 mg/kg body weight (bw) per day for an adult weighing 60 kg. No details were reported on toxicological data, the basis of evaluation and conclusion or any references. However, a maximum level of 3 g/kg dry matter in fine bakers' wares corresponding to an average daily intake from fine bakery wares of 60 mg stearyl tartrate/adult/day was proposed (SCF, 1978).

In the report from the 55th JECFA Meeting (JECFA, 2001), it was noted that no new data were submitted or were found in a literature search. Therefore, the Committee referred to the data reviewed at its ninth meeting in 1965 (JECFA, 1965). However, the references on which the corresponding monograph was based were no longer available and the Committee concluded that 'either the original toxicological and metabolic studies should be made available or that new studies demonstrating hydrolysis in vivo should be submitted before the substance could be re-evaluated'. The Committee also asked for data on oral exposure. The Committee noted that the intake of stearyl tartrate relative to the acceptable daily intake (ADI) of L(+)-tartaric acid (30 mg/kg bw per day) should be considered.

In the TemaNord monograph on stearyl tartrate (E 483), the following recommendation is given 'Stearyl tartrate should be re-evaluated. Data on hydrolysis are required to show whether the supposed hydrolysis to constituents, normally occurring naturally in food, takes place' (TemaNord, 2002).

2. Data and methodologies

Data

The Panel on Food Additives and Flavourings (FAF) was not provided with a newly submitted dossier. EFSA launched a public call for data[6,7,8,9] to collect information from interested parties.

The Panel based its assessment on information submitted to EFSA following the public calls for data, information from previous evaluations and additional available literature up to January 2020. Attempts were made at retrieving relevant original study reports on which previous evaluations or reviews were based, however not always these were available to the Panel.

Food consumption data used to estimate the dietary exposure to stearyl tartrate (E 483) were derived from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database[10]).

The Mintel's Global New Products Database (GNPD) was used to verify the use of stearyl tartrate (E 483) in food and beverage products and food supplements within the EU's market. The Mintel's GNPD is an online database that contains the compulsory ingredient information present on the label of numerous products.

Methodologies

This opinion was formulated following the principles described in the EFSA Guidance on transparency with regard to scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing Guidances from the EFSA Scientific Committee.

The FAF Panel assessed the safety of stearyl tartrate as a food additive in line with the principles laid down in Regulation (EU) 257/2010 and in the relevant guidance documents: Guidance on submission for food additive evaluations by the Scientific Committee on Food (SCF, 2001).

[6] Call for scientific data on stearyl tartrate (E 483). Published: 5 July 2012. Available from: http://www.efsa.europa.eu/en/dataclosed/call/120706

[7] Call for scientific data on selected food additives permitted in the EU. Published: 24 march 2014 (batch A), 1 November 2014 (batch B) Available online: http://www.efsa.europa.eu/en/dataclosed/call/140324.htm

[8] Call for food additives usage level and/or concentration data in food and beverages intended for human consumption (batch 4). Published 12 October 2015. Available online: http://www.efsa.europa.eu/en/data/call/151012

[9] Call for scientific data on L(+)-tartaric acid (E 334) and related food additives authorised in the EU. Published: 3 may2016. Available from https://www.efsa.europa.eu/sites/default/files/consultation/160531.pdf

[10] Available online: http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm

When in animal studies, the test substance was administered in the feed or in drinking water, but doses were not explicitly reported by the authors as mg/kg bw per day based on actual feed or water consumption, the daily intake is calculated by the Panel using the relevant default values. In case of rodents, the values as indicated in the EFSA Scientific Committee Guidance document (EFSA Scientific Committee, 2012) are applied. In the case of other animal species, the default values by JECFA (2000) are used. In these cases, the dose was expressed as 'equivalent to mg/kg bw per day'.

Dietary exposure to stearyl palmitate (E 483) from its use as a food additive was estimated combining food consumption data available within the EFSA Comprehensive European Food Consumption Database with the maximum permitted levels (MPLs). A scenario was used to calculate the exposure (see Section 3.3.1). Uncertainties on the exposure assessment were identified and discussed.

3. Assessment

3.1. Technical data

3.1.1. Identity of the substance

According to Commission Regulation (EU) No 231/2012 stearyl tartrate (E 483) is defined as follows: 'Product of the esterification of tartaric acid with commercial stearyl alcohol, which consists essentially of stearyl and palmityl alcohols. It consists mainly of diester, with minor amounts of monoester and of unchanged starting materials'. The additive is described by a content of total ester not less than 90% corresponding to an ester value[11] within the range of 163–180. Chemical name, chemical formula and molecular weight refer to: distearyl tartrate, dipalmityl tartrate and stearylpalmityl tartrate.

The Panel noted that the name 'stearyl tartrate' for E 483 (Commission Regulation (EU) No 231/2012) does not reflect the composition of the food additive since it is a mixture of three different esters (distearyl tartrate, dipalmityl tartrate and stearylpalmityl tartrate).

In Table 1, the main parameters referring to the identity of the diesters are given. Their structural formula is presented in Figure 1. However, the stereochemistry has not been considered in the structural formula, as no indication is given in the EU specifications or in the JECFA specifications (2006).

Table 1: Identity of the diesters of stearyl tartrate (E 483)

	Distearyl tartrate	**Stearylpalmityl tartrate**	**Dipalmityl tartrate**
Chemical name	Dioctadecyl 2,3-dihydroxybutanedioate	Hexadecyl octadecyl 2,3-dihydroxybutanedioate	Dihexadecyl 2,3-dihydroxybutanedioate
Molecular formula	$C_{40}H_{78}O_6$	$C_{38}H_{74}O_6$	$C_{36}H_{70}O_6$
Molecular weight (g/mol)	655.06	627.00	598.95

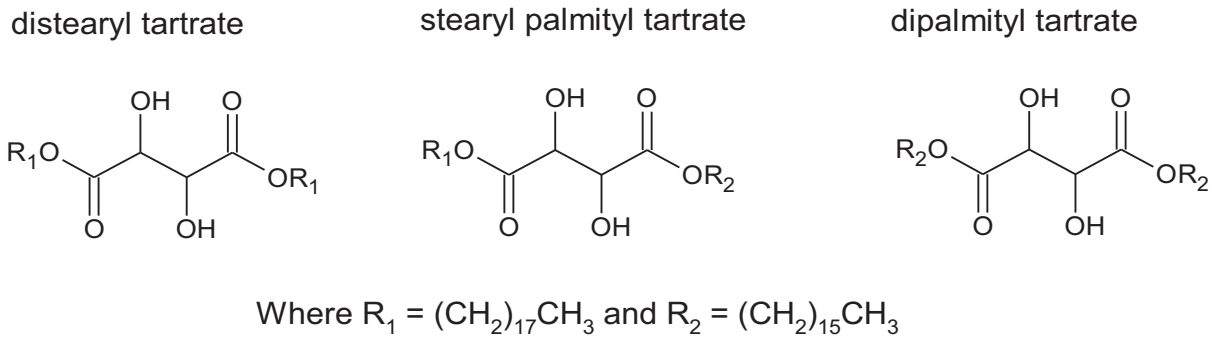

Figure 1: Structural formula of the diesters of E 483

Synonyms: Stearyl palmityl tartrate

[11] The ester value is the number of mg of potassium hydroxide required to saponify the esters in 1.0 g of the substance.

3.1.2. Specifications

The specifications for stearyl tartrate (E 483) as defined in the Commission Regulation (EU) No 231/2012 and by JECFA (2006) are listed in Table 2.

Table 2: Specifications for stearyl tartrate (E 483) according to Commission Regulation (EU) No 231/2012 and JECFA (2006)

	Commission Regulation (EU) No 231/2012	**JECFA (2006)**
Definition	Product of the esterification of tartaric acid with commercial stearyl alcohol, which consists essentially of stearyl and palmityl alcohols. It consists mainly of diester, with minor amounts of monoester and of unchanged starting materials	The product of the esterification of tartaric acid with commercial stearyl alcohol, which consists essentially of stearyl and palmityl alcohols; consists mainly of diester, with minor amounts of monoester and of unchanged starting materials
Assay	Content of total ester not less than 90% corresponding to an ester value of not less than 163 and not more than 180	Not less than 90% of total ester content corresponding to an ester value within the range of 163 to 180
Description	Cream-coloured unctuous solid (at 25°C)	Cream-coloured unctuous substance
Identification		
Solubility		Insoluble in water, insoluble in cold ethanol, soluble in hot ethanol[(a)]
Melting range	Between 67 °C and 77 °C. After saponification the saturated long chain fatty alcohols have a melting range of 49–55 °C	67–77°
Test for tartrate	Passes test	Passes test
Purity		
Hydroxyl value	Not less than 200 and not more than 220	200 to 220
Sulfated ash	Not more than 0.5% (800 ± 25°C)	Not more than 0.5%, test 2 g of the sample[(b)]
Total tartaric acid	Not less than 18% and not more than 35%	Not less than 18% and not more than 35%
Unsaponifiable matter	Not less than 77% and not more than 83%	Not less than 77% and not more than 83%
Acid value	Not more than 5.6	Not more than 6
Arsenic	Not more than 3 mg/kg	
Lead	Not more than 2 mg/kg	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg	
Cadmium	Not more than 1 mg/kg	
Iodine value	Not more than 4 (Wijs method)	

(a): within specification by JECFA used as additional identification parameter.
(b): according to JECFA (2006) measured at 800 ± 25°C.

The Panel noted that, according to the EU specifications for stearyl tartrate (E 483), impurities of the toxic elements arsenic, lead, cadmium and mercury are accepted up to concentrations of 3, 2, 1 and 1 mg/kg, respectively. Contamination at those levels could have a significant impact on the exposure, which is already are close to the health-based guidance values or benchmark doses (lower confidence limits) established by EFSA (EFSA CONTAM Panel, 2009a,b, 2010, 2012a,b,c 2014).

The Panel noted that the stereochemistry of the tartaric acid used as a starting material and of the tartrate moiety in the esters present in stearyl tartrate (E 483) is not included in EU specifications. Only L(+)-tartaric acid is authorised for the food additive E 334. Given the adverse effects reported for DL-tartaric acid (EFSA FAF Panel, 2020), only L(+)-tartaric acid should be used for the manufacturing process of food additives containing tartaric acid.

3.1.3. Manufacturing process

Only limited information about the manufacturing process is available in the literature. No information was obtained on the manufacturing process from the public call. The only available

information is based on the specifications given in Commission Regulation (EU) No 231/2012 and JECFA (2006): stearyl tartrate (E 483) is the reaction product of the esterification of tartaric acid with commercial stearyl alcohol, which consists essentially of stearyl alcohol and palmityl alcohol.

No information has been submitted to EFSA regarding tartaric acid stereoisomer use in the manufacturing process of this food additive.

3.1.4. Methods of analysis in food

Only limited information is available for the analysis of stearyl tartrate (E 483) in food.

In a review of analytical methods food additives (Wood et al., 2004), it is indicated that there are no methods published for the determination of stearyl tartrate in foodstuffs and that analytical methods need to be developed.

Williams (1964) presented a method only for the detection and the approximate determination of stearyl tartrate in bread. The author calculated the amount of stearyl tartrate via measurement of the proportion of stearyl alcohol after acid hydrolysis and saponification. Stearyl alcohol was determined semi-quantitatively in the unsaponifiable matter by thin-layer chromatography.

3.1.5. Stability of the substance, and reaction and fate in food

The Panel noted that no data on stability of the additive in food are available.

3.2. Authorised uses and use levels

Maximum levels of stearyl tartrate (E 483) have been defined in Annex II to Regulation (EC) No 1333/2008 on food additives, as amended. In this document, these levels are named MPLs.

Currently, stearyl tartrate (E 483) is an authorised food additive in four food categories at MPLs ranging from 4,000 to 5,000 mg/kg (or mg/L as appropriate) set by Annex II to Regulation (EC) No 1333/2008 and summarised in Table 3.

Table 3: MPLs of stearyl tartrate (E 483) in foods according to Annex II to Regulation (EC) No 1333/2008

Food category number	Food category name	E-number/ Group	Restrictions/exception	MPL (mg/L or mg/kg as appropriate)
01.4	Flavoured fermented milk products including heat-treated products	E 483		5,000
07.1	Bread and rolls	E 483	except products in 7.1.1 and 7.1.2	4,000
07.2	Fine bakery wares	E 483		4,000
16	Desserts excluding products covered in categories 1, 3 and 4	E 483		5,000

MPL: maximum permitted level.

Stearyl tartrate (E 483) is not authorised according to Annex III to Regulation (EC) No 1333/2008, which lists food additives approved for use in food additives, food enzymes, food flavourings and nutrients, and their conditions of use and as such, their presence in the final food would be only due to carry-over.

3.3. Exposure data

3.3.1. Reported use levels or data on analytical levels of stearyl tartrate (E 483)

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. Therefore, information on actual use levels is required for performing a more realistic exposure assessment.

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued a public call[12] for occurrence data (use level and/or analytical data) on stearyl tartrate (E 483).

[12] http://www.efsa.europa.eu/sites/default/files/consultation/151012.pdf

In response to this call, no occurrence data for stearyl tartrate (E 483) in foods were made available by the Member States or Industry or other interested parties.

3.3.2. Summarised data extracted from the Mintel's Global New Products Database

The Mintel's GNPD is an online database which monitors new introductions of packaged goods in the market worldwide. It contains information of over 2.5 million food and beverage products of which more than 1,000,000 are or have been available on the European food market. Mintel started covering EU's food markets in 1996, currently having 25 out of its 28 member countries and Norway presented in the Mintel GNPD.[13]

For the purpose of this Scientific Opinion, the Mintel's GNPD[14] was used for checking the labelling of food and beverages products and food supplements for stearyl tartrate (E 483) within the EU's food market as the database contains the compulsory ingredient information on the label.

According to the Mintel's GNPD, stearyl tartrate (E 483) was labelled on one product belonging to the food subcategory of Chilled Desserts and one product of food subcategory Cakes, Pastries & Sweet Goods. Both products were listed in 2015. The food subcategories belong to Mintel's GNPD food classification.

Appendix A lists the percentage of the food products labelled with stearyl tartrate (E 483) out of the total number of food products per food subcategories according to the Mintel's GNPD food classification. The average percentage of foods labelled to contain stearyl tartrate (E 483) and belonging to food subcategories with at least one food labelled with the additive was 0.01%.

3.3.3. Food consumption data used for exposure assessment

EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a). Consumption surveys added in the Comprehensive database in 2015 were also taken into account in this assessment.[10]

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons may not be appropriate. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database includes the currently best available food consumption data across Europe.

Food consumption data of infants, toddlers, children, adolescents, adults and the elderly were used in the exposure assessment. For the present assessment, food consumption data were available from 33 different dietary surveys carried out in 19 European countries (Table 4).

Table 4: Population groups considered for the exposure estimates of stearyl tartrate (E 483)

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From more than 12 weeks up to and including 11 months of age	Bulgaria, Denmark, Finland, Germany, Italy, UK
Toddlers[(a)]	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Denmark, Finland, Germany, Italy, Netherlands, Spain, UK
Children[(b)]	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden, UK
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Italy, Latvia, Netherlands, Spain, Sweden, UK

[13] Missing Cyprus, Luxembourg and Malta.
[14] http://www.gnpd.com/sinatra/home/ accessed on 5/11/2019.

Population	Age range	Countries with food consumption surveys covering more than 1 day
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Romania, Spain, Sweden, UK
The elderly[(b)]	From 65 years of age and older	Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Romania, Netherlands, Sweden, UK

(a): The term 'toddlers' in the EFSA Comprehensive Database (EFSA, 2011a) corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013.
(b): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in the EFSA Comprehensive Database (EFSA, 2011a).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the food categorisation system (FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure assessments. In practice, the FoodEx food codes were matched to the FCS food categories.

Food categories considered for the exposure assessment of stearyl tartrate (E 483)

The food categories in which the use of stearyl tartrate (E 483) is authorised were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system), at the most detailed level possible (up to FoodEx Level 4) (EFSA, 2011b).

For FC 07.1 Bread and rolls, the exception 'except products in 7.1.1 and 7.1.2' could not be taken into account since the consumption data in the EFSA Comprehensive Database was not precise enough. As the exception represents only a minor part of the whole food category, the full food category was taken into account.

Overall, all four food categories in which the use of stearyl tartrate (E 483) is authorised were included in the present exposure assessment (Appendix B).

3.4. Exposure estimate

3.4.1. Exposure to stearyl tartrate (E 483) from its use as a food additive

The Panel estimated the chronic dietary exposure to stearyl tartrate (E 483) for the following population groups: infants, toddlers, children, adolescents, adults and the elderly. Dietary exposure to stearyl tartrate (E 483) was calculated by multiplying MPLs of stearyl tartrate (E 483) per food category (Appendix B) with their respective consumption amount per kilogram body weight for each individual in the Comprehensive Database. The exposure per food category was subsequently added to derive an individual total exposure per day. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only 1 day per subject were excluded as they are considered as not adequate to assess repeated exposure.

This was carried out for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 4). Based on these distributions, the mean and 95th percentiles of exposure were calculated per survey and per population group. The 95th percentile of exposure was only calculated for those population groups with a sufficiently large sample size (EFSA, 2011a). Therefore, in the present assessment, the 95th percentile of exposure for infants from Italy and for toddlers from Belgium, Italy and Spain was not estimated.

Exposure assessment to stearyl tartrate (E 483) was carried out by the FAF Panel based on MPLs as set down in the EU legislation (defined as the *regulatory maximum level exposure assessment scenario*) and listed in Table 3.

The Panel considers the resulting exposure estimates as the most conservative since it is assumed that the population will be exposed to the food additive present in food at the MPL over a long period of time.

Dietary exposure to stearyl tartrate (E 483)

Table 5 summarises the estimated exposure to stearyl tartrate (E 483) from its use as a food additive in six population groups (Table 4) according to the regulatory maximum level exposure assessment scenario. Detailed results per population group and survey are presented in Appendix C.

Table 5: Summary of dietary exposure to stearyl tartrate (E 483) from its use as a food additive in the regulatory maximum level exposure assessment scenario in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks–11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Regulatory maximum level exposure assessment scenario						
• Mean	0.1–25.0	22.4–82.5	19.8–70.8	6.7–27.4	6.0–16.2	7.7–14.3
• 95th percentile	0[(a)]–79.0	66.1–192.7	43.8–162.6	20.7–62.1	13.4–36.0	17.2–28.1

bw: body weight.
(a): 95th percentile is lower than mean due to the low number of consumers in a survey i.e. less than 5% person consume at least one food belonging to one of the FC listed in Table 3.

The mean exposure to stearyl tartrate (E 483) from its use as a food additive ranged from 0.1 mg/kg bw per day in infants to 82.5 mg/kg bw per day in toddlers. The 95th percentile of exposure to stearyl tartrate (E 483) ranged from 0 mg/kg bw per day in infants to 192.7 mg/kg bw per day in toddlers.

Main food categories contributing to exposure for the general population

The main contributing food categories to the total mean exposure estimates for infants, toddlers, children and adolescents were FC 01.4 Flavoured fermented milk products and FC 07.1 Bread and rolls. For adults and the elderly, the main contributing food categories were FC 07.1 Bread and rolls and FC 07.2 Fine bakery wares (see Appendix D for more details).

Uncertainty analysis

Potential sources of uncertainty in the exposure assessment of stearyl tartrate (E 483) have been discussed above. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 6.

Table 6: Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction[(a)]
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/–
Methodology used to estimate high percentiles (95th) long-term (chronic) exposure based on data from food consumption surveys covering only a few days	+
Concentration data: – MPLs considered applicable to all foods within the entire food category, whereas on average 0.01% of the foods, belonging to food categories with foods labelled with additive, were labelled with the additive	+
Food categories selected for the exposure assessment: inclusion of food categories without considering the restriction/exception (MPL scenario n = 1 out of 4 food categories)	+
Regulatory maximum level exposure assessment scenario: – exposure calculations based on the MPL according to Annex II to Regulation (EC) No 1333/2008	+

MPL: maximum permitted level.
(a): +, uncertainty with potential to cause overestimation of exposure; –, uncertainty with potential to cause underestimation of exposure.

The Panel considered overall that the uncertainties identified resulted in an large overestimation of the exposure to stearyl tartrate (E 483) from its use as a food additive in European countries considered in the EFSA Comprehensive Database, especially due to the assumption that all foods belonging to the authorised food categorised contained the additive at MPL.

Stearyl tartrate (E 483) is authorised in four food categories whereas no use levels were reported by industry. The Panel noted that this is in line with information from the Mintel's GNPD (Appendix A) indicating that only two products have been labelled with stearyl tartrate (E 483) since 1996.

3.5. Biological and Toxicological data

3.5.1. Absorption, distribution, metabolism and excretion

Frazer et al. (1954a) stated that distearyl tartrate is insoluble in water, in intestinal juices or in bile, and it is sparingly soluble in fats up to 1% at 37°C; they assumed that the substance is absorbed from the intestine only when solubilised in fats, but not when un-solubilised.

Oral absorption was measured by Frazer et al. (1954a) in eight rats (no data on strain and gender) after gavage of ^{14}C-labelled distearyl tartrate (labelling of alpha-carbon of the stearyl moiety) in olive oil in metabolism cages. The amount of active substance dosed varied between 6.0 and 29.8 mg/rat. The authors estimated the proportion absorbed from the difference between administered radioactivity and the radioactivity found in the faeces. Based on this procedure, between 22% and 84% of the applied radioactivity was calculated to be absorbed in the gastrointestinal (GI) tract; however, no data were given on possible excretion of radioactivity via the bile. The high variance observed for absorption was not further discussed by the authors. Exhalation of labelled CO_2 was measured for several days after gavage and data are given for five rats which showed an oral absorption rate $\geq$ 50% ($>$ 10 mg/rat). For four of them, the sum of the exhaled radioactivity could be calculated by the Panel, based on the data given. In the four rats, the exhalation accounted for 56.3 $\pm$ 7.43% of the absorbed radioactivity within 7–12 days. However, the graphical representation of the cumulative excretion indicates that exhalation of radioactivity was not completed in many animals within the extended time frame of 12 days. Frazer et al. (1954a) also claimed that the test substance is not affected by intestinal enzymes and is not hydrolysed in the intestinal lumen without giving supporting data for this statement.

Frazer (1955) reported that distearyl tartrate solubilised in oil remained unchanged in the lumen of the small intestine and the author concluded that it was not hydrolysed by pancreatic lipase. From the study of residual material in both acute and chronic experiments in rats, the absorption of distearyl tartrate was shown to be negligible in the absence of an oily vehicle. It was not absorbed in an unemulsified form while about 60% absorption occurred when mixed with long chain glycerides to be absorbed. No absorption was observed if a short-chain glyceride was used instead. The author concluded that 'absorption of distearyl tartrate requires more detailed consideration'.

Overall, there was no evidence of an efficient hydrolysis of distearyl tartrate by pancreatic lipase in the small intestine. Radioactivity associated with distearyl tartrate is absorbed to variable extent in rats. There is evidence for splitting of the ester bond after absorption because $^{14}CO_2$ is found in the exhaled air in rats after administration of distearyl tartrate labelled at the alpha-carbon of the stearyl moiety. However, cumulative exhalation of $^{14}CO_2$ did not reach a plateau even within 12 days after administration in some animals. Even assuming that part of the radioactivity is incorporated into tissue components, this rate of exhalation is too slow to assume rapid hydrolysis. The Panel noted that a definitive conclusion for the amount and the form in which distearyl tartrate is absorbed cannot be drawn from these two reports by Frazer (1954a, 1955)

Therefore, the Panel considered that the extent of hydrolysis of stearyl tartrate in the GI tract and presystemically or extent of absorption or metabolism cannot be deduced from the data available.

3.5.2. Acute toxicity

Stearyl tartrate was tested in mice, rats, guinea-pigs, rabbits and dogs (Frazer et al., 1954b, as referred to by JECFA, 1965). No abnormalities were detected after single oral doses of up to 5,000 mg/kg bw in aqueous or oily vehicle.

3.5.3. Short-term and subchronic toxicity

No data were available.

3.5.4. Genotoxicity

No data were available.

The substances distearyl L(+)-tartrate (CAS n. 17977-66-1), stearylpalmityl L(+)-tartrate (CAS n. 93966-44-0) and dipalmityl L(+)-tartrate (CAS n. 65270-95-3) were analysed through the OECD QSAR toolbox (version 4.3) in order to identify potential structural alerts for genotoxicity.

One structural alert for possible positive results in the *in vivo* MN assay was identified for all the 3 substances: 'H-acceptor-path3-H-acceptor'. This structural alert encodes a structural motif potentially able of noncovalent interactions with proteins or DNA. This alert, even though present in many chemicals positive in MN, has a low positive predictivity and may generate false positive results (Benigni et al., 2012). An *in silico* read across analysis was performed, that pointed to structurally related substances (for which experimental data are available in the Toolbox databases) with the same alert: these analogues resulted to be negative or inconclusive in the *in vivo* MN test. In addition, considering that the predictive value of this structural alert for *in vivo* MN positivity is relatively low (estimated as 63%, Benigni et al., 2012), the relevance of this finding as possible indication of a genotoxic activity is limited, in this case.

3.5.5. Chronic toxicity and carcinogenicity

Four groups of 10 male and 10 female rats were fed diets containing 57% of bread either untreated or treated with 3.2% of stearyl tartrate, 3.2% of glyceryl monostearate or 3.2% of stearyl tartrate plus 3.2% of glyceryl monostearate. No specification and indication of stereochemistry of stearyl tartrate were given. These diets were fed for the life span. The appearance, behaviour, rate of weight gain, and general health of these animals was kept under close observation. At the end of the period, the survivors were killed and necropsied. The main organs were examined microscopically. There were no differences in tumour incidence, nor other pathological changes (Frazer et al., 1954b, as referred to by JECFA, 1965). The Panel considered the study inadequate for hazard identification.

3.5.6. Reproductive and developmental toxicity

Four groups of male and female mice were fed diets containing either 57% of untreated bread, or 57% of bread treated with 3.2% of stearyl tartrate, or diets containing 3.2% of glyceryl monostearate or 3.2% of stearyl tartrate plus 3.2% of glyceryl monostearate. No specification and indication of stereochemistry of stearyl tartrate were given. Nine generations of mice were studied. At the start of the experiment one of the stearyl tartrate groups developed an infection and the group had to be restocked; however, a further nine generations were produced on this diet without any difficulties. No significant difference was observed between the groups, in regard to reproduction, lactation, weight gain of the young, general health, appearance and survival (Frazer et al., 1954b, as referred to by JECFA, 1965).

Four groups of male and female rats were fed the diets described in Section 3.5.5. Four generations of rats were studied. No significant difference was observed between the different groups in regard to reproduction, lactation, rate of weight gain of young, general appearance and survival (Frazer et al., 1954b, as referred to by JECFA, 1965).

Groups of 10 male and 40 female rats were fed a control diet and diets containing bread treated with 1 or 5% stearyl tartrate (no specification and indication of stereochemistry of the test substance). The second and third generations of animals on these diets were followed for their life span. At 36 weeks, there was no significant difference in body weight gain. Hepatic function, reproduction and lactation, and morbidity or mortality showed no significant difference between the three groups (Frazer et al., 1954b, as referred to by JECFA, 1965).

Overall, the Panel considered the data inadequate for hazard identification.

3.5.7. Other studies

Ten volunteers consumed a diet containing bread with 0.075% stearyl tartrate during a period of 4 years. Five additional volunteers received untreated bread as a control group. In comparison to controls, no effects on general health, appetite, body weight, haemoglobin, and blood counts were found (Frazer et al., 1954b, as referred to by JECFA, 1965). The Panel considered that this information was not relevant for the re-evaluation of stearyl tartrate.

4. Discussion

In 1978, the SCF considered acceptable an intake of 1,200 mg stearyl tartrate per adult per day, corresponding to 20 mg/kg bw per day for an adult weighing 60 kg. The rational for this conclusion was, however, not provided in the SCF report.

Commission Regulation 231/2012 does not stipulate which isomer of tartaric acid should be used for the manufacturing process of stearyl tartrate (E 483) and, therefore, currently any isomer of tartaric acid can be used. The Panel considered that only L(+)-tartaric acid should be used in the manufacturing process of stearyl tartrate (E 483).

The Panel noted that the name 'stearyl tartrate' for E 483 (Commission Regulation (EU) No 231/2012) does not reflect the composition of the food additive since it is a mixture of three different esters (distearyl tartrate, dipalmityl tartrate and stearylpalmityl tartrate).

The Panel noted that neither technical or biological data nor information on current use levels have been submitted in response to any of the EFSA public calls for data.[6–8]

The limited available ADME data are not sufficient to confirm the extent of hydrolysis of stearyl tartrate in the GI tract and presystemically or the extent of absorption or metabolism. In the absence of additional data, the Panel noted that the kinetic fate of this food additive remains uncertain. Therefore, read-across from data on its constituents is not applicable.

JECFA in its latest evaluation concluded that 'either the original toxicological and metabolic studies should be made available or that new studies demonstrating hydrolysis in vivo should be submitted before the substance could be re-evaluated' (JECFA, 2001). Also, TemaNord had recommended that data on hydrolysis of stearyl tartrate were required to show whether or not the supposed hydrolysis to constituents takes place (TemaNord, 2002).

The toxicological studies evaluated by JECFA in 1965 were not available. The Panel considered the information on chronic toxicity and reproduction summarised by JECFA (1965) inadequate for hazard identification. No genotoxicity data were available to the Panel, however, no relevant structural alert for genotoxicity was found analysing distearyl L(+)-tartrate, stearylpalmityl L(+)-tartrate and dipalmityl L(+)-tartrate through the OECD QSAR toolbox (version 4.3).

Due to the absence of use levels and analytical data, the exposure to stearyl tartrate (E 483) from the four authorised food categories was estimated using the regulatory maximum level exposure assessment scenario. The calculated exposure was maximally 82.5 mg/kg bw per day at the mean and 193 mg/kg bw per day at the high level (p95), both in toddlers. Based on the information from the Mintel's GNPD, the Panel presumed that the food additive is rarely used and in the absence of data on uses and use levels, the Panel was unable to perform a refined exposure assessment.

5. Conclusions

The Panel concluded that adequate toxicity data on stearyl tartrate were not available for its re-evaluation. In addition, adequate data demonstrating the complete hydrolysis of stearyl tartrate (E 483) in the GI tract and/or presystemically, that could allow read-across from data on its constituents, were lacking. Therefore, its safety of use as a food additive cannot be assessed and the acceptable intake established by the SCF in 1978 cannot be confirmed.

6. Recommendations

The Panel recommended that:

- the use of stearyl tartrate (E 483) by industry, considering the low number of labelled uses in the Mintel's GNPD (n = 2), should be confirmed. If confirmed, information on use and use levels should be made available in order to perform a refined exposure assessment.
- data showing complete presystemic hydrolysis and/or appropriate toxicity studies should be made available in accordance with the Guidance on the submission of food additives (EFSA ANS Panel, 2012), in order to assess the safety of stearyl tartrate (E 483).
- the European Commission should consider revising the EU specifications for stearyl tartrate (E 483) by specifying that only L-tartaric acid can be used in the manufacturing process.
- the European Commission should consider setting lower maximum limits for toxic elements (arsenic, cadmium, lead and mercury) in the EU specifications for stearyl tartrate (E 483) in order to ensure that their use as a food additive will not be a significant source of exposure to these toxic elements in food.
- the European Commission should consider revising the name of the food additive E 483 since is a mixture of three different esters (distearyl tartrate, dipalmityl tartrate and stearylpalmityl tartrate), e.g. stearyl palmityl tartrate.

Documentation provided to EFSA

1) Pre-evaluation document prepared by the Fraunhofer ITEM. June 2011. Deliverable of procurement contract EFSA-Q-2010-00751.

References

Benigni R, Bossa C, Tcheremenskaia O, Battistelli CL and Crettaz P, 2012. The new ISSMIC database on in vivo micronucleus and its role in assessing genotoxicity testing strategies. Mutagenesis, 27, 87–92.

EFSA (European Food Safety Authority), 2007. Scientific opinion of the Scientific Committee related to uncertainties in dietary exposure assessment. EFSA Journal 2007;5(1):438, 54 pp. https://doi.org/10.2903/j.efsa.2007.438

EFSA (European Food Safety Authority), 2011a. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097, 34 pp. https://doi.org/10.2903/j.efsa.2011.2097

EFSA (European Food Safety Authority), 2011b. Evaluation of the FoodEx, the food classification system applied to the development of the EFSA Comprehensive European Food Consumption Database. EFSA Journal 2011;9(3):1970, 27 pp. https://doi.org/10.2903/j.efsa.2011.1970

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2012. Guidance for submission for food additive evaluations. EFSA Journal 2012;10(7):2760, 60 pp. https://doi.org/10.2903/j.efsa.2012.2760

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2009a. Scientific opinion on cadmium in food. EFSA Journal 2009;7(10):980, 139 pp. https://doi.org/10.2903/j.efsa.2009.980

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2009b. Scientific Opinion on arsenic in food. EFSA Journal 2009;7(10):1351, 199 pp. https://doi.org/10.2903/j.efsa.2009.1351

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2010. Scientific Opinion on lead in food. EFSA Journal 2010;8(4):1570, 151 pp. https://doi.org/10.2903/j.efsa.2010.1570

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2012a. Scientific Opinion on the risk for public health related to the presence of mercury and methylmercury in food. EFSA Journal 2012;10(12):2985, 241 pp. https://doi.org/10.2903/j.efsa.2012.2985

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2012b. Scientific Opinion on lead dietary exposure in the European population. EFSA Journal 2012;10(7):2831, 59 pp. https://doi.org/10.2903/j.efsa.2012.2831

EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2014. Scientific Opinion on dietary exposure to inorganic arsenic in the European population. EFSA Journal 2014;12(3):3597, 68 pp. https://doi.org/10.2903/j.efsa.2014.3597

EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), Younes M, Aquilina G, Castle L, Engel K-H, Fowler P, Frutos Fernandez M J, Fürst P, Gürtler R, Gundert-Remy U, Husøy T, Mennes W, Shah R, Waalkens-Berendsen I, Wölfle D, Boon P, Tobback P, Wright M, Aguilera J, Rincon AM, Tard A and Moldeus P, 2020. Scientific Opinion on the re-evaluation of L(+)-tartaric acid (E 334), sodium tartrates (E 335), potassium tartrates (E 336), potassium sodium tartrate (E 337) and calcium tartrate (E 354) as food additives. EFSA Journal 2020;18(3):6030, 58 pp. https://doi.org/10.2903/j.efsa.2020.6030

EFSA Scientific Committee, 2009. Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: General Principles. EFSA Journal 2009;7(7):1051, 22 pp. https://doi.org/10.2903/j.efsa.2009.1051

EFSA Scientific Committee, 2012. Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. EFSA Journal 2012;10(3):2579, 32 pp. https://doi.org/10.2903/j.efsa.2012.2579

Frazer AC, 1955. Lipid absorption. Voeding, 16, 235–542.

Frazer AC, Pover WFR and Simmons HG, 1954a. Measurement of the elimination rate of 14C labelled organic compounds in the rat, with special reference to cumulation. Proc. Second Radio-Isotope Conference, 298–305.

Frazer AC, Ahmad NU, Hickman JR, Sharratt M, Pover WFR and Sammons HG, 1954b. Unpublished report submitted to WHO, as reported to in JECFA (1965).

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1965. Toxicological evaluation of some antimicrobials, antioxidants, emulsifiers, stabilizers, flour treatment agents, acids, and basesFAO Nutrition Meetings Report Series, No. 40A, B, C; WHO/Food Add/67.29.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2000. Guidelines for the preparation of toxicological working papers for the Joint FAO/WHO Expert Committee on Food Additives. Geneva, Switzerland.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2001. Evaluation of certain food additives and contaminants. 55th Meeting of JECFA. WHO Technical Report Series, No. 901, Geneva.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2006. Stearyl tartrate. Combined Compendium of Food Additive Specifications – all Specifications Monographs from the 1st to the 65th Meeting (1956-2005). FAO JECFA Monographs 1, Food Additives Vol.1-3, 2006

SCF, 1978. Reports of the Scientific Committee for Food (5th series). Opinion expressed 1978. Food science and techniques, 1978.
SCF (Scientific Committee for Food), 2001.Guidance on submissions for food additive evaluations by the Scientific Committee on Food. SCF/CS/ADD/GEN/26 Final. 12 July 2001
TemaNord, 2002. Nordic Council of Ministers. E 483 Stearyl tartrate. In: Food Additives in Europe 2000 – Status of safety assessments of food additives presently permitted in the EU. 495-497.
Williams EI, 1964. The detection and approximate determination of stearyl tartrate in bread. Analyst, 89, 289–290.
Wood R, Foster L, Damant A and Key P, 2004. Analytical methods for food additives. CRC Press, Boca, Raton.

Abbreviations

ADME	absorption, distribution, metabolism, excretion
ADI	acceptable daily intake
CAS	Chemical Abstracts Service
FAF	EFSA Panel on Food Additives and Flavourings
FCS	food categorisation system
GI	gastrointestinal
GNPD	Global New Products Database
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MPL	maximum permitted level
OECD	Organisation for Economic Co-operation and Development
QSAR	quantitative structure–activity relationship
SCF	Scientific Committee on Food
TemaNord	is a publishing series for results of the often research-based work that working groups or projects under Nordic Council of Ministers have put in motion
WHO	World Health Organization

Appendix A – Number and percentage of food products labelled with stearyl tartrate (E 483) out of the total number of food products present in the Mintel GNPD per food subcategory between 2014 and 2019

Appendix B – Concentration levels of stearyl tartrate (E 483) used in the regulatory maximum exposure assessment scenario (mg/kg or mL/kg as appropriate)

Appendix C – Summary of total estimated exposure of stearyl tartrate (E 483) from its use as food additive for the regulatory maximum level exposure scenario per population group and survey: mean and 95th percentile (mg/kg bw per day)

Appendix D – Main food categories contributing to exposure to stearyl tartrate (E 483) using the regulatory maximum level exposure assessment scenario (> 5% to the total mean exposure)

Appendix A–D can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2020.6033