Report of the Scientific Committee of the Spanish Agency for Consumers Affairs, Food Safety and Nutrition (AECOSAN) on the use of an aqueous solution of phosphoric acid and propylene glycol as a processing aid in the stabilization of the chlorine used to wash fresh cut vegetables and ready-to-eat leafy vegetables

Section of Food Safety and Nutrition

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Abstract

The company SmartWash Solutions, LLC has requested a safety assessment of the use as a processing aid of an aqueous solution of phosphoric acid (18-25 %) and propylene glycol (5-10 %) in the processing of fresh cut vegetables and ready-to-eat leafy vegetables. Both substances are authorised in the European Union as food additives in different food categories.

The proposed use for the processing aid is as a pH stabilising solution in order to enhance the antimicrobial activity of the chlorine used for the washing water disinfection required in the processing of fresh cut vegetables and ready-to-eat leafy vegetables. The desired effect of this solution is to reduce the pH levels of the washing waters to levels between 5.5-6.5. The use concentration varies, depending on the requirements of the product and the chemical composition of the washing waters, with 0.1 % as the maximum concentration requested.

The applicant analysed the residues on lettuce and spinach samples, and did not detect propylene glycol residues in any of the samples tested. In the case of phosphates, the detected concentrations in the samples washed with the processing aid were not significantly different from those detected in the same washed samples without the processing aid.

The Scientific Committee concludes that, based on the information provided by the applicant and taking into account the proposed composition and conditions of use, the use of this processing aid does not involve a health risk for the consumer.

Key words

Phosphoric acid, propylene glycol, processing aid, vegetables, leafy vegetables.

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1. Introduction

The company SmartWash Solutions, LLC in Salinas (California, United States) has requested a safety assessment of the use of an aqueous solution of phosphoric acid (18-25 %) and propylene glycol (5-10 %) as a pH stabilising solution in order to enhance the antimicrobial activity of the chlorine used for the washing water disinfection required in the processing of fresh cut vegetables (for example, grated cabbage and chopped onion) and ready-to-eat leafy vegetables (for example, lettuce, spinach and spring greens).

The applicant states that chlorine is the sanitizer most used by the food industry to disinfect the process water used in the processing of fresh cut vegetables primarily due to its antimicrobial capacity and low cost. The antimicrobial activity of chlorine depends on the amount of hypochlorous acid (HOCl) in the water, whereby the pH of the water must be between 5.5 and 6.5.

The purpose of this stabilising solution is to reduce the pH of the washing waters to levels between 5.5-6.5. The use concentration varies depending on the requirements of the product and the chemical composition of the washing waters, with 0.1 % as the maximum concentration requested.

The two components in the composition of the pH stabilising solution, phosphoric acid and propylene glycol, are considered GRAS (Generally Recognised As Safe) in the United States and are present in human food as additives. Furthermore, the JECFA (Joint FAO/WHO Expert Committee on Food Additives) has established an acceptable daily intake (ADI) of 25 mg/kg b.w. for propylene glycol (JECFA, 1973) and a maximum tolerable daily intake (MTDI) of 70 mg/kg b.w. (expressed as phosphorous) for the sum of phosphates and polyphosphates (JECFA, 1982).

In response to the application, the Executive Council of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) has asked the Section of Food Safety and Nutrition of the Scientific Committee for a safety assessment of the use of the above referred solution as a pH stabiliser processing aid to enhance the antimicrobial activity of the chlorine used for the washing water disinfection required in the processing of fresh cut vegetables and ready-to-eat leafy vegetables, considering the "Guidelines indicating the necessary documentation for the assessment of processing aids intended for use in human food" (AECOSAN, 2010).

According to the applicant, as residues are not detected in the vegetables following the use of the stabilising solution, in accordance with the criteria established in the aforementioned guidelines, the processing aid is classified as situation 3: an authorised substance in human food whose use does not result in detectable residues. In line with this situation, the product applicant presents information relating to the following aspects:

- Administrative data and general overview.
- Physicochemical properties.
- Technological function.
- Analyses of residues: analytical method and validation of the method.

2. Administrative data and general overview

2.1 Commercial name and precise description

The product, with commercial name SmartWash SW, proposed as a processing aid, is an aqueous solution of phosphoric acid (18-25 %) and propylene glycol (5-10 %).

2.2 Intended use of the substance

Processing aid as a pH stabilising solution to enhance the antimicrobial activity of the chlorine used for the washing water disinfection required in the processing of fresh cut vegetables and ready-to-eat leafy vegetables.

2.3 Authorised use in human food

Phosphoric acid is authorised as a food additive (E 338) in the European Union in over 50 food categories, with maximum doses ranging from 500 mg/l in prepared table waters or sports drinks to 50 000 mg/l in beverage whiteners for vending machines. In chewing gum and food supplements the maximum dose is *quantum satis* (EU, 2008).

Propylene glycol is authorised in the European Union (E 1520) as a carrier for its use in food additives, food enzymes, food flavourings and nutrients, with maximum doses ranging from 500 g/kg in enzyme preparations to 1 000 mg/kg in the final food product as a carrier of food additives. A maximum dose is also established when used as an additive in flavourings, from all sources in food products: 3 000 mg/kg (alone or combined with E 1505, E 1517 and E 1518). In the case of beverages, except for cream liqueurs, the maximum level of E 1520 shall be 1 000 mg/l from all sources (EU, 2008).

Both substances are considered GRAS (Generally Recognized As Safe) in the United States (FDA, 2017a, 2017b).

The applicant states that SmartWash is authorised as a processing aid in the washing of fruit and vegetables in Canada and the United States. As such, it provides letters sent by the Food and Drugs Administration (FDA) and the Canadian Food Inspection Agency (CFIA) in which there are no objections to the use of SmartWash in fruit and vegetable washing; moreover, it is included in the reference listing of products accepted by the CFIA (2017).

2.4 Acceptable Daily Intakes

Both phosphoric acid and propylene glycol have been assessed by JECFA, establishing an ADI of 25 mg/kg b.w. for propylene glycol (JEFCA, 1973) and an MTDI of 70 mg/kg b.w. (expressed as phosphorous) for the total amount of phosphates and polyphosphates present both in additives and naturally in foods (JECFA, 1982).

3. Physicochemical properties

3.1 Composition and detailed formula

The product proposed as a processing aid is an aqueous solution of phosphoric acid (18-25 %) and propylene glycol (5-10 %). Its composition is shown in table 2.

Table 2. Composition of the processing aid

Component	Chemical formula	CAS No.	Molecular weight (g/mol)
Phosphoric acid	H_3PO_4	7664-38-2	98
Propylene glycol	$C_3H_8O_2$	57-55-6	76.1

3.2 Product specifications

Table 3. Specifications and analytical results of the processing aid

Specifications (%)		Results of the analysis of three batches (%)		
Phosphoric acid	18-25	24	21.7	22.3
Propylene glycol	5-10	6.0	5.6	5.5

3.2.1 Product stability

The applicant states that the solution has a shelf life of 2 years. It has provided the results of HPLC (High Performance Liquid Chromatography) analyses of 10 samples of various phosphoric acid and propylene glycol batches manufactured 2 years prior to analysis and 10 recently manufactured samples. The results obtained show an average phosphoric acid concentration of 20.7 ± 1.7 % for the recently manufactured samples, and 21.9 ± 1.4 % for those manufactured 2 years before, without detecting significant differences between both groups. In the case of propylene glycol, the results show an average concentration of 8.2 ± 0.4 % for the recently manufactured samples, and 8.0 ± 0.5 % for those manufactured 2 years previously, again with no significant differences.

In addition, the applicant provides the results of the FTIR (Fourier Transform Infrared Spectroscopy) analyses of 10 samples manufactured 2 years ago and 10 recently manufactured samples, indicating that there is no degradation.

3.2.2 Reactivity

The applicant indicates that acid-base reactions are the only reactivity expected.

In accordance with the opinion of the FDA provided by the applicant, the Administration confirmed in 2014 that data on the absence of acetol as a by-product of the reaction of the processing aid with sodium hypochlorite were adequate. Furthermore, acetol has been assessed by JECFA, establishing an acceptable ADI (JECFA, 2010).

4. Technological function

4.1 Alleged technological use

Processing aid for pH stabilisation to enhance the antimicrobial activity of the chlorine used in washing water disinfection required for the processing of fresh cut vegetables and ready-to-eat leafy vegetables.

4.2 Target foods or food group

The target foods or food groups are fresh cut vegetables and ready-to-eat leafy vegetables.

4.3 Level of use requested

As stated by the applicant, the maximum use concentration of the processing aid shall be 0.1 % added to the washing water of fresh cut vegetables and ready-to-eat leafy vegetables. Following the washing, there shall be a final rinse with drinking water.

4.4 Description of the process

4.4.1 Ways of adding the processing aid

The applicant indicates that the processing aid is added to the washing water, together with the chlorine, through an automated system. It should be noted that, to ensure its effectiveness in the disinfection, the concentration of free chlorine should exceed 10 ppm and given that the addition of chlorine increases the alkalinity of the washing solution, it is necessary to add a processing aid (using a positive displacement pump) in order to keep the operational pH between 5.5 and 6.5. Upon recirculating the washing water, a proportion remains on the surface of the washed plant product. That volume is replaced with clean water to which the chlorine and processing aid are added in order to maintain the free chlorine concentration and pH.

4.4.2 Identifying the processing aid elimination phases

It should be noted that, once the washing process of the plant products has finished, there is a final rinse with drinking water. Then, excess water is removed from the surface of the plant products through drying.

4.5 Justification of use, interest and efficacy

Regarding the efficacy of the proposed processing aid, it is alleged that the addition of the processing aid to the washing water with chlorine (as sodium or calcium hypochlorite) increases the efficacy of the chlorine to control the pH (between 5.5 and 6.5) and stabilising it as hypochlorous acid. The disinfectant efficacy of hypochlorous acid decreases at pH> 6.5.

The applicant highlights that there are other stabilisers such as citric acid used by the fruit and vegetable industry to control pH when chlorine is used a disinfecting agent. Citric acid introduces organic material to the washing water, causing the consumption of chlorine and the formation of disinfection by-products to increase (Fan and Sokorai, 2015). In the case of SmartWash, the applicant indicates that its use does not add organic material to the washing water per se, which favours a lower chlorine consumption.

It is also stated that, when there is a large amount of organic material, the incorrect administration of chlorine can cause unwanted by-products such as trihalomethanes, which include chloroform, to be produced and that suitable pH monitoring and chlorine dosing can largely reduce these risks.

4.5.1 Efficacy studies

The applicant submits two studies undertaken using the product T128 which, as the applicant attests, has the same composition as the processing aid SmartWash SW under assessment. Both studies have been published (Nou et al., 2011) (Luo et al., 2012).

The ability of the product T128 to stabilise free chlorine when used in lettuce washing water with high organic load was evaluated (Nou et al., 2011). For the study, iceberg lettuce and spinach leaves were inoculated with strains of *Escherichia coli* O157:H7 and *Salmonella enterica* sv. *typhimurium*. The initial aqueous chlorine solution (20 ppm free chlorine) was prepared by adding 6 % hypochlorite sodium to the water, before the product T128 was added (0.05 and 0.1 %). In order to increase the organic load in the washing water, extracts of lettuce and soil were added. As a control, an aqueous chlorine solution (20 ppm free chlorine) using citric acid to adjust the pH (6.4-6.5) was also prepared.

The results of the study show that the presence of T128 significantly reduced ($P<0.001$) the loss of free chlorine in the presence of soil, while the loss only slightly reduced when there were lettuce extracts present. Furthermore, the presence of T128 reduced the survival of pathogenic bacteria in the washing water, as well as possible cross-contamination when contaminated and uncontaminated products were washed together. However, the presence of T128 did not enhance the effectiveness of the chlorine solution in reducing the microbial load of the contaminated iceberg lettuce.

The pilot study carried out by Luo et al. (2012) studied the impact of the use of product T128 on the efficacy of the chlorinated washing water against pathogens and cross-contamination. For this study, spinach leaves inoculated with a strain of *Escherichia coli* O157:H7 ($2x10^5$ CFU/g), and iceberg lettuce leaves which were not inoculated, were washed with an aqueous chlorine solution in the presence and absence of T128. During washing, the changes in the washing water and the survival of the pathogens and cross-contamination were monitored every 2 minutes (for 36 minutes). The initial aqueous chlorine solution was prepared by adding 700 ml of sodium hypochlorite (12.5 %) to the water in order to obtain approximately 20 mg/l of free chlorine in the washing water. During the washing process, sodium hypochlorite was added twice to compensate for the loss of chlorine.

The results showed that the use of T128 did not have a significant influence ($P>0.05$) over the deterioration of the washing water, nor over the retention of the pathogens on the inoculated spinach leaves. However, the study highlights that in the absence of T128, there was a high survival rate of *Escherichia coli* in the washing water and frequent cross-contamination of lettuce leaves which were not inoculated when the free chlorine concentration was lower than 1 mg/l during the washing process. On the other hand, the use of T128 significantly reduced the presence of *Escherichia coli* in the washing water as well as cross-contamination on the lettuce leaves which were not inoculated. According to the authors of the study, this suggests that the presence of T128 in fresh product washing systems based on the use of chlorine increases the safety margin of the process (Luo et al., 2012).

5. Analyses of residues

Regarding the possible presence of phosphoric acid and propylene glycol residues in products treated with the processing aid, 4 samples of romaine lettuce and 4 samples of spinach from different batches washed with water containing chlorine and 0.1 % of the processing aid were analysed. Following the washing, the samples underwent a final rinse with drinking water. In addition, 4 lettuce and 4 spinach samples were analysed after being washed with a chlorine solution without the processing aid. The applicant indicates that romaine lettuce and spinach were used to analyse the residues as lettuce is the most traded ready-to-eat fresh plant product, while spinach is one of the plant products which absorbs the most chemical residues during washing.

Phosphates were analysed by Monterey Bay Analytical Services using ion chromatography with a quantification limit of 0.1 mg/l (0.3 mg/kg product). The method is based on the official EPA 300.0 method of the Environmental Protection Agency in the United States (EPA, 1993).

In the case of propylene glycol, the analyses were carried out by McCampbell Analytical Inc, using HPLC with a 2 mg/l detection limit (6 mg/kg product). The method is based on the official EPA 8319 method (EPA, 1986), amended in accordance with Kuo et al. (2002).

Propylene glycol residues were not detected in any of the samples analysed (detection limit: 6 mg/kg). In the case of phosphates, the residue concentrations detected in the samples washed with the processing aid were not significantly different ($P>0.12$ for lettuce, and $P>0.36$ for spinach) from those detected in the same washed samples without the processing aid (Table 3).

Table 3. Phosphate and propylene glycol residues in spinach and lettuce

Samples	Washed without SmartWash		Washed with SmartWash	
	Phosphates (mg/kg)	Propylene glycol (mg/kg)	Phosphates (mg/kg)	Propylene glycol (mg/kg)
Mean value ± s.d.[1] Spinach	3.2 ± 1.0	n.d.[2]	3.5 ± 0.6	n.d.
Mean value ± s.d. Lettuce	4.5 ± 0.9	n.d.	5.3 ± 0.8	n.d.

[1]s.d.: standard deviation; [2]n.d.: not detected.

Both propylene glycol and phosphoric acid are authorised as food additives at much higher concentrations than those which could possibly appear as residues. It is therefore considered that the contribution to the exposure of these substances derived from their use as a processing aid would be negligible.

Conclusions of the Scientific Committee

The Scientific Committee, after having analysed the application file for the use of an aqueous solution of phosphoric acid and propylene glycol as a processing aid to stabilise the chlorine used in the washing of fresh cut vegetables and ready-to-eat leafy vegetables, concludes that, based on the information provided by the applicant and considering the proposed composition and

conditions of use, the use of the processing aid does not involve a health risk for the consumer. The conclusions of this report refer exclusively to the product under assessment as a processing aid under the proposed conditions of use and with its current composition. They cannot be extrapolated to other formulations or conditions other than those assessed.

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