CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance sodium hydrogen carbonate

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Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Austria for the pesticide active substance sodium hydrogen carbonate are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative use of sodium hydrogen carbonate as a fungicide on grapes. The reliable endpoints, appropriate for use in regulatory risk assessment are presented.

Keywords: sodium hydrogen carbonate, peer review, risk assessment, pesticide, fungicide

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Summary

Sodium hydrogen carbonate is a new active substance for which, in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (hereinafter referred to as 'the Regulation'), the rapporteur Member State (RMS), Austria, received an application from BIOFA AG on 18 March 2016 for approval. In accordance with Article 8(1)(g) of the Regulation, BIOFA AG submitted an application for inclusion of sodium hydrogen carbonate in Annex IV of Regulation (EC) No 396/2005. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 26 April 2016.

The RMS provided its initial evaluation of the dossier on sodium hydrogen carbonate in the draft assessment report (DAR), which was received by the European Food Safety Authority (EFSA) on 7 September 2017. The DAR included a proposal to include the active substance in Annex IV of Regulation (EC) No 396/2005. The peer review was initiated on 22 November 2017 by dispatching the DAR for consultation to the Member States and the applicant, BIOFA AG.

Following consideration of the comments received on the DAR, it was concluded that additional information should be requested from the applicant, and that there was no need to conduct an expert consultation.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether sodium hydrogen carbonate can be expected to meet the approval criteria provided for in Article 4 of the Regulation taking into consideration recital (10) of the Regulation and give a reasoned opinion concerning the MRL application, as referred to in Article 10(1) of Regulation (EC) No 396/2005. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005, provided the active substance will be approved under Regulation (EC) No 1107/2009 without restrictions affecting the residue assessment.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative use of sodium hydrogen carbonate as a fungicide on grapes, as proposed by the applicant. Full details of the representative use can be found in Appendix A of this report.

Very limited efficacy trials were submitted; bridging information was used from potassium hydrogen carbonate.

There were no data gaps identified in the area of identity, physical and chemical properties and analytical methods.

In the area of mammalian toxicology, no data gaps or areas of concerns were identified.

In the area of residues, no data gaps or areas of concerns were identified. Sodium hydrogen carbonate is proposed a candidate for inclusion into Annex IV of Regulation (EC) No 396/2005.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at the European Union (EU) level for the representative uses assessed.

In the area of ecotoxicology, data gaps or areas of concerns were not identified.

Table of contents

Background

Regulation (EC) No 1107/2009 of the European Parliament and of the Council[1] (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure and conditions for approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant(s) for comments on the initial evaluation in the draft assessment report (DAR), provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 12 of the Regulation, EFSA is required to adopt a conclusion on whether an active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation (also taking into consideration recital (10) of the Regulation) within 120 days from the end of the period provided for the submission of written comments, subject to an extension of 30 days where an expert consultation is necessary, and a further extension of up to 150 days where additional information is required to be submitted by the applicant(s) in accordance with Article 12(3).

Sodium hydrogen carbonate is a new active substance for which, in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (hereinafter referred to as 'the Regulation'), the RMS Austria (hereinafter referred to as the 'RMS'), received an application from BIOFA AG on 18 March 2016 for approval of the active substance sodium hydrogen carbonate. In accordance with Article 8(1)(g) of the Regulation, BIOFA AG submitted an application for inclusion of sodium hydrogen carbonate in Annex IV of Regulation (EC) No 396/2005[2]. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 26 April 2016.

The RMS provided its initial evaluation of the dossier on sodium hydrogen carbonate in the DAR, which was received by EFSA on 7 September 2017 (Austria, 2017). The DAR included a proposal to include the active substance in Annex IV of Regulation (EC) No 396/2005. The peer review was initiated on 22 November 2017 by dispatching the DAR for consultation to the Member States and the applicant, BIOFA AG, for consultation and comments. EFSA also provided comments. In addition, EFSA conducted a public consultation on the DAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 12(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 6 March 2018. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that there was no need to conduct an expert consultation.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table were reported in the final column of the evaluation table.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether sodium hydrogen carbonate can be expected to meet the approval criteria provided for in Article 4 of the Regulation, taking into consideration recital (10) of the Regulation, and give a reasoned opinion concerning the MRL application, as referred to in Article 10(1) of Regulation (EC) No 396/2005. A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in July 2018.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative use of sodium hydrogen carbonate as a fungicide on grapes as proposed by the applicant. Furthermore,

[1] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council 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] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005, provided the active substance will be approved under Regulation (EC) No 1107/2009 without restrictions affecting the residue assessment. In the event of a non-approval of the active substance or an approval with restrictions that have an impact on the residue assessment, the Annex IV proposal from this conclusion might no longer be relevant and a new assessment under Article 12 of Regulation (EC) No 396/2005 will be required. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2018), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the comments received on the DAR;
- the reporting table (6 March 2018);
- the evaluation table (3 August 2018);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its revisions (Austria, 2018) and the peer review report, both documents are considered as background documents to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the European Union (EU) for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Sodium hydrogen carbonate (IUPAC) is considered by the International Organization for Standardization not to require a common name.

The representative formulated product for the evaluation was 'NatriSan', a water-soluble powder (SP), containing 989 g/kg sodium hydrogen carbonate.

The representative uses evaluated comprise spraying applications on grapes as a fungicide against powdery mildew in the southern and central European zones. Full details of the Good Agricultural Practice (GAP) can be found in the list of end points in Appendix A.

It should be noted that the submitted efficacy trials following the guidance document SANCO/10054/2013-rev. 3 (European Commission, 2013) were very limited, bridging information was used from potassium hydrogen carbonate.

Conclusions of the evaluation

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3029/99-rev. 4 (European Commission, 2000a), SANCO/3030/99-rev. 4 (European Commission, 2000b) and SANCO/825/00-rev. 8.1 (European Commission, 2010).

The minimum purity of sodium hydrogen carbonate is 990 g/kg. No FAO specification exists.

During the peer review, it was concluded that lead, mercury and arsenic should be considered relevant impurities in sodium hydrogen carbonate used as a plant protection product, with maximum limits of 2 mg/kg, 1 mg/kg and 3 mg/kg, respectively (see Section 2). The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of sodium hydrogen carbonate or the representative formulation. The main data regarding the identity of sodium hydrogen carbonate and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of sodium hydrogen carbonate and the relevant impurities in the technical material and in the representative formulation.

Residue definitions for monitoring purposes were not set. The need for methods of analysis for monitoring this compound in food of plant and animal origin, in the environment and in body fluids and tissues have been waived due to the nature of the compound.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000-rev. 10-final (European Commission, 2003), SANCO/10597/2003-rev. 10.1 (European Commission, 2012), Guidance on Dermal Absorption (EFSA PPR Panel, 2012) and Guidance on the Application of the CLP Criteria (ECHA, 2017).

Sodium hydrogen carbonate is registered as a food and feed additive in Europe (E500). In order to be in line with food additive limits (Commission Regulation (EU) No 231/2012[3], amended by Commission Regulation (EU) No 2016/1814[4]), maximum levels of 3 mg/kg for arsenic, 2 mg/kg for lead and 1 mg/kg for mercury (toxicologically relevant impurities) have been set for the technical specification.

The database provided for sodium hydrogen carbonate is rather old and limited, however, based on the available evidence and assessments from other uses (e.g. in food additives or for medical products (European Pharmacopoeia, 214, in: Austria, 2018) no further data are required.

From a toxicological point of view, no significant differences are expected for the different salts of hydrogen carbonate, therefore acute and repeat-dose toxicity studies with potassium hydrogen carbonate (EFSA, 2012) have been considered as applicable also to sodium hydrogen carbonate, together with publically available data. On the basis of the available information and data, sodium hydrogen carbonate is concluded as unlikely to be genotoxic and not carcinogenic. Even though sodium and potassium salts of a variety of anions (including potassium hydrogen carbonate) have been shown to be non-genotoxic promotors of bladder tumours in male rats, the mechanism was considered as not relevant to humans and with a clear threshold.

No generational studies were provided for sodium hydrogen carbonate. Published data on developmental toxicity did not provide any evidence of teratogenic effects. Sodium hydrogen carbonate was therefore concluded as not presenting a potential for reproductive toxicity, neurotoxicity or immunotoxicity.

Sodium hydrogen carbonate is not classified or proposed to be classified as carcinogenic or toxic for reproduction category 2, on this basis, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine-disrupting (ED) properties are not met. No indications of an endocrine-mediated activity were seen in the available toxicological data or in the literature review. Considering the dissociation of the compound into sodium ions and hydrogen carbonate anions, it is concluded that no metabolites of toxicological concern are formed. Even though the dermal absorption was expected to be very low, default values of 25% for the concentrate and 75% for all in-use dilutions were applied in the absence of experimental data.

No suitable data are available to set reference values. However, it should be taken into account that sodium hydrogen carbonate is a major constituent of normal human physiology, has food additive and medical uses (e.g. Ringer's solution); therefore, the setting of reference values (i.e. acceptable daily intake (ADI), acceptable operator exposure level (AOEL), acute acceptable operator exposure level (AAOEL), acute reference dose (ARfD)) for the consumer and non-dietary risk assessment is not considered necessary. A quantitative non-dietary risk assessment was done comparing the reference value based on the dietary needs of sodium (about 1.5 g sodium/day in adults,[5] calculated as equivalent to 78.6 mg sodium hydrogen carbonate/kg body weight (bw) per day) to the exposure estimates for operators, bystanders, residents and workers. The non-dietary exposure is far below dietary needs of sodium.

3. Residues

Standard studies according to EU/OECD guidance documents and EU data requirements have not been submitted to address the residue behaviour of sodium hydrogen carbonate from the proposed use. Due to the nature of the active substance such studies are not required.

Sodium hydrogen carbonate is a naturally occurring inorganic salt and is used in food preparation both at industrial scale and home cooking as, e.g. baking powder. For the proposed representative

[3] 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.

[4] Commission Regulation (EU) 2016/1814 of 13 October 2016 amending the Annex to 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 as regards specifications for steviol glycosides (E 960). OJ L 278, 14.10.2016, p. 37–41.

[5] https://www.efsa.europa.eu/sites/default/files/engage/170929_draft-opinion.pdf

use, consumers are not expected to be exposed to it as such, as the substance will undergo hydrolysis (see Section 4). Therefore, and as no health based reference values have been established a meaningful consumer risk assessment for its proposed use is not feasible.

However, the proposed use levels on both wine and table grapes of up to 72 kg/ha in the central zone are very high and a hypothetical calculation using worst-case assumption for the remaining sodium on the surface of the grapes has been provided and resulted in a hypothetical worst case residue of ca 200 mg additional sodium/kg grapes (approx. 10-fold the reported naturally occurring concentration of sodium in grapes). Using the estimated worst-case residues of additional sodium/kg grapes in a chronic dietary exposure assessment, consumption of treated grapes is estimated to result in an additional daily intake of 50 mg sodium at the maximum for adult consumers (FR all population) and of 4 mg sodium at the maximum for children (DE child). Highest acute intakes were estimated as 400 mg sodium for adults (table grapes, NL general population) and 42 mg sodium for children (table grapes, DE child).

It is acknowledged that tolerable upper intake levels for sodium have not been established (EFSA, 2005) but are under development[5]. Excess sodium intake is associated with adverse effects (e.g. cardiovascular diseases). Given that sodium is not only a natural constituent of food but also intentionally added to food and/or diet, e.g. in form of food additives and food supplements, it seems advisable to limit any additional sodium intake to the human diet and establish a system keeping track of proportions of 'natural' intake vs. Plant Protection Product (PPP) contributions to exposure to maintain justification that PPP contribution is playing a minor role in total dietary intake as suggested for such substances in the SANTE Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005.

With regard to the representative use, estimated maximum sodium residues on grapes upon treatment with sodium hydrogen carbonate result in dietary exposure below dietary needs for sodium. Sodium hydrogen carbonate is proposed a candidate for inclusion into Annex IV of Regulation (EC) No 396/2005.

4. Environmental fate and behaviour

When the preparation (a SP) containing sodium hydrogen carbonate is diluted in water in the spray tank before spraying, it dissolves, dissociating to sodium and hydrogen carbonate ions. When reaching soil, depending on the soil type and soil pH, the hydrogen carbonate ions will either remain or be transformed to carbonate. At low pH, hydrogen carbonate and free hydrogen ions will form carbon dioxide and water in equilibrium with carbonic acid. The further dissociation of carbonic acid will in turn release more hydrogen carbonate ions. In more alkaline soils, the hydrogen carbonate anion remains as an anion being associated with any free cations in the soil. At high pH values, hydrogen carbonate will dissociate to carbonate anions. In practice, there is a carbonate equilibrium (buffering) mechanism that controls the concentration of carbonic acid hydrogen carbonate or carbonate in soil, depending on the systems pH. Sodium ions are naturally present in soil typically between 5 and 100 mg/kg. They are taken up by plants and leached out of topsoil by rainfall. Sodium, hydrogen carbonate and carbonate ions as well as carbonic acid all have the potential to be mobile and reach groundwater. These ions and carbonic acid will be naturally present in groundwater aquifers independent of the use of sodium hydrogen carbonate as a fungicide. Sodium, hydrogen carbonate and carbonate ions and carbonic acid are degradation products of no concern at step 1 of the guidance document on the relevance of metabolites in groundwater (SANCO/221/2000-rev.10-final (European Commission, 2003)). As these are all inorganic compounds, they would also not come under the definition of pesticides in the Council Directive 98/83/EC[6] on the quality of water intended for human consumption. Consequently considering Commission Regulation (EU) No 2018/676[7] a comparison against the parametric drinking water limit of 0.1 μg/L for pesticides and their relevant metabolites as prescribed in Council Directive 98/83/EC is not needed for decision making.

When reaching surface water via spray drift, sodium and hydrogen carbonate ions will behave as discussed above for soil, depending on the pH of the aquatic system. Sodium ions are naturally present in natural waters typically between 1.5 and 68 mg/L.

[6] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1998, p. 3.

[7] Commission Regulation (EU) 2018/676 of 3 May 2018 correcting Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and the of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 114.8, 4.5.2018, p. 2.

The applicant provided appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water. The conclusion of this consideration was that sodium, hydrogen carbonate, and carbonate ions and carbonic acid, would not be expected to undergo any substantial transformation due to oxidation at the disinfection stage of usual water treatment processes.

The predicted environmental concentrations (PEC) in soil and surface water (expressed as sodium hydrogen carbonate equivalents) covering the representative uses assessed can be found in Appendix A of this conclusion. PEC surface water were calculated considering just the spray drift route of entry to surface water (FOCUS, 2001 spray drift values) and that this was deposited in a static 30-cm deep water body, 3 m distance from the treated crop.

5. Ecotoxicology

Standard toxicity studies addressing the effects of sodium hydrogen carbonate on non-target organisms were not available. The ecotoxicity data set was largely based on literature studies. The available information covered only acute toxicity in some groups of organisms (birds and mammals, aquatic invertebrates and fish and honeybees). Studies performed with potassium hydrogen carbonate (EFSA, 2012) were also considered in the assessment since significant differences in term of toxicity are not expected between these two different salts of hydrogen carbonate. As reported in Section 4, sodium hydrogen carbonate is expected to dissociate once diluted in water in the spray tank to sodium and hydrogen carbonate. The latter are expected to naturally occur in the environment and in animals' metabolism. From the available information, it is not expected that background levels of sodium and hydrogen carbonate are exceeded in the aquatic and soil compartments as a consequence of the use of sodium hydrogen carbonate. It is further noted that sodium hydrogen carbonate is registered as a food and feed additive in Europe.

Considering all the available information and the environmental fate and behaviour of sodium hydrogen carbonate, a low risk to non-target organisms could be concluded.

Data were not available to address the potential endocrine disrupting properties of sodium hydrogen carbonate in non-target organisms. However, due to the nature of this active substance, the provision of further information was considered unnecessary (see also Section 2).

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

Table 1: Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Sodium ions	No data not required	Low risk
Hydrogen carbonate ions	No data not required	Low risk
Carbonate ions	No data not required	Low risk
Carbonic acid	No data not required	Low risk

Sodium, hydrogen carbonate, and carbonate ions and carbonic acid.

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses	Pesticidal activity	Toxicological relevance
Sodium ions	No data not required	Not applicable for inorganic pesticides[a]	Yes	Not assessed
Hydrogen carbonate ions	No data not required		Yes	
Carbonate ions	No data not required	Exposure estimate not needed as are degradation products of no concern at step 1 of the guidance document on the relevance of metabolites in groundwater (SANCO/221/2000-rev.10-final European Commission, 2003))	No	No as are degradation products of no concern at step 1 of the guidance document on the relevance of metabolites in groundwater (SANCO/221/2000-rev.10-final (European Commission, 2003))
Carbonic acid	No data not required		No	

(a): Commission Regulation (EU) 2018/676 of 3 May 2018 correcting Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and the of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 114.8, 4.5.2018, p. 2) and Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1998, p. 3.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Sodium ions	Low risk
Hydrogen carbonate ions	Low risk
Carbonate ions	Low risk
Carbonic acid	Low risk

Table 4: Air

Compound (name and/or code)	Toxicology
Sodium ions	Not toxic by inhalation
Hydrogen carbonate ions	Not toxic by inhalation

7. Data gaps

No data gaps have been identified for the representative uses evaluated.

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

No particular conditions are proposed for the representative uses evaluated.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the uniform principles in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011[8] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation.

No issues that could not be finalised have been identified for representative uses assessed.

9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29 (6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at the higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of the Regulation.

No critical areas of concern have been identified for representative uses assessed.

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

[8] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

Table 5: Overview of concerns

Representative use		Wine grapes and table grapes 8 × 5.1 kg a.s./ha	Wine grapes and table grapes 6 × 12 kg a.s./ha
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Resident/bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised		
Risk to wild non-target terrestrial vertebrates	Risk identified		
	Assessment not finalised		
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised		
Risk to aquatic organisms	Risk identified		
	Assessment not finalised		
Groundwater exposure to active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure to metabolites	Legal parametric value breached		
	Parametric value of 10 μg/L[(a)] breached		
	Assessment not finalised		

a.s.: active substance.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003).

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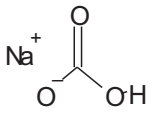
Abbreviations

a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
bw	body weight
DAR	draft assessment report
DAT	days after treatment
ECHA	European Chemicals Agency
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
InChiKey	International Chemical Identifier Keys
IUPAC	International Union of Pure and Applied Chemistry
MRL	maximum residue level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PPP	Plant Protection Product
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RMS	rapporteur Member State
SMILES	simplified molecular-input line-entry system
SP	water-soluble powder

Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2018.5407

Appendix B – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Sodium hydrogen carbonate	Sodium hydrogen carbonate [Na+].[O-]C(=O)O UIIMBOGNXHQVGW-UHFFFAOYSA-M	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Keys.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).
(c): ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).