Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on the safe use of an aqueous solution of Sodium lauryl ether sulphate as processing aid for washing apples, peaches, bananas, tomatoes, peppers and citrus fruits in processing plants

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Abstract

The company Productos Citrosol S.A. has requested an assessment of the safety of using an aqueous solution of Sodium lauryl ether sulphate (27 %) as a processing aid, with comercial designation Citroboost. The proposed use is the washing of apples, peaches, bananas, tomatoes, peppers and citrus fruits in processing plants.

The dose of the processing aid to be used will be 0.4 % V/V in all cases, so that the final concen-

tration of Sodium lauryl ether sulphate in the washing solutions will be 1080 ppm.

Considering the most adverse scenario of the presence of residues in apples, peaches, bananas, tomatoes, peppers and citrus fruits, and their consumption in Europe, an Estimated Daily Intake (EDI) of these residues as well as a consumer risk assessment by calculating the Margin of Safety (MOS) have been made.

It is the conclusion of the Scientific Committee that, based on the information provided by the applicant and taking into account the proposed composition and conditions of use, the use of the aqueous solution of Sodium lauryl ether sulphate as a processing aid does not pose risks to consumer health.

Key words

Apples, peaches, bananas, tomatoes, peppers, citrus fruits, processing aid, washing.

Suggested citation

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1. Introduction

Productos Citrosol S.A., a company located in Potríes (Valencia), has requested a safety assessment on the use of an aqueous solution of Sodium lauryl ether sulphate as a processing aid in the washing process of apples, peaches, bananas, tomatoes, peppers and citrus on arrival at processing plants.

Following this request, the Management Board of the Spanish Agency for Food Safety and Nutrition (AESAN) has requested the Scientific Committee to assess the safety of the aforementioned aqueous solution for use as a processing aid, taking into account the "Guidelines of the relevant documentation for the assessment of processing aids intended for use in human food" (AESAN, 2010).

As regards authorised uses, Sodium lauryl ether sulphate (SLES) is not authorised for human consumption.

Since the presence of residues in the final products (fruits and vegetables) after the use of this aqueous solution cannot be ruled out, in accordance with the criteria established in the aforementioned Guidelines, the processing aid is classified within situation 6: unauthorised substance in human food whose Acceptable Daily Intake (ADI) is not established and which use may lead to the presence of technically unavoidable residues. According to that situation, the applicant submits information on the following aspects:

- Administrative data and general presentation.
- Physicochemical characteristics.
- Technological function.
- Residue studies: analytical method and validation of method.
- Studies and data relating on safety.
- Study of consumption and assessment of anticipated intake levels by the consumer.

2. General presentation and physicochemical characteristics

2.1 Detailed composition and formulation

The product proposed as a processing aid, under the trade name Citroboost, is an aqueous solution of sodium lauryl ether sulphate (27 %). Table 1 shows the composition.

Table 1. Composition of the processing aid

Subtance	Function	CAS No.	Concentration (% w/w)
Sodium lauryl ether sulphate	Active substance	68891-38-3	27

Likewise, unsulphate compounds (≤1.08 %) and CMIT/MIT (chloromethylisothiazolinone/methylisothiazolinone, <0.03 %) have been identified as impurities.

The pH of the solution is 7-7.5 (10 %).

2.2 Product Specifications

Table 2 includes specifications and results of the analyses of five batches of the processing aid.

Table 2. Specifications and analytical results

Substance	Specifications (% w/w)	Certificates of analysis (% w/w)				
Sodium lauryl ether sulphate	26-28	26.8	26.4	27.1	26.9	27.2

2.2.1 Product stability

As indicated by the applicant, the processing aid is stable at room temperature (Schönfeldt, 1969).

2.2.2 Reactivity

The applicant indicates that Sodium lauryl ether sulphate is an anionic surfactant with no direct reaction to the environment (water and plant products), being its principal activity associated with a decrease in the surface tension of washing water.

2.3 Authorised uses in human food

Sodium lauryl ether sulphate has no authorised uses in human nutrition. It is used in industrial and domestic cosmetics and detergents.

At the household level, alcohol ethoxy sulphates are used to manufacture detergents (for laundry, dishwashers and surface cleaners) and personal care products. The risk of oral exposure to these substances has been assessed by HERA (Human & Environmental Risk Assessment on ingredients of European household cleaning products) (HERA, 2003).

Alcohol ethoxy sulphates are also registered in ECHA (European Chemicals Agency) under Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (EU, 2006) with different uses, one of them being washing of kitchenware (ECHA, 2022a, b).

On the other hand, the use of this type of alcohol as an inert surfactant in pesticides, with a concentration below 30 %, is registered in the United States, with no maximum tolerance established for its residues (CFR, 2022).

2.4 Acceptable Daily Intake

No Acceptable Daily Intake (ADI) for Sodium lauryl ether sulphate has been established (EFSA, 2022a) (JECFA, 2022).

3. Technological function

3.1 Technological use claimed

The applicant indicates that the technological use is for washing apples, peaches, bananas, tomatoes, peppers and citrus fruits upon arrival at the processing plants, favouring the homogeneous wetting of the entire surface of these fruits and vegetables by decreasing the surface tension during

the washing process. The decrease in surface tension also gives sodium lauryl ether sulphate the ability to remove dirt from surfaces and foam-forming capacity. It also allows reducing the microbial population on the surface by physical detachment.

3.2 Level of use requested

As indicated by the applicant, the dose of processing aid to be used is 0.4 % V/V in all cases, resulting in a final concentration of 1080 ppm of Sodium lauryl ether sulphate in the washing solutions of the fruits and vegetables under assessment.

In all cases, the contact time of the fruits and vegetables with the washing solution shall be 30 seconds, and there shall be no recirculation of said solution. After washing, the fruits and vegetables will be rinsed with potable water.

3.3 Justification of use, interest and efficacy

As indicated, washing is the first post-harvest treatment carried out on fresh and minimally processed fruit and vegetable products. Its main objective is remove dirt from the harvesting process, as well as mecanically reduce part of the microbial population on the surface (Wardoski et al., 1986) (Matthews et al., 2016) (FAO/WHO, 1998, 2008).

Recommendations from WHO (World Health Organization) regarding the surface decontamination of fruits and vegetables that are eaten raw include implementing sanitation programs to minimise contamination of fruits and vegetables throughout the food chain, with post-harvest processing being a critical point, because it is the last control point before marketing (FAO/WHO, 1998, 2008).

This recommendation is also collected by the FDA (U.S Food and Drug Administration) in its Guide to Minimize Microbiological Food Safety Hazards for Fresh Fruits and Vegetables, where it is stated that washing plant products can reduce the potential danger of microbiological contamination since it occurs mainly on the surface of these foods. If pathogens are not removed, inactivated or controlled at this early stage, they can spread contamination to other fruits during processing. Appropriate washing of fresh fruits and vegetables prior to any industrial processing operation can potentially reduce, but not eliminate, surface contamination (FDA, 2008).

On the other hand, the marketing standards for fruits and vegetables set out in Regulation (EU) No. 543/2011 establish as a minimum quality requirement that fruits and vegetables must be clean and practically free of any visible foreign matter after preparation and packaging (EU, 2011).

The use of detergents and surfactants facilitates the washing processes of these plant-based products.

3.3.1 Efficacy studies

The applicant provides the results of trials carried out on a pilot scale in order to establish the dosage of use of the processing aid. The trials carried out with the fruits and vegetables under evaluation made it possible to establish a use level of 0.4 % for all cases since, at this level, it was possible to obtain both the degree of cleanliness and wetting uniformity desired. At lower doses, there is a decrease in surface tension. In comparison, there could be excessive foaming at higher doses,

reducing the effectiveness of washing by interposing the foam between the brushes and the fruits and vegetables, hindering the final rinsing with potable water.

In terms of phytotoxicity, no harmful effects on the skin or staining on the surface of fruits and vegetables were observed at any of the tested doses in the studies submitted by the applicant.

3.4 Description of the process

3.4.1 Forms of incorporating the processing aid

The incorporation of the processing aid occurs during the washing of the fruits and vegetables on arrival at the processing plants. In the case of citrus fruits and apples, washing can take place either by immersion in a drum, or through a "drencher" or pallet shower. The maximum stay time in the drum is 30 seconds, and a final rinse with potable water through showers takes place after washing.

The washing of other vegetable products (peaches, bananas, tomatoes and peppers) can be carried out by immersion in a drum or by pressure showers or jets. In both cases, the maximum contact time with the washing solution is 30 seconds, and a final rinse with potable water through showers takes place after washing.

In all cases, the processing aid is added to the wash water through automatic programmable dosing devices.

3.4.2 Identification of the phases of elimination of the processing aid

As indicated, the presence of Sodium lauryl ether sulphate on fruits and vegetables surfaces is expected to be negligible, given its low concentration in washing solutions. In addition, both fruits and vegetables are subjected to a final rinse with potable water, thus avoiding the possible presence of residues of sodium lauryl ether sulphate on their surfaces, given its high solubility in water.

4. Residue studies

The results of studies carried out to determine Sodium lauryl ether sulphate (SLES) residues are presented. The studies were carried out in a semi-industrial pilot plant to simulate washing conditions as close to reality as possible. The concentration of SLES in processing aids used was 26.2 % for citrus fruits (1048 ppm of SLES in washing solution) and 26.3 % for the other fruits and vegetables under evaluation (1052 ppm of SLES in washing solutions).

Samples were taken, in triplicate, corresponding to three stages of the washing process of citrus fruits, apples, peaches, bananas, tomatoes and fresh peppers:

- Pre-treatment solution: sampling after addition of 0.4 % of the processing aid to the washing solution and before starting the treatment on fruits and vegetables.
- Unrinsed surface: sampling of the surface of the fruits and vegetables after immersion in the washing solution for 30 seconds.
- Surface with rinsing: sampling of the surface of fruits and vegetables after final rinsing with potable water.

SLES analyses were carried out by an external laboratory using a validated internal procedure based on the UNE-EN ISO 16265:2012 standard, modified for aqueous extraction of fruit/vegetable sample, and subsequent analysis by photometric detection in automated segmented flow equipment with a limit of quantification (LOQ) of 0.27 mg/kg (Table 3).

Table 3. SLES average contents in pre-treatment solutions and on the surface of fruits and vegetables (with and without final rinsing)

Samples		Pre-treatment solution (mg/l)	Unrinsed surface (mg/kg)	Surface with rinsing (mg/kg)
Citrus fruits	Oranges	985.7 ± 22.7	1.81 ± 0.08	0.282
	Mandarins	994.7 ± 32.2	1.08 ± 0.22	<LOQ
	Lemons	1020.3 ± 173.4	1.00 ± 0.05	<LOQ
Apples		772 ± 36	1.383 ± 0.163	<LOQ
Peaches		940 ± 51	1.500 ± 0.354	<LOQ
Bananas		1253.33 ± 97.3	1.260 ± 0.125	<LOQ
Tomatoes		1013.33 ± 65.06	0.429 ± 0.106	<LOQ
Peppers		879.33 ± 31.56	0.747 ± 0.101	<LOQ

After treatment with the washing solutions (0.4 % of processing aid), the results obtained show, in all cases, less than 2 mg/kg of SLES residues on the unrinsed surfaces. After final rinsing with potable water, the residues of SLES on the surfaces are below the limit of quantification in all cases except for one of the orange samples (0.282 mg/kg).

5. Studies and data relating to the safety of SLES

As already indicated, there is no ADI established for SLES. Similar to procedures followed for other processing aids, the risk assessment is based on the determination of the Margin of Safety (MOS), as alcohol ethoxysulphates are considered non-carcinogenic and non-genotoxic substances (HERA, 2003) (ECHA, 2022a), considering that, when the MOS is >100, there is no risk for the consumer. The MOS is calculated taking into account the NOAEL (No Observed Adverse Effect Level) and the Estimated Daily Intake (EDI).

For NOAEL, chronic and subchronic oral toxicity studies with alcohol ethoxysulphates showed no effects at 75 mg/kg b.w./day or adverse effects at the maximum administered dose (250 mg/kg b.w./day) (HERA, 2003). Likewise, ECHA (2022a) includes a NOAEL of 300 mg/kg b.w./day for the entire group of alcohol ethoxysulphates in the registered dossier.

For acute oral toxicity, LD_{50} has been established for this type of alcohol ethoxysulphates: >2000 mg/kg b.w. (HERA, 2003) and 2870 mg/kg b.w. (ECHA, 2022a).

For estimating chronic exposure, the most restrictive of all the established NOAEL (75 mg/kg b.w./day) is selected, derived from a chronic toxicity study (2 years) in rats which were administered these alcohols via drinking water. In line with that established by HERA (2003) for assessing the risk associated with human exposure to these alcohols due to their use in cleaning and laundry products.

As regards possible impurities present in the processing aid (non-sulphated and CMIT/MIT), the study carried out by HERA (2003) indicates that commercially produced alcohol ethoxysulphates contain approximately 2-4 % of non-sulphated (ethoxylated alcohols and alcohols). As indicated by the applicant, since these products (detergents) are not purified and are marketed practically as obtained, the toxicological studies carried out and evaluated have been done in the presence of these impurities.

In the specific case of CMIT and MIT, the European Food Safety Authority (EFSA) issued in 2010 a report on the safety of these compounds used as biocidal products in materials in contact with food, such as coatings, paper and cardboard. It was concluded that there is no risk to consumer safety if the maximum residue in the finished product is less than 25 µg/dm² (EFSA, 2010). The theoretical calculation of the residue of CMIT/MIT that would remain on the surface of the treated fruits and vegetables, assuming that rinsing will produce a removal equal to that observed experimentally for SLES, would result in an estimated residue of 15 µg/dm², which does not pose a risk to consumer safety.

6. Study of consumption and assessment of the anticipated intake level of SLES by the consumer

To estimate the exposure to SLES, the data of the European Union country with the highest (chronic) consumption (mean and 95th percentile consumers only) have been taken into account, both for adults and children aged 1-3 years (toddlers) and under 1 year (infants), in accordance with the Comprehensive European Food Consumption Database of EFSA (2022b) (data updated to February 2022):

- For adults, the highest average and 95th percentile intakes are 8.05 and 22.97 g/kg b.w./day, respectively, for apples (sum of apple and apple juice intakes, data from Germany); 4.45 and 9.20 g/kg b.w./day for peaches (sum of peach and peach juice intakes, data from Estonia); 1.78 and 4.23 g/kg b.w./day for bananas (sum of plantain and bananas, data from Estonia); 3.10 and 8.73 g/kg b.w./day for tomatoes (data from Germany); 0.60 and 1.71 g/kg b.w./day for peppers (data from Hungary); and 6.11 and 18.49 g/kg b.w./day for citrus fruits (sum of oranges, mandarins, lemons, orange juice, lemon juice and citrus juice, data from Germany).
- For children aged 1 to 3 years, consumption is 16.16 and 50.24 g/kg b.w./day for apples (sum of apple and apple juice intake, data from Estonia); 16.19 and 34.79 g/kg b.w./day for peaches (sum of peaches and peach juice, data from Spain); 8.08 and 18.65 g/kg b.w./day for bananas (sum of plantain and bananas, data from Estonia); 8.17 and 15.31 g/kg b.w./day for tomatoes (data from Bulgaria); 1.66 and 3.87 g/kg b.w./day for peppers (data from Italy); and 24.14 and 46.39 g/kg b.w./day for citrus fruits (sum of oranges, mandarins, lemons, orange juice, lemon juice and citrus juice, data from Bulgaria).
- On the same basis, for children under 1 year of age, the highest intakes for the mean and 95th percentile correspond to 13.58 and 40.53 g/kg b.w./day, respectively, for apples (data from Slovenia); 11.76 and 29.30 g/kg b.w./day for peaches (data from Bulgaria); 8.09 and 21.78 g/kg b.w./day for bananas (data from Latvia); 10.61 and 14.38 g/kg b.w./day for tomatoes (data from Bulgaria); 0.87 and 3.06 g/kg b.w./day for peppers (data from Bulgaria); and 17.86 and 37.07 g/kg b.w./day

for citrus fruits (data from Spain).

To obtain the Estimated Daily Intake (EDI), estimated residues of SLES (limit of quantification (0.27 mg/kg) for apples, peaches, bananas, tomatoes and peppers, and 0.282 mg/kg for citrus fruits) were also considered. The Margins of Safety (MOS) are calculated based on the EDI and NOAEL (75 mg SLES/kg b.w./day) (Tables 4, 5 and 6).

Table 4. Estimated exposure to SLES in adults and calculation of the Margin of Safety

Product		Consumption (g/kg b.w./day)	EDI (mg SLES/kg b.w./day)	MOS
Apples	Mean	8.05	0.0022	34 091
	P95	22.97	0.0062	12 097
Peaches	Mean	4.45	0.0012	62 500
	P95	9.20	0.0025	30 000
Bananas	Mean	1.78	0.0005	150 000
	P95	4.23	0.0011	68 181
Tomatoes	Mean	3.10	0.0008	93 750
	P95	8.73	0.0024	31 250
Peppers	Mean	0.60	0.0002	375 000
	P95	1.71	0.0005	150 000
Citrus fruits	Mean	6.11	0.0017	44 118
	P95	18.49	0.0052	14 423

Table 5. Estimated exposure to SLES in toddlers and calculation of the Margin of Safety

Product		Consumption (g/kg b.w. day)	EDI (mg SLES/kg b.w./day)	MOS
Apples	Mean	16.16	0.0044	17 045
	P95	50.24	0.0136	5515
Peaches	Mean	16.19	0.0044	17 045
	P95	34.79	0.0094	7979
Bananas	Mean	8.08	0.0022	34 091
	P95	18.65	0.0050	15 000
Tomatoes	Mean	8.17	0.0022	34 091
	P95	15.31	0.0041	18 293
Peppers	Mean	1.66	0.0004	187 500
	P95	3.87	0.0010	75 000
Citrus fruits	Mean	24.14	0.0068	11 029
	P95	46.39	0.0131	5725

Table 6. Estimated SLES exposure in infants and calculation of the Margin of Safety

Product		Consumption (g/kg b.w./day)	EDI (mg SLES/kg b.w./day)	MOS
Apples	Mean	13.58	0.0037	20 270
	P95	40.53	0.0109	6881
Peaches	Mean	11.76	0.0032	23 438
	P95	29.30	0.0079	9 494
Bananas	Mean	8.09	0.0022	34 091
	P95	21.78	0.0059	12 712
Tomatoes	Mean	10.61	0.0029	25 862
	P95	14.38	0.0039	19 231
Peppers	Mean	0.87	0.0002	375 000
	P95	3.06	0.0008	93 750
Citrus fruits	Mean	17.86	0.0050	15 000
	P95	37.07	0.0105	7143

Conclusions of the Scientific Committee

The Scientific Committee, having assessed the dossier of the application for a safety assessment of the use of an aqueous solution of Sodium lauryl ether sulphate (27 %) as a processing aid in the process of washing apples, peaches, bananas, tomatoes, peppers and citrus fruits in processing plants, concludes that, on the basis of the information provided by the applicant, and taking into account the proposed composition and conditions of use, the use of the processing aid does not pose a risk to the health of the consumer.

The conclusions of this report refer exclusively to the solution under assessment as a processing aid under the conditions of use proposed and the current composition. They cannot be extended to other formulations or conditions other than those assessed, including the joint use with other substances.

This assessment does not constitute an authorisation for the use nor does it affect uses other than as a processing aid in the process of washing apples, peaches, bananas, tomatoes, peppers and citrus in processing plants. This use involves a final rinsing with potable water immediately after applying wash water and processing aid so as to remove any possible residues on the fruit and vegetables.

The products thus processed must comply with all food legislation. Once on the market, the operator must ensure the absence of undesirable contaminants, residues or undesirable microorganisms or their presence below the maximum limits established.

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