TECHNICAL REPORT

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Outcome of the consultation with Member States and EFSA on the basic substance application for potassium sorbate for use in plant protection as fungicide on citrus, stone and pome fruits

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context, EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for potassium sorbate are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of potassium sorbate as a basic substance for use in plant protection as fungicide. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

Keywords: potassium sorbate, basic substance, application, consultation, plant protection, pesticide, fungicide

Requestor: European Commission

Question number: EFSA-Q-2017-00104

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Summary

Potassium sorbate is an active substance for which, in accordance with Article 23(3) of Regulation (EC) No 1107/2009, the European Commission received an application from Decco Iberica Post Cosecha S.A.U for approval as a 'basic substance'. Regulation (EC) No 1107/2009 introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest in applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in February 2017, EFSA was asked to organise a consultation on the basic substance application for potassium sorbate, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table within three months of acceptance of the specific request.

A consultation on the basic substance application for potassium sorbate, organised by EFSA, was conducted with Member States via a written procedure in November 2016-January 2017. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by EFSA on the basic substance application for potassium sorbate and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Potassium sorbate is the common name for potassium (2*E*,4*E*)-2,4-hexadienoate (IUPAC). The predominant use of potassium sorbate is as food additive. Potassium sorbate is also approved as a biocidal active substance. The specification proposed for this substance should be according to Commission Regulation (EU) No 231/2012 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. The product to be used is a soluble concentrate containing 500 g/L potassium sorbate.

The intended uses of potassium sorbate as a fungistatic substance are post-harvest applications by dipping or drenching on citrus, pome fruits and stone fruits against fungi and moulds.

The toxicological profile of potassium sorbate has been assessed at EU level as a food additive and biocide. As a food additive, the EFSA ANS Panel set a temporary acceptable daily intake (ADI) of 3 mg/kg bw per day (EFSA ANS Panel, 2015). As biocide (ECHA BPC, 2014), the RMS Germany set an acceptable exposure level (AEL) of 13.4 mg/kg bw per day (Germany, 2015). ECHA RAC (2013) proposed classification and labelling of potassium sorbate as Eye irritant category 2. Under the current intended uses as a plant protection product in order to prevent any exposure to operators, workers, bystanders and residents authorization should be limited to indoor treatment of fruits with a closed drenching system. The applicant considered that no manual mixing and loading task is needed for the use of this product in a post-harvest drenching treatment.

Very limited information on residue levels following post-harvest treatment of citrus and stone fruit with potassium sorbate have been submitted and no information is available for pome fruit. Altogether the quality of the residue trial data has to be considered poor, specifically in view of contradictory or missing information with regard to the most pertinent parameters such as the explicit application rate, the determined residue levels in some samples as well as important analytical information. Therefore the residue levels on oranges, lemons, peaches, nectarines, apricots, plums, apples and pears treated according to the intended GAP and the consumer exposure resulting from these residues are uncertain, and therefore a reliable consumer risk assessment cannot be conducted for the requested uses.

Given the attested consumer exposure related to the use of sorbic acid and its salts (including potassium sorbate) as a food additive (EFSA ANS Panel, 2015) and the requested use as a post-harvest pesticide on fruit, a chronic dietary exposure assessment considering the different possible dietary exposure routes should be conducted to exclude an unacceptable consumer risk, specifically for the most vulnerable consumer groups. In this context it is noteworthy that the ANS Panel stated that the most realistic approach using reported use levels and analytical data in the non-brand-loyal scenario lead to an exceedance of the temporary ADI for toddlers and for children in one Member State. It should be further noted that the above assessment by the ANS Panel did only consider concentrations up to 2.5 mg/kg in fresh citrus fruit but not any other fresh fruit. The available residue data following dipping/drenching of fruit, although of limited quality, point towards higher levels that might be expected as residues on fruit treated to cGAP conditions (up to or greater than 20 mg/kg with a highest residue for whole fruits of >40 mg/kg). Therefore, residues in fruit resulting from the pesticide use will likely further increase the consumer exposure estimated by the ANS Panel. An updated consumer risk assessment, considering residue levels of potassium sorbate on fresh fruit is required to estimate the impact of the use as a pesticide on the overall dietary consumer exposure and to conclude on the dietary consumer risk.

In order to prevent any exposure to ground water or risk for the environment, authorization should be limited to uses for indoor treatment of fruits with a closed drenching system where no liquid releases are produced and where end-residual solid product is managed by an authorised waste management company.

As described above, a low risk to non-target organisms is expected as long as the uses of potassium sorbate are limited to indoor treatment of fruits and the end-residual solid products are managed appropriately.

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1. Introduction

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

Regulation (EC) No 1107/2009[1] (hereinafter referred to as 'the Regulation') introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as 'basic' and used for plant protection purposes.

Potassium sorbate is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Decco Iberica Post Cosecha S.A.U for approval as a 'basic substance' for use in plant protection as fungicide on citrus, stone and pome fruits.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for potassium sorbate, which was conducted via a written procedure in November 2016-January 2017. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for potassium sorbate and to present EFSA's scientific views on the individual comments received in the format of a reporting table.

The application and, where relevant, any update thereof submitted by the applicant for approval of potassium sorbate as a 'basic substance' in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (Decco Iberica; 2016, 2017).

1.2. Interpretation of the Terms of Reference

On 6 March 2013 the European Commission requested EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 13 February 2017, EFSA was asked to organise a consultation on the basic substance application for potassium sorbate, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The agreed deadline for providing the finalised report is 13 May 2017.

On the basis of the reporting table, the European Commission may decide to further consult EFSA to conduct a full or focussed peer review and to provide its conclusions on certain specific points.

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

2. Assessment

The comments received on the basic substance application for potassium sorbate and the conclusions drawn by EFSA are presented in the format of a reporting table.

The comments received are summarised in columns 2 and 3 of the reporting table. The applicant's considerations of the comments, where available, are provided in column 4, while EFSA's scientific views and conclusions are outlined in column 5 of the table.

The finalised reporting table is provided in Appendix A of this report. In addition, an overview table on the identity and biological properties of the substance and the list of intended uses in plant protection (GAP table) are provided in Appendix B and C, respectively.

Documentation provided to EFSA

1. Decco Iberica, 2016. Basic substance application on potassium sorbate submitted in the context of Article 23 of Regulation (EC) No 1107/2009. July 2016. Documentation made available to EFSA by the European Commission.

2. Decco Iberica, 2017. Basic substance application update on potassium sorbate submitted in the context of Article 23 of Regulation (EC) No 1107/2009. March 2017. Documentation made available to EFSA by the applicant.

References

ECHA BPC (ECHA Biocidal Products Committee), 2014. Opinion on the application for approval of the active substance potassium sorbate for product type 8. ECHA/BPC/37/2014. Adopted, 4 December 2014.

ECHA RAC (ECHA Committee for Risk Assessment), 2013. Opinion proposing harmonised classification and labelling at EU level of potassium sorbate. Adopted 6 March 2013.

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2015. Scientific Opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives. EFSA Journal 2015;13(6):4144, 91 pp. doi:10.2903/j.efsa.2015.4144

Germany, 2015. Assessment report on potassium sorbate prepared by the rapporteur Member State Germany under Regulation (EU) 528/2012 concerning the making available on the market the use of biocidal products. February 2015.

Abbreviations

ADI	acceptable daily intake
AEL	acceptable exposure level
ALARA	As Low As Reasonably Achievable
a.s.	active substance
DAR	draft assessment report
ECHA	European Agency of Cheimcals
cGAP	crtical good agricultural practice
GAP	good agricultural practice
LOQ	limit of quantification
MRL	maximum residue level
MS	Member State
PPE	personal protective equipment
PRIMo	Pesticide Residue Intake Model
pTMRL	proposed temporary MRL
RAC	raw agricultural commodity
RMS	rapporteur Member State
STP	sewage treatment plants

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for potassium sorbate and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)	Purpose of the application, Page 4	DE: Potassium sorbate is an approved biocidal active substance on the basis of its fungicidal/fungistatic effects (Wood preservative, Reg (EU) 2015/1729[2]). In addition, it is under review to be used as a preservative for products during storage (in the framework of Reg. (EU) No 528/2012[3]). Hence, the basic substance application for potassium sorbate needs to be in alignment to the relevant evaluation as biocidal active substance.		Amended	Addressed: The application has been amended accordingly.
1(2)		UK - No comments.			Noted.
1(3)		NL: The dossier suggests that DECCOPLUS will be marketed as a		Amended	Addressed: The application has

[2] Commission Implementing Regulation (EU) 2015/1729 of 28 September 2015 approving potassium sorbate as an existing active substance for use in biocidal products for product-type 8 .OJ L 252, 29.9.2015, p. 24–26.

[3] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. OJ L 167, 27.6.2012, p. 1–123.

General					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		plant protection product. However, a basic substance may not be sold on the market as a plant protection product, even after approval.			been amended.
1(4)	1. Purpose of the application, p.4 and 2.1 Identity, p. 5	EFSA: it is stated that is not placed on the market as a Plant Protection Product, however there are products on the market designated as preservative on citrus fruit with given trade names.	On the webpage: http://www.deccoitalia.it/?post_type=portfolio&p=1182&lang=en it is stated that this is the only approved food additive on citrus fruit, applied post harvest or http://www.deccoiberica.es/producto/deccoplus/ It is proposed to remove the reference to a trademark product, like Deccoplus	All references to the trade mark DECCOPLUS have been removed from the Dossier. The name of the reference product to be assessed is DECCO-KS	Addressed: References to the trade mark DECCOPLUS have been removed from the application.

2. Identity of the substance/product as available on the market and predominant use

2.1. Identity and Physical and chemical properties of the substance and product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	pp5-6	UK – It is unclear if the product is just a simple dilution of potassium sorbate in water and, if it is, how the product as presented relates to potassium sorbate available commercially as a food additive. If the product is more than a simple solution, we do not consider it to be a basic substance according to Article 23 point 1(c).	UK - The applicant should clarify the full composition of the product and how it relates to commercial, food-additive sources of potassium sorbate.	Please see the confidential annex II of the amended dossier.	Addressed: The composition of the product was presented in the confidential annex II of the updated application.
2(2)		DE: It seems that this application is made for the formulated product DECCOPLUS, which seems to be on the market already for post-harvest treatment of fruit: http://www.deccoiberica.es/producto/deccoplus/	Please check for conflicts with the provisions for basic substances according to 1107/2009.	All references to the trade mark DECCOPLUS have been removed from the DECCO web site.	Addressed: References to the trade mark DECCOPLUS have been removed from the submission.
2(3)	Identity and physical chemical properties of the substance and product to be used Page 6	DE: Specification requirement for potassium sorbate for lead is <2 ppm (according to Reg (EU) No 231/2012)[4]. For the substance to be used, a concentration <5 ppm is given for lead. Hence, the requirement on specification as food supplement is not met. This is not in accordance with the ALARA principle (as low as reasonably achievable) that applies for lead.		Type error amended. Please see the attached document in the section 2: "2.1.a_Analysis and identification.pdf"	Addressed: The typo has been corrected in document "2.1.a_Analysis and identification.pdf", Lead: Not more than 2 mg/kg.
2(4)	2.1 Identity	EFSA: the relevant impurity content of the	Clarification is needed on the	Please refer to the new	Addressed:

[4] 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. 1–295

2.1. Identity and Physical and chemical properties of the substance and product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
	and 2.1.5 Specification of the a.s.	proposed substance to be used is not meeting the requirements of the specification according to the Regulation (EC) Nº 1333/2008[5]	specification of the proposed basic substance.	attached document named Quality Information Pack [redacted]	The specification proposed for this basic substance should be according to 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
2(5)	2.1.	NL: The literature source of the data is not mentioned.		Amended	Addressed.
2(6)	2.1	NL: The physical chemical properties of the product should be reported in English.		Amended	Addressed.
2(7)	2.1.5 and 2.1.7.2	NL: The method for the determination of formaldehyde mentions a controlling solution containing 15 IJg or 15 g of formaldehyde. This should be rectified to 15 µg.		Amended	Addressed.
2(8)	2.1.7.3	NL; The residue analytical method for plant matrices has been performed on a high water content matrix. The applied uses include acidic matrices (citrus fruit). A method for acidic matrices should be included.		New analytical methods have been attached to the updated dossier.	Addressed: New analytical methods have been added to the updated application.

[5] 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,

2.2. Current Former and in case proposed trade names					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(9)		UK - No comments.			Noted.
2(10)	2.2 Products on the market, p.8	EFSA: if a formulated product called Deccoplus is on the market, means that this is not a basic substance.	A basic substance application cannot be for an already existing formulated product on the market. The reference to Deccoplus should be removed. Any potassium sorbate, manufactured by any company, meeting the identity and purity requirements can be the basic substance.	All references to the trade mark DECCOPLUS have been removed from the Dossier. Potassium sorbate (50% w/v)	Addressed: All references to the trade mark DECCOPLUS have been removed from the application.

2.3. Manufacturer of the substance/products					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(11)		UK - No comments.			Noted.
2(12)	2.3 Manufacturer of the product	EFSA: the reference to the product already on the marked should be removed		All references to the trade mark DECCOPLUS have been removed from the Dossier. Potassium sorbate (50% w/v)	Addressed: All references to the trade mark DECCOPLUS have been removed from the application.

2.4. Type of preparation					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(13)	2.4	DE: Information should be provided regarding the composition of the product DECCOPLUS, e.g. whether it consists only of potassium sorbate and water or if other substances are added. (The addition of other substances than water would only be possible if they are also basic substances.)		Amended	Addressed: 2.4.Type of preparation of the substance has been modified accordingly: the substance can be considered as a soluble powder and used as a soluble concentrate.
2(14)	2.4	UK - No comments.			Addressed
2(15)	2.4. Type of preparation of the substance/product	NL: Since Potassium sorbate is a solid, the formulation should be considered a SP (soluble powder)		Amended	Addressed: 2.4.Type of preparation of the substance has been modified accordingly: the substance can be considered as a soluble powder.
2(16)	2.4 Type of preparation	EFSA: the basic substance is solid crystalline powder, not a liquid dissolved in water		Amended	Addressed: 2.4.Type of preparation of the substance has been modified accordingly: the substance can be considered as a soluble powder

2.5. Description of the recipe for the product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(17)		UK - No comments.			Noted.
2(18)	2.5. Description of the preparation for the product to be used	NL: This section should describe how the end-user can prepare the spraying solution from commercially available Potassium sorbate.		The marketed product is a mixture of water (50% w/v)+ potassium sorbate (50% w/v), but when the product is applied the end concentration of potassium sorbate is set at 2% or 4%(w/v) (depending of fruit to be treated), because the product is diluted at the time of application.	Addressed. 2.5.Description of the preparation for the product to be used has been amended accordingly.
2(19)	2.5. Description of the preparation for the product to be used	NL: The widely used levels of of 250 ppm to 1000 ppm do not correspond to the common use levels range from 0.5 – 1% (but rather with 0.025 – 0.1%)		Amended to 0.025 – 0.1%)	Addressed. Typo was corrected.

3. Uses of the substance and its product

3.1. Field of use

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		UK - No comments.			Noted.

3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(2)		UK - No comments.			Noted.
3(3)		DE: K-Sorbat can be phytotoxic or reduce quality of fruits if applied after harvest in concentrations intended for use (see GAP table/application rate of 1-2 %): in one trial the firmness of stone fruits was significantly reduced after dipping in 1.5 % K-Sorbat (Gregori et al, 2008), in another trial phytotoxic effects occurred on citrus fruits after dipping in 2 % K-Sorbat (Mascarós and Brunetti, 2007).	Please address.	This concern is not relevant under the proposed intended use as the contact time under the drenching/dipping procedure is lower than 60 seconds. In the study Gregory et al. 2008, states 120 seconds which not real in practise. This basic substance is intended to be applied in post-harvest and not in crops. In the dossier, we included a study, Mascaros J. & Brunetti (L7-L0602) which states that no phytotoxicity has been shown in fruits.	Addressed: The study Mascaros J. & Brunetti (L7-L0602) was included stating that no phytotoxicity has been shown in fruits.

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(4)		UK - No comments.			Noted.
3(5)		DE: The numeration in this reporting table does not correspond to the numeration in the application: "Summary of intended uses" is numerated as 3.4 in the application instead of 3.3 here.		Amended	Addressed.
3(6)		DE: The abbreviations are not explained (SL, as, n.a.). First column "Application rate" (a.i./hl) is not filled in ("n.a." is not correct).	Please explain and complete.	Amended. Further details can be seen in the corresponding section	Addressed.
3(7)		DE: The substance is intended only for use in southern European countries although it could be useful also in northern countries (pome fruits).	Please consider whether the application can be extended.	The intended European areas to be used are extended to Northern European countries.	Addressed: The table "Summary of intended uses", however was not amended in the revised submission.
3(8)	3.4 GAP table	EFSA: the product's trade name should be removed			Addressed: The table "Summary of intended uses" in the revised submission, however still contained reference to DECCO-KS, which is removed in the technical report.

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(9)	3.4 GAP table	EFSA: the application rate columns g a.i./hl and water l/quantity should be filled in, these are also relevant			Addressed: The respective fields were amended.

4. Classification and labelling of the substance

Classification and labelling of the substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
4(1)	p12	UK: Potassium sorbate has a hazardous classification of Eye Irrit. 2 (H319). The product is a 50% solution and, therefore, also exceeds the generic 10% concentration triggering classification. As it meets the criteria to be classified as hazardous, potassium sorbate is, therefore, a substance of concern and fails to meet the basic substances approval criterion 1(a) of Article 23.	N/A - the application should be rejected.	We agree with the UK classification about the toxicity of the product. However based on the intended application method, we do not consider potassium sorbate as a substance of concern. Another precedent as basic substance is for example, vinegar which is classified as more toxic than potassium sorbate and it was considered to meet this basic substance approval criterion. In addition potassium sorbate is approved as food additive and it may be present in many food commodities so the consumer exposure to the product residues should be higher as a food additive rather than as basic substance. Therefore, the applicant asks MS to reconsider this argument and accept the application as valid.	ECHA RAC (2013) proposed classification and labelling of potassium sorbate as Eye irritant category 2.

Classification and labelling of the substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
4(2)	Classification and Labelling Page 12	DE: It is agreed to the applicant that potassium sorbate has to be classified for Eye Irrit. 2, H319 according to the Committee for Risk Assessment (RAC) (Opinion of proposing harmonised classification and labelling at EU level of potassium sorbate (March, 2013; Ref. No: CLH-O-0000002524-78-03/F)).		Noted	See comment 4(1).

5. Impact on Human and Animal Health

UK: no comments

5.1. Toxicokinetics and metabolism in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)		PL: No comments			Noted.
5(2)	Chapter 5. Impact on human and animal health, p. 13	DE: During the re-evaluation process of food supplements (Scientific opinion, EFSA Journal 2015; 13/6:4144), EFSA derived an ADI of 3 mg/kg bw/d from the 2-generation study in rats and the developmental toxicity study in rabbits. Consequently, a risk assessment has to be performed but was not considered by the applicant.		This EFSA document was published after the submission of the application so it could not be taken into account. In order to address this data gap, a risk assessment has been performed by PRIMOMODEL and supplied in the new dossier. As conclusion, the estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. Therefore a long-term intake of residues of POTASSIUM SORBATE is unlikely to present a public health concern.	The assessment done by EFSA ANS Panel (2015) was taken into account in the updated report. EFSA ANS Panel set a temporary acceptable daily intake (ADI) of 3 mg/kg bw per day for potassium sorbate (EFSA ANS Panel, 2015) See also comment 6(4)
5(3)	General comment to all sections	NL: throughout the section on impact on human health the main document referred to WHO evaluation from 1974. This document is quite old.		A brief summary from the EFSA document is done	See 5(2).

5.1. Toxicokinetics and metabolism in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		We would have therefore liked to have seen more information included from the EFSA evaluation from 2015 (EFSA Journal 2015; 13(6):4144).			
5(4)	General comment	EFSA: Please consider the most updated EU assessment on potassium sorbate by the EFSA ANS Panel. EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2015. Scientific Opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives. EFSA Journal 2015;13(6):4144, 91 pp. doi:10.2903/j.efsa.2015.4144		Done	See 5(2).
5(5)	General comment	EFSA: Please considered whether potential reaction products that may result from the interaction of sorbic acid with nitrites and with ascorbic acid in the presence of iron salts under the proposed plant protection uses can occur Potential concerns (i.e. reaction products have been shown to be formed under optimal experimental conditions in		This concern is not relevant for the proposed use where the product based on potassium sorbate is intended to be used in post-harvest and not in the field. The possibility of formation of these reaction products can be excluded as the product is diluted with water prior to use and the water quality is regularly controlled by the Spanish Regional	Under the current intended uses as a plant protection product in order to prevent any exposure to non-dietary exposure groups (i.e. operators, workers, bystanders and residents), authorization should be limited to uses for indoor treatment of fruits with a closed drenching system. The applicant considered that no manual mixing and loading

5.1. Toxicokinetics and metabolism in humans					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		an aqueous environment) were raised by the EFSA ANS Panel, 2015.		Governments for the limits of metals. In addition to this, the represented product will be used indoor in a closed system where product residues are not released to the environment as a result of this use. Moreover, the product residue is solid and managed as a hazardous waste, so no exposure to any environmental compartment is expected.	task is needed for the use of this product in a post-harvest drenching treatment. See also comment 5(21)

5.2. Acute toxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(6)		PL: No comments			Noted.

5.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(7)		PL: The informations contained in this chapter apply to subchronic or chronic toxicity. Moreover, some of the informations applies to carcinogenicity studies. All these data should be included in Section 5.5 "Long-term toxicity." (according to recent classification: acute toxicity – only one dose; repeated dose toxicity – up to 28 days; subchronic toxicity – 90 days; chronic toxicity – minimum 12 months)		Amended	Addressed.

5.4. Genotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(8)		NL: It is stated that several studies conclude that the food additive family sorbates is not genotoxic. This is followed by a summary of		Amended	See 5(2).

5.4. Genotoxicity					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		three public literature while a far larger number of studies on the genotoxicity of postassium sorbate are available. Moreover, two of the three studies referred to actually conclude that stored sodium sorbate does have weak genotoxic potential. This seems contradictory to the conclusion that potassium sorbate is not genotoxic. It would be helpful to include more details on the genotoxicity evaluation which was carried out by the EFSA panel of food additives and nutrient sources added to food (EFSA Journal 2015; 13(6):4144).			

5.5. Long-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(9)		PL: The informations contained in this chapter apply to subchronic toxicity (mouse) or carcinogeni-city study. Moreover, some of the informations applies to reproductive toxicity and should be also included in Section 5.6 "Reproductive toxicity."		Amended	Addressed.

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(10)		PL : No comments			Noted.
5(11)	Page 19	DE: During the re-evaluation process on potassium sorbate (EFSA Journal 2015; 13/6:4144), EFSA derived an ADI of 3 mg/kg bw/d from the 2-generation study in rats and the developmental toxicity study in rabbits.		Amended	See comment 5(2).

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		These studies are not part of this basic substance application. Consequently, the application as basic substance cannot be assessed as important information is lacking.			

5.7. Neurotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(12)		PL : No comments			Noted.

5.8. Toxicity studies on metabolites

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(13)		PL : No comments			Noted.

5.9. Medical Data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(14)		PL : No comments			Noted.

5.10. Additional Information related to therapeutic properties or health claims

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(15)		PL : No comments			Noted.

5.11. Additional information related to use as food

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(16)		PL : No comments			Noted.

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(17)		PL : No comments			Noted.
5(18)	5.12, Acceptable	DE: During the approval of		Noted.	The report was amended

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
	Operator Exposure Level	potassium sorbate as biocidal active substance an AEL of 13.4 mg/kg bw was derived. This should be mentioned.			accordingly.
5(19)	ADI	NL: In 2015 the EFSA panel on food additives and nutrient sources added to food (ANS) proposed to lower the ADI of 25 mg/kg bw/day to 3 mg/kg bw/day based on new reproductive toxicity data (EFSA Journal 2015; 13(6):4144).		done	See comment 5(2).

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(20)		PL : No comments			Noted.
5(21)	5.13, Non-dietary exposure	DE: Even if the process of dipping/drenching is highly automated, exposure might occur during preparation of the dipping/drenching solution and during cleaning. Moreover, workers might		Due to the volume (20 L of DECCO-KS in 1000L of water) used in the treatment, mechanical process is used where the human presence is only needed to operate the machine. Therefore, no	Under the current intended uses as a plant protection product in order to prevent any exposure to non-dietary exposure groups (i.e. operators, workers, bystanders and residents),

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		come in contact with the treated fruits/fruit boxes. Nevertheless, with respect to the risk assessment performed during approval of potassium sorbate as biocidal active substance exposure is expected to be below the AEL of 13.4 mg/kg bw when PPE is used.		manual mixing and loading task is regarded for the use of this product in a post-harvest drenching treatment. An annex with a description of the process is attached in the supplied application. Regarding to the worst case scenario where the workers might come in contact with the treated fruits/fruit boxes a new assessment is provided.	authorization should be limited to uses for indoor treatment of fruits with a closed drenching system. The applicant considered that no manual mixing and loading task is needed for the use of this product in a post-harvest drenching treatment. See also comment 5(5)
5(22)		NL: while dipping and drenching is an automated application it does often require a mixing/loading step. Could the applicant clarify if exposure during mixing and loading of the product could occur?		Due to the volume (20 L of DECCO-KS in 1000L of water) used in the treatment, mechanical process is used where the human presence is only needed to operate the machine. Therefore, no manual mixing and loading task is regarded for the use of this product in a post-harvest drenching treatment. An annex with a description of the process is attached in the supplied application.	See comment 5(21).

6. Residues

UK: no comments

Residues

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)	6	NL: Argumentation is provided that residues are mainly on the peel, and therefore, there is no risk of consuming potassium sorbate. However, many fruits (e.g. pome fruit, stone fruit) are eaten with peel.		Please be aware that the main use of this product is in citrus fruit due to the fact the quantity of citrus treated with potassium sorbate is higher than in pome and stone fruit. However in order to support additional uses in pome and stone fruits we have perform a new risk assessment for your consideration.	Citrus is usually not consumed with the peel in contrary to the other fruits in the list of uses. Moreover it is not reproducible from the GAP table that citrus should be the critical use compared to e.g. pome fruit, stone fruit (the application rate seems in fact higher for the latter crops, likely leading to higher residues on those crops). % crop treated is not a factor currently considered in the EU dietary risk assessment on pesticides (and it is irrelevant in acute dietary risk assessments should this be necessary). See also comment 6(4)
6(2)	6	NL: More details on the conducted residue trials should have been shown.		New residue tests as well as testing protocol have been submitted within this dossier.	The applicant submitted additional information regarding residue trials

Residues					
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		For example, it is not clear now how many trials are available for each crop. The bibliography only contains analytical reports, but without any details on the underlying study, these analytical results are not useful.		I addition a list of residue data has been presented now in a standard table format for a better comprehension.	08/L0101, 09/L0604 and 10/L010124; however the information is incomplete and in part contradictory to an earlier submission (Decco, 2009[6]). The following is noted with regard to magnitude of residues data: 1) In the document Gomez, 2009, Part II pt. 6 'Reaction and fate in food' it was reported that residue trials were conducted with dipping of citrus fruit in 0.3% or 3% potassium sorbate (ambiguous information given) and in Annex IV and VI it can be found that the trial reference codes are apparently corresponding to 08/L0101 and 09/L0604. The resubmitted analytical documentation for these trials (08/L0101 and 09/L0604) in a stand-alone report (without

[6] Decco, 2009. Request of extension of use of the food additive potassium sorbate (E-202), as surface treatment on citrus fruits applied by drenching or dipping prepared by Decco Iberica, E. Gomez, 2009.

Residues					
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					any signature or GLP indication on the field trial part) is however stating that the experiment was conducted with dipping in 1% (08/L0101) or 2% a.s. (4% product; 09/L0604), respectively. In the application form a concentration of potassium sorbate i.e. active substance of 4% is stated for trial 09/L0604. The actual treatment conditions in the trials are unclear, and the reported dose rates are contradictory for the same experiment and therefore not reliable. 2) In the document Gomez, 2009, Annex VI stated that samples were analysed within hours. From the resubmitted documentation it can be deduced that in the trial 08/L0101 samples were likely stored for up to 14 days before completing analysis, and that up to 12 days have passed between reception of samples and finalisation of

Residues					
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					analysis in trial 09/L0604. Sample and/or extract storage conditions in the lab were not reported, however might be relevant as a storage stability issue with potassium sorbate in aqueous solution was reported (-30% in 14 days; Gomez, 2009 Annex V). 3) The preparation of samples for analysis and the analytical method PAQ064 used were not described, nor is information available regarding the method validation and the actual LOQs that can be reached. 4) The residue results reported for trial 09/L0604 for the respective sample codes in the summary table are different from the results in the analytical report sheets. 5) Although the treatment was conducted with potassium sorbate, the residues were determined and reported as sorbic acid and not expressed as

Residues					
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					potassium sorbate in trial 08/L0101. 6) A sample no. 8 with residues >20 mg/kg was reported in trial 08/L0101 but does not show up in the residue summary table. 7) In trial 08/L0101 the sample of day 0 was lost in the laboratory and no results for this sampling interval are available nor was a retain sample sent to the lab for analysis. As no minimum waiting period after application is specified in the GAP table, residue levels at a very short waiting period might be relevant for the risk assessment. 8) In trials 08/L0101 and 10/L010124 for many samples residues were reported as <20 mg/kg although this seems not to be the LOQ in view of results reported for other samples or in other experiments using the same analytical method. The actual residue

Residues					
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					concentration in the concerned samples is therefore unknown. 9) The submitted report on trial 10/L010124 (stone fruit) does neither report any detail on the treatment, not even the application rate, nor on the sampling interval of the fruits after the treatment except for the day 0 sample. The application report stated the other samples were taken 15 days after treatment, yet this information is not given in the trial report, hence the report seems largely incomplete. It is noted that the cGAP, using the highest application rate, is on stone fruit. 10) The processing trial in report 10/L010124 for juice of stone fruit was conducted with peeled fruit which is not considered a representative condition, however in view of the use of potassium sorbate as food additive in fruit processed product processing

Residues					
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					trials on the magnitude of residues are considered as of low importance. 11) No trial is available to address the GAP on apples or pears. **Altogether the quality of the submitted reports has to be considered poor, specifically for the contradictory information reported on pertinent parameters such as the application rate and the determined residue levels. As currently reported, the results cannot be considered reliable to address the exposure potential for consumers in view of the requested GAP in citrus, pome fruit and stone fruit.**
6(3)	6	EFSA: The reporting of residue data is insufficient to assess whether the reported residue levels are relevant to the notified GAP. Similarly, the scarce reporting of residues trials in processed		More detail residue data is provided.	EFSA takes note that some more details on testing of citrus and stone fruit have been submitted. Apart from the questionable reliability of these studies (refer to 6(2)), the number of trials is very

Residues					
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		commodities cannot be related to the requested GAP. The standard tabled reporting for residue trials should be used and trials should be evaluated against the cGAP; post-harvest trials are not exempted from this requirement.			limited (2 in citrus and 1 in stone fruit), and the LOQ seems very high (20 mg/kg) for some samples and expression of final results is not consistent (K-sorbate vs. sorbic acid). But most importantly it is not clear how the trial design does relate to the requested GAP, e.g. residues in trial 1 in citrus significantly exceed 20 mg/kg, a level referenced as the 'MRL' by the applicant. Therefore the consumer exposure actually expected from GAP treatment is unknown. It is further unclear how residue levels following a post-harvest treatment will vary.
6(4)	6	EFSA: As for consumer risk assessment it is currently not possible to conclude based on the scarce presentation of information how the requested use would relate to a use as food additive. Further, in view of the ADI set		In order to address this data gap a new risk assessment is provided.	A new consumer risk assessment using PRIMo was announced by the applicant; however the submitted file does not contain any calculations. The mg/kg bw intakes presented in the application are not reproducible in view of the

Residues					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		for potassium sorbate, a consumer dietary intake and risk assessment should be conducted.			residue data submitted. The applicant proposed an MRL of 20 mg/kg that again is not sufficiently supported by the residue data submitted. Ideally new trials in full compliance with the intended GAP should be conducted, and all information necessary to validate the results should be documented in sufficient detail. It is also noted in this context that the EFSA ANS Panel (2015) has conducted a combined consumer risk assessment for sorbic acid and sorbates used as a food additive. The ANS Panel concluded that in a risk assessment using the maximum permitted levels (MPLs), the ADI of 3 mg/kg bw per day (provisional) was exceeded for all consumer groups. The provisional ADI was still exceeded for toddlers and children of one MS in a refined risk assessment (considering

Residues					
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					analytical data on market samples and non-brand loyal consumer behaviour). **It should be noted that in the refined assessment conducted by the ANS Panel fresh fruit was largely not considered with the exception of fresh citrus fruit up to levels of 2.5 mg/kg only.** The available residue data following dipping/drenching of fruit, although of limited quality, point towards higher levels that might be expected as residues on fruit treated to cGAP conditions (up to or greater than 20 mg/kg with a highest residue for whole fruits of >40 mg/kg). Therefore, residues in fruit resulting from the pesticide use will likely further increase the consumer exposure estimated by the ANS Panel in the refined assessment. **An updated consumer risk assessment, considering expected residue levels on**

Residues					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					fresh apples, pears, plums, nectarines, peaches and apricots is required to estimate the impact of the use as a pesticide on these crops on the overall dietary consumer exposure. Residues of potassium sorbate on oranges and lemon (RAC) might be considered of low relevance in a refined consumer exposure and risk assessment since the peel is usually not consumed and sorbate residues are not expected to penetrate the pulp in significantly higher concentrations than considered by the ANS Panel. However, in cases where the zest is used, given the high residues on the peel, an additional contribution also from raw citrus crops may not be fully excluded. Apart from the uncertainties related to residue levels that might be expected on

Residues					
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					different fruits following the requested uses of dipping/drenching in potassium sorbate, an indicative assessment using the EFSA PRIMo is not considered meaningful since other dietary contributors to the total exposure (i.e. processed food containing sorbate/ sorbic acid as food additive) cannot be considered by PRIMo, nor can the results obtained by the two assessment methods be added up.

7. Fate and Behaviour in the environment

UK: no comments

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	7.1	NL: can applicant elaborate a bit more on the OECD 301B/CEE 92/69 C4 study? In what context was this study done? Reference to the study might be included in the section.			Addressed Further details on the readily biodegradation test have been incorporated into the application document. Sorbic acid can be considered to be readily biodegradable
7(2)		EFSA: Use proposed is limited to post harvest treatment. Therefore, it is assumed that exposure to environment can be avoided by standard good practices of chemical and residues handing. In case other uses were proposed in the future, implying spread into the environment, further information / data would need to be provided and assessed (e.g. potential ground water contamination and reactions with iron and ascorbic acid).	However see comment from NL 7(3) on the need to address the exposure route by wastewater from the dipping/drenching treatment that might discharged to surface water via an STP.	The drenching method explained and described in the confidential annex shows a process with a closed system where no liquid releases are available. The end-residual product is solid and it must to be managed by an authorised waste management company.	Authorization should be limited to indoor uses with a closed drenching system where no liquid releases are produced and end-residual solid product is managed by an authorised waste management company. According to the applicant, the drenching procedure, which complies with this requirement, is presented as confidential. Risk managers may need to consider how users can be informed of the use procedure proposed.

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
7(3)	7.2	NL: it is argued that no exposure is expected to animal and the environment. However, wastewater from the dipping/drenching treatment might discharged to surface water via an STP. Can applicant elaborate on this exposure route, and estimate potassium sodium concentrations in the wastewater and STP?		The drenching method explained and described in the confidential annex shows a process with a closed system where no liquid releases are available. The end-residual product is solid and it must to be managed by an authorised waste management company.	See comment 7(2)

8. Effects on non-target species

UK: no comments

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		EFSA: Since the proposed use is limited to indoor treatment of fruits (by dipping and drenching) after harvest, the potential for exposure of non-target organisms can be considered as low, provided that standard good practices of chemical and residues handing are implemented. See also 7(2)		Noted.	A low risk to non-target organisms is expected as long as the use of potassium sorbate is limited to indoor treatment of fruits by dipping and drenching after harvest. Additionally, it should be ensured that the end-residual solid product is managed appropriately, see also comment 7(2).

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(2)	8.2	NL: Following our comment on 7(2) an indication would already give some inside if further attention is relevant		Please refer to our comment under the point 7(2)	Addressed Authorisation should be limited to indoor uses with a closed drenching system where no liquid releases are

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					produced and end-residual solid product is managed by an authorised waste management company. See also comments 7(2) and 8(1)

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(3)		DE: Not relevant as applied after harvest.		Noted.	Noted.
8(4)		EFSA: See 8(1)			Noted.

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(5)		DE: Not relevant as applied after harvest.		Noted.	Noted.
8(6)		EFSA: See 8(1)			Noted.

8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(7)		DE: Not relevant as applied after harvest.		Noted.	Noted.
8(8)		EFSA: See 8(1)		Noted.	Noted.

8.6. Effects on other non-target organisms (flora and fauna)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(9)		EFSA: See 8(1)			Noted.

8.7. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(10)		NL: Following our comment on 7.2 some elaboration is wanted		Noted.	Addressed. Authorisation should be limited to indoor uses with a closed drenching system where no liquid releases are produced and end-residual solid product is managed by an authorised waste management company.

8.7. Effects on biological methods of sewage treatment					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
					See also comments 7(2) and 8(1)

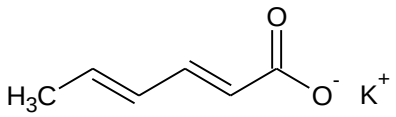
9. Overall conclusions with respect of eligibility of the substance to be approved as basic substance

Overall conclusions with respect of eligibility of the substance to be approved as basic substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
9(1)	p.27 point 9(a).	UK: See comment 4(1) above. As potassium sorbate meets the criteria to be classified as hazardous it is a substance of concern and, therefore, fails to meet the basic substances approval criterion 1(a) of Article 23.	Potassium sorbate should not be approved as a basic substance.	As stated under point 4.1 based on the intended application method, we do not consider potassium sorbate as a substance of concern. Another precedent as basic substance is for example, vinegar which is classified as more toxic than potassium sorbate and it was considered to meet this basic substance approval criterion. In addition potassium sorbate is approve as food additive and it may be present in many food commodities so the consumer exposure to the product residues should be higher as a food additive rather than as basic substances. Therefore, the applicant request EFSA to reconsider this argument and accept the application as valid.	See comment 4(1). The issue whether potassium sorbate fulfils the criteria laid down in Article 23 (1a) is considered a risk management issue.

10. Other comments

Other comments					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
10(1)		UK - No comments.			Noted.

Appendix B – Identity and biological properties

Common name (ISO)	Potassium sorbate
Chemical name (IUPAC)	potassium (2*E*,4*E*)-2,4-hexadienoate
Chemical name (CA)	potassium (2E,4E)-2,4-hexadienoate
Common names	sorbic acid, potassium salt; BB powder; 2,4-hexadienoic acid, potassium salt; Potassium salt of *trans*, *trans*-2,4-hexadienoic acid
CAS No	24634-61-5
CIPAC No and EEC No	246-376-1 (Einecs)
FAO specification	none
Minimum purity	99%
Relevant impurities	Aldehydes: max 0.1% (as formaldehyde) As: max. 3 mg/kg Pb: max 2 mg/kg Hg: max 1 mg/kg
Molar mass and structural formula	150.22 g/mol 
Mode of Use	drenching
Preparation to be used	500g/L soluble concentrate (SL)
Function of plant protection	fungicide

Appendix C – List of uses

Crop and/ or situation (a)	Member State or Country	Example product name as available on the market	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate			PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	kg a.s./hl min max	Water l/tonne min max	Total rate each application (l) kg a.s./tonne		
Citrus fruit (oranges, lemon)	EU	Potassium sorbate (50% w/v)	I	*Penicillium digitatum, P. itallicum* and *Geotrichum citri-aurantii*	SL	500 g/L	Dipping/ drenching	Post-harvest	1	n.a	1 - 2			n.a	The product can be used only for post-harvest application
Stone fruit (peaches, nectarines, plums, apricots)	EU	Potassium sorbate (50% w/v)	I	*Monilinia spp Rhizopus spp*	SL	500 g/L	Dipping/ drenching	Post-harvest	1	n.a	2 - 4			n.a	The product can be used only for post-harvest applicatio
Pome fruit (apple, pears)	EU	Potassium sorbate (50% w/v)	I	*Penicillium digitatum, P. itallicum*	SL	500 g/L	Dipping/ drenching	Post-harvest	1	n.a	1 -2			n.a	The product can be used only for post-harvest application

(a): For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b): Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c): e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor

(d): e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..
(e): GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f): All abbreviations used must be explained
(g): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i): g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)
(j): Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k): Indicate the minimum and maximum number of application possible under practical conditions of use
(l): The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m): PHI - minimum pre-harvest interval