CONCLUSION ON PESTICIDES PEER REVIEW

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

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Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, the Netherlands and co-rapporteur Member State, Greece, for the pesticide active substance potassium hydrogen carbonate and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative uses of potassium hydrogen carbonate as a fungicide on strawberry, wine and table grapes, pome fruits, stone fruits, ornamentals and cucurbits. The reliable end points, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are not identified.

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

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Summary

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 as amended by Commission Implementing Regulation (EU) No 2016/183. Potassium hydrogen carbonate is one of the active substances listed in that Regulation.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), the Netherlands, and co-rapporteur Member State (co-RMS), Greece, received applications from Agronaturalis Limited and Biofa GmbH for the renewal of approval of the active substance potassium hydrogen carbonate.

An initial evaluation of the dossier on potassium hydrogen carbonate was provided by the RMS in the renewal assessment report (RAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The following conclusions are derived.

The uses of potassium hydrogen carbonate according to the representative uses by spray applications in field, permanent greenhouses and walk-in tunnels as a fungicide on pome fruit, stone fruit, grapes, strawberry, cucurbits and ornamentals as proposed at European Union (EU) level result in a sufficient fungicidal efficacy against the target organisms.

In the area of identity, physical–chemical properties and analytical methods, there were not any critical areas of concern.

In the area of mammalian toxicology, the assessment of the data package revealed no issues that could not be finalised for the representative uses as a fungicide, or that need to be included as critical areas of concerns.

No health-based guidance values (HBGV) were set and a consumer risk assessment is not necessary neither for the representative uses nor for the uses submitted in the context of the procedure under Article 12 of Regulation (EC) No 396/2005. Inclusion of the substance in Annex IV is supported.

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

In the area of ecotoxicology, low risk to birds and mammals, aquatic organisms, non-target arthropods, earthworms and soil microorganisms, non-target terrestrial plants and sewage treatment organisms is concluded for all the representative uses. Critical areas of concern or issues that could not be finalised were not identified.

According to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, it can be concluded that potassium hydrogen carbonate is not an endocrine disruptor.

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Background

Commission Implementing Regulation (EU) No 844/2012[1], as amended by Commission Implementing Regulation (EU) No 2018/1659[2], (hereinafter referred to as 'the Regulation'), lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009[3]. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3). Furthermore, in accordance with Article 13(3a), where the information available in the dossier is not sufficient to conclude the assessment on whether the approval criteria for endocrine disruption are met, additional information can be requested to be submitted in a period of minimum 3 months, not exceeding 30 months, depending on the type of information requested.

In accordance with Article 1 of the Regulation, the RMS, the Netherlands, and co-RMS, Greece, received applications from Agronaturalis Limited and Biofa GmbH for the renewal of approval of the active substance potassium hydrogen carbonate. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicants, the co-RMS (Greece), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on potassium hydrogen carbonate in the RAR, which was received by EFSA on 19 December 2019 (The Netherlands, 2019). The RAR included a proposal to include the substance into Annex IV 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.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicants, Agronaturalis Limited and Biofa GmbH, for consultation and comments on 27 February 2020. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 30 April 2020. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of reporting table. In addition, the applicants were invited to respond to the comments received. The comments and the applicants' 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 applicants in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 18 June 2020. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicants, and that EFSA should conduct an expert consultation in the areas of endocrine disruption properties.

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, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

[1] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

[2] Commission Implementing Regulation (EU) No 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605.

[3] 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.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment and on the Article 12 MRL review of Regulation (EC) No 396/2005 took place with Member States via a written procedure in March 2021.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of potassium hydrogen carbonate as a fungicide on strawberry (field and greenhouse uses), wine and table grapes (field uses), pome fruits, stone fruits (field uses), ornamentals (field use) and cucurbits (field use), as proposed by the applicants. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review, if any, are presented in the conclusion. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005. On 2 March 2020, EFSA invited the Member States to submit their Good Agricultural Practices (GAPs) that are authorised nationally, in the format of specific GAP forms. All the GAPs were collected by EFSA and they are made publicly available as a background document to this conclusion, in the format of a specific GAP overview file.

A list of the relevant end points for the active substance and the formulations is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for potassium hydrogen carbonate according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2021), 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 RAR;
- the reporting table (19 June 2020);
- the evaluation table (31 March 2021);
- the report(s) of the scientific consultation with Member State experts;
- the comments received on the assessment of the additional information;
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (The Netherlands, 2021), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion and its background documents would not be accepted to support any registration outside the 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

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

The representative formulated products for the evaluation were 'ANL-F001' and 'VitiSan', both water soluble powders (SP), containing 850 g/kg and 990 g/kg potassium hydrogen carbonate, respectively.

The representative uses evaluated for 'ANL-F001' comprise spray applications as a fungicide on apples against *Venturia inaequalis* and spray applications on field and protected strawberry (permanent structures and walk-in tunnels) against *Podosphaera aphanis* in the EU. The representative uses evaluated for 'VitiSan' comprise field spray applications as a fungicide on grapes against powdery mildew and grey mould in the CEU and SEU zones; against scab in pome fruits in the CEU and SEU zones; against blossom blight and brown rot in stone fruits in the EU; against powdery mildew in ornamentals in CEU and against powdery mildew in open field and walk-in tunnels strawberry and cucurbits in the EU. Full details of the GAP can be found in the list of end points in Appendix B.

Data were submitted to conclude that the representative uses of potassium hydrogen carbonate proposed at EU level result in a sufficient fungicidal effect following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014).

A data gap has been identified for a transparent description of the criteria for study relevance of the scientific peer-reviewed open literature search in the environmental fate and behaviour and ecotoxicology sections in accordance with the EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

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 European Commission (2000a,b, 2010).

The minimum purity of potassium hydrogen carbonate is 990 g/kg. No FAO specification exists. It was proposed to update the reference specification based on all batch data of the renewal, taking also into consideration the analytical methods used for the determination of the active substance. A data gap was identified for the content of one significant impurity in the batches of applicant Biofa.

During the peer review, it was concluded that lead and arsenic should be considered relevant impurities in potassium hydrogen carbonate used as a plant protection product, with maximum limits of 2 mg/kg and 0.75 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 potassium hydrogen carbonate or the representative formulations. The main data regarding the identity of potassium hydrogen carbonate and its physical and chemical properties are given in Appendix B.

Adequate analytical methods are available for the determination of potassium hydrogen carbonate and the relevant impurities in the technical material and in the representative formulations; however, specification of 0.75 mg/kg arsenic in the active substance leads to a data gap of acceptably validated analytical methods for arsenic in the technical material as well as in the formulations.

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 (European Commission, 2012; EFSA NDA Panel, 2016; EFSA, 2017; ECHA, 2017).

Potassium hydrogen carbonate is approved as a food additive in the EU (E501) and is also registered as an ingredient in pharmaceutical preparations. The impurities arsenic and lead are considered to be relevant impurities. In order to be in line with food additive limits (Commission Regulation (EU) No 231/2012[4], amended by Commission Regulation (EU) No 2016/1814[5]) and the EFSA CONTAM Panel Scientific Opinions (EFSA CONTAM Panel, 2009, 2010), the maximum levels of 0.75 mg/kg for arsenic and 2 mg/kg for lead have been set for the technical specification (see Section 1). The analytical methods used in the toxicological studies were considered fit-for-purpose.

Potassium hydrogen carbonate is rapidly **absorbed** (> 90%) in humans, as reported in the EFSA Scientific Opinion on the dietary reference values for potassium (EFSA NDA Panel, 2016). The compound is widely distributed in the body and mainly excreted via urine. No comparative *in vitro* metabolism study was provided based on the physico-chemical properties of the substance and the natural occurrence of the potassium hydrogen carbonate in the body.

Potassium hydrogen carbonate is considered of **low acute toxicity** by the oral, dermal and inhalation routes based on GLP and non-GLP compliant acute toxicity studies, and studies reported in the REACH Registration dossier. It is not a skin irritant, eye irritant or a skin sensitiser.

From **short-term toxicity** studies by oral route, exposure to potassium hydrogen carbonate exceeding normal dietary intake of potassium (3.5 g/adult per day) seems associated with changes in

[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.

[5] 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.

clinical chemistry parameters, hypertrophy of the adrenal zona glomerulosa and urinary bladder hyperplasia. These effects were observed in three published studies, a 4-week, 13-week and 26-week rat studies. No short-term toxicity studies by other routes were provided based on the high background exposure and the physiological importance of the active substance.

For **genotoxicity,** the *in vitro* studies provided is rather of low reliability; however, based on the available evidence, it was concluded that potassium hydrogen carbonate is unlikely to be genotoxic and no further data are required. **Long-term toxicity** effects were observed in an 18-month and 30-month study from the literature and included body weight decrease, change in clinical chemistry parameters, hypertrophy of adrenal zona glomerulosa, simple urothelial hyperplasia of urinary bladder and papillary/modular hyperplasia, with doses exceeding normal dietary intake of potassium. The **carcinogenicity** effects reported in the same two above studies, i.e. hyperplasia, papilloma and carcinoma of urinary bladder in rats, were not considered relevant to humans.

No **reproductive, developmental toxicity and neurotoxicity** studies were provided based on the high background exposure levels of potassium in nature, the wide use of the compound as a drug and food additive and the physiological importance of potassium as essential component for humans.

Based on the low acute toxic potential of the active substance and the physiological importance and the medical usage of the active substance, derivation of an acceptable daily intake (**ADI**), acute reference dose (**ARfD**) and an acute acceptable operator exposure level (**AAOEL**) were not considered necessary for potassium hydrogen carbonate. Based on the recommended daily intake for potassium for the adult (3.5 g/adult per day) (EFSA NDA Panel, 2016), the acceptable operator exposure level (**AOEL**) is 149 mg/kg body weight per day, without additional uncertainty factors.

The **dermal absorption** values used for the representative formulations 'VitiSan' and 'ANL-F001' are the default values of 10% (concentrate) and 50% (spray dilution) (EFSA, 2017). **Non-dietary exposure** estimates were calculated by using the EFSA AOEM model (BfR, 2015) for the outdoor uses (professional field uses) and the Dutch Greenhouse model for the indoor use (professional greenhouse use). Operators, workers, bystanders and residents are not exposed to levels exceeding the AOEL, without personal protection equipment (PPE) for both representative formulations, 'VitiSan' and 'ANL-F001'.

3. Residues

Standard studies according to EU/OECD guidance documents and EU data requirements have not been submitted to address the residue behaviour of potassium hydrogen carbonate from the proposed uses on pome and stone fruit, cucurbits, wine and table grapes and strawberries. Due to the nature of the active substance, such studies are not required. Potassium hydrogen carbonate is a naturally occurring inorganic salt. It is an approved food additive and used in food preparation both at industrial scale and home cooking. For the proposed representative uses, consumers are not expected to be exposed to it as such, as the substance will dissociate in water (see Section 4). Therefore, and as no health-based guidance values have been established, a consumer risk assessment for the representative uses is not necessary.

As regards the submitted European authorised uses in different crop groups which were collected for the assessment required from EFSA under Article 12 of Regulation (EV) no 396/2005, some of these uses are not covered by the representative uses. However, the criteria for the final inclusion of this active substance in the Annex IV of Regulation (EC) No 396/2005 are met (no identified hazardous properties) and MRLs are not required for the authorised uses.

4. Environmental fate and behaviour

Specific studies investigating the environmental fate and behaviour of potassium hydrogen carbonate were not available in the dossier. The available environmental exposure assessment for the representative uses assessed was based on published scientific literature.

Potassium hydrogen carbonate is a naturally occurring inorganic compound that dissociates to potassium ions (K^+) and hydrogen carbonate ions (HCO_3^-) in water. Therefore, the environmental behaviour of the active substance is dependent on the fate of the dissociation products.

For the use of potassium hydrogen carbonate in 'ANL-F001' and 'VitiSan' as plant protection products, the environmental exposure assessment was based on a comparison between the maximum amounts of potassium hydrogen carbonate added to the environmental compartments following the use patterns proposed and the naturally occurring background levels of K^+ and HCO_3^- in soil and

water. The available initial PEC (Predicted Environmental Concentrations) in soil for potassium ions (5.5–15 mg/kg) are within the range (< 50–> 400 mg/kg) of the reported exchangeable potassium contents in EU cropped land reported in the LUCAS Topsoil Survey (Tóth et al., 2013). For hydrogen carbonate ions (initial PECsoil 8.7–23.4 mg/kg), it was considered unnecessary to have a comparison with the natural background levels of bicarbonate in soil, as its concentration is very variable (depending on the moisture and pH of the soil) and that which is present, is in an equilibrium with atmospheric CO_2 and the CO_2 produced by plant roots.

The necessary surface water and sediment exposure assessments (PEC_{sw} and PEC_{sed} calculations) were carried out for potassium ions and hydrogen carbonate ions using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator) and taking into consideration spray drift and run-off/drainage as entry routes into surface water. Due to the lack of experimental data on the transformation rates of the dissociation products of potassium hydrogen carbonate in aerobic natural sediment water systems, worst-case default DT_{50} in sediment and water of 1000 days were used. The resulting theoretical worst-case PEC in surface water for potassium ions (0.45–3.18 mg/L) and hydrogen carbonate ions (0.70–4.97 mg/L) are within the range of concentrations of potassium and carbonate in surface water reported in the Geochemical Atlas of Europe (0.05–182 mg/L and non-detectable – 1,804.4 mg/L, respectively). The predicted environmental concentration in sediment was calculated to be 0 μg/kg for all scenarios.

Based on the definition of what is a pesticide in Council Directive 98/83/EC[6] on the quality of drinking water intended for human consumption, potassium hydrogen carbonate and its dissociation products, as inorganic compounds are not considered as pesticides and therefore the parametric drinking water limit of 0.1 μg/L for pesticides, usually used as a decision-making criterion regarding groundwater exposure is not applicable. Parametric drinking water quality standards have not been set in this directive for potassium ions and hydrogen carbonate ions.

The PEC soil, surface water and sediment calculations covering the representative uses assessed have been presented in more detail in Appendix B of this conclusion.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a,b), SETAC (2001), EFSA (2009, 2013) and EFSA PPR Panel (2013).

Standard toxicity studies addressing the effects of potassium hydrogen carbonate were available for some groups of non-target organisms. As reported in Section 4, potassium hydrogen carbonate is expected to dissociate once diluted in water in the spray tank to potassium ions (K^+) and hydrogen carbonate ions (HCO_3^-). The latter are expected to naturally occur in the environment and in animals' metabolism. From the available information, it is not expected that naturally occurring background levels of potassium and hydrogen carbonate ions are exceeded in the aquatic and soil compartments as a consequence of the use of potassium hydrogen carbonate. Besides, as noted in Section 3, potassium hydrogen carbonate is a naturally occurring inorganic salt and is used in food preparation both at industrial scale and home cooking.

For **birds**, standard toxicity studies on the effects of potassium hydrogen carbonate were not available and the ecotoxicity data set was largely based on literature data. Studies performed with sodium hydrogen carbonate (EFSA, 2012, 2018) were considered in the assessment since significant differences in terms of toxicity are not expected between these two different salts of hydrogen carbonate. These are long-term feeding studies, where chickens were fed with high concentration of sodium hydrogen carbonate in the diet, and no adverse effects were observed. The available risk assessments for wild birds are based on the endpoints derived from one of the studies conducted with sodium hydrogen carbonate and contain extrapolation. A low risk to birds from the use of potassium hydrogen carbonate as a plant protection product based on the representative uses was concluded (at screening and Tier 1).

Valid acute toxicity endpoints were available with **mammals** and potassium hydrogen carbonate, and the representative formulation 'ANL-F001' (EFSA, 2012). Developmental toxicity studies for mammals were also available with sodium hydrogen carbonate (EFSA, 2018), and as for birds, the endpoint derived from one of these studies (rabbit) was used in the long-term risk assessment to mammals. It is also noted that the ecotoxicity data set for mammals was largely based on literature

[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. 32–54.

data, which was used in a weight of evidence approach. Quantitative risk assessments were available for the representative uses, which indicated high acute and long-term risk to mammals at first tiers (screening and Tier 1). No higher tier data and assessments (e.g. refinements of the standard exposure scenarios) were available. A weight of evidence approach was made available considering the nature of the active substance, the available toxicity data on vertebrates, and that the dissociation products of potassium hydrogen carbonate are widespread elements of the environment; therefore, wildlife will often be exposed to them. It is also noted that naturally occurring background levels of potassium and hydrogen carbonate ions are not expected to be exceeded in the environment as a consequence of the representative uses. On this basis, the acute and long-term risk to non-target vertebrates, such as wild mammals, arising from the uses of potassium hydrogen carbonate was concluded to be low.

Acute toxicity data were available with **aquatic organisms** (fish, *Daphnia magna* and algae) and potassium hydrogen carbonate. There were also acute toxicity studies with aquatic invertebrates (*D. magna*) and algae and the representative formulation 'ANL-F001'. Acute risk assessments were available considering a worst-case approach via spray drift exposure of the aquatic environment, and resulted in a low acute risk at Tier 1 from the use of potassium hydrogen carbonate as a plant protection product based on the representative uses. Standard chronic toxicity data with aquatic organisms and potassium hydrogen carbonate were not available. There were chronic toxicity data for *D. magna* and fish with sodium bicarbonate not resulting in reliable endpoints but not indicating high toxicity. Considering this, and the environmental fate and behaviour of potassium hydrogen carbonate in the aquatic compartment (see Section 4), as well as that its representative uses are not expected to result in concentrations exceeding the naturally occurring background levels of potassium and hydrogen carbonate ions in the natural aquatic systems, further chronic toxicity data and risk assessments for aquatic organisms were not needed. Toxicity data with 'ANL-F001' were available (though not triggered) for **sediment-dwelling organisms** (*Chironomus riparius*), and a low risk was concluded at Tier 1.

Acute oral and contact studies with honey**bees** and the two representative formulations 'ANL–F001' and 'VitiSan' were available. In addition, appropriate chronic data were submitted for adult honeybees and larvae with potassium hydrogen carbonate. A risk assessment performed in line with the EFSA bee guidance document (EFSA, 2013) showed a low acute risk to honey bees from contact exposure for all uses evaluated (the same conclusion would be reached by applying the guidance document on terrestrial ecotoxicology (European Commission, 2002a). A low acute risk from oral exposure was also concluded for all the representative uses of 'ANL–F001' (screening step) and 'VitiSan' (tier 1 step), with the exception of the uses of 'VitiSan' on stone fruits and grapes (BBCH 10–69) in the treated crop for which a high risk could not be excluded. However, given that the exposure:toxicity ratio values for such uses were only slightly above the trigger and the endpoints were greater than values, and that the concentration of potassium and hydrogen carbonate ions following application of the representative formulations is not expected to exceed the naturally occurring background levels in pollen and nectar, the acute risk to honeybees for exposure to residues in that scenario could also be considered as low.

A low chronic risk to honeybee larvae was concluded in the screening step for all uses of 'ANL–F001'. For this formulation, the chronic risk assessment to honeybee adults resulted in a low risk except for the exposure to residues from pollen and nectar in the treated crop (BBCH 10–69) and from flowering weeds (BBCH 10 in crop) for the uses in apple orchards. However, it is not expected that the background levels of potassium and hydrogen carbonate ions are exceeded in pollen and nectar as a consequence of the representative uses of potassium hydrogen carbonate. Thus, a low chronic risk to honeybee adults and larvae was considered for the uses of 'ANL–F001' in apple orchards. The same conclusion was applied for all intended uses of 'VitiSan' for which chronic risk assessments for adults and larvae were not available. The risk from exposure to contaminated surface and puddle water was assessed as low. No assessment was available for consumption via guttation fluid; however, the risk from this scenario was considered as low. An assessment of accumulative effects was not available. No data were available to address the risk to honeybees from sublethal effects, e.g. hypopharyngeal glands (data gap, see Section 10). Toxicity data and risk assessment were not provided for bumblebees or solitary bees.

Tier 1 toxicity tests on two **non-target arthropods**, namely the parasitic wasp *Aphidius rhopalosiphi* and the predatory mite *Typhlodromus pyri*, were available with potassium hydrogen carbonate. In addition, reliable extended laboratory studies on these two indicator species were submitted with one of the representative formulations ('ANL–F001'). The first tier risk assessment resulted in a low in– and off–field risk for all the representative uses of 'VitiSan'. A refined risk

assessment was performed for the uses of 'ANL–F001' that took into account the behaviour of potassium hydrogen carbonate and the effects observed in the extended studies. Based on such refined assessment, a low risk was also concluded for all intended uses of 'ANL–F001'.

Standard toxicity studies addressing the effects of potassium hydrogen carbonate on **earthworms**, **other soil macro-organisms** and **soil microorganisms** were not available. However, considering the environmental fate and behaviour of potassium hydrogen carbonate in the soil compartment (see Section 4), a low risk to those non-target organisms could be concluded for all the representative uses. A low risk was also identified to **non-target terrestrial plants** and **organisms involved in sewage treatment processes** for the representative uses of potassium hydrogen carbonate.

6. Endocrine disruption properties

The endocrine disruptive (ED) properties of potassium hydrogen carbonate were discussed at the Pesticides Peer Review Teleconference 40 on joint ED in January 2021.

With regard to the assessment of the endocrine-disrupting properties of potassium hydrogen carbonate for **humans** and **non-target organisms**, no (eco)toxicological data to perform a full assessment in line with the ECHA/EFSA ED guidance (2018) were available. However, such assessment was not considered scientifically justified for the following main aspects:

- It is ubiquitous in the environment and is a major component of the normal physiology of humans as well as other vertebrates;
- Potassium is the predominant intracellular cation, an essential nutrient involved in fluid, acid and electrolyte balance and is required for normal cellular function;
- Bicarbonate is the predominant buffer system in the blood and tissues;
- It is used as food additive.

According to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, it can be concluded that potassium hydrogen carbonate is not an endocrine disruptor.

7. 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)	Ecotoxicology
Potassium ions	Low risk to soil organisms
Hydrogen carbonate ions	Low risk to soil organisms

Table 2: Groundwater[(a)]

Compound (name and/or code)	> 0.1 µg/L at 1 m depth for the representative uses[(b)] Step 2	Biological (pesticidal) activity/ relevance Step 3a	Hazard identified Steps 3b and 3c	Consumer RA triggered Steps 4 and 5	Human health relevance
Potassium ions	Not applicable for inorganic compounds[(c)]. Other European parametric drinking water quality standard not set	Not applicable for inorganic compounds[(c)]	–	–	Not triggered
Hydrogen carbonate ions	Not applicable for inorganic compounds[(c)]. Other European parametric drinking water quality standard not set	Not applicable for inorganic compounds[(c)]	–	–	Not triggered

(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).
(b): FOCUS scenarios or relevant lysimeter.
(c): Inorganic fungicides are not defined as pesticides in Council Directive 98/83/EC[6].

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Potassium ions	Low risk to aquatic organisms
Hydrogen carbonate ions	Low risk to aquatic organisms

Table 4: Air

Compound (name and/or code)	Toxicology
Potassium hydrogen carbonate	Rat LC_{50} inhalation > 4.88 mg/L air/4 h (nose-only) (no classification required)

8. Particular conditions proposed to be taken into account by risk managers

Risk mitigation measures (RMMs) identified following consideration of Member State (MS) and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level.

No particular conditions are proposed for the representative uses evaluated.

9. Concerns and related data gaps

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 one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[7] 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 Regulation (EC) No 1107/2009.

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

Issues that could not be finalised were not identified.

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 Regulation (EC) No 1107/2009 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.

[7] 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.

An issue is also listed as a critical area of concern if the assessment at a 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 Regulation (EC) No 1107/2009.

The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:

Critical areas of concerns were not identified.

9.3. Overview of the concerns identified for each representative use considered (Table 5)

(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.)

Table 5: Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios

		Apple	Strawberry	Strawberry	Strawberry	Wine grapes and table grapes	Wine grapes and table grapes	Wine grapes and table grapes	Wine grapes and table grapes	Pome fruits	Pome fruits	Stone fruits	Stone fruits	Ornamentals	Cucurbits
Representative use		**Open field**	**Field use and greenhouse not strictly closed (e.g. plastic tunnel)**	**Greenhouse strictly closed (permanent structure)**	**Use for open field and walk-in tunnels**	**F BBCH 12–85**	**F BBCH 68–89**	**F BBCH 12–85**	**F BBCH 68–89**	**F Central Zone**	**F Southern Zone**	**F BBCH 60–69**	**F BBCH 84–87**	**F**	**Use for open field and walk-in tunnels**
		4.25 kg/ha	**2.55 kg/ha**	**2.55 kg/ha**	**5.0 kg/ha**	**12 kg/ha**	**12 kg/ha**	**6 kg/ha**	**6 kg/ha**	**7.5 kg/ha**	**7.5 kg/ha**	**7.5 kg/ha**	**15.0 kg/ha**	**3.0 kg/ha**	**5.0 kg/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														

		Apple	Strawberry	Strawberry	Strawberry	Wine grapes and table grapes	Wine grapes and table grapes	Wine grapes and table grapes	Wine grapes and table grapes	Pome fruits	Pome fruits	Stone fruits	Stone fruits	Ornamentals	Cucurbits
Representative use		**Open field**	**Field use and greenhouse not strictly closed (e.g. plastic tunnel)**	**Greenhouse strictly closed (permanent structure)**	**Use for open field and walk-in tunnels**	**F BBCH 12–85**	**F BBCH 68–89**	**F BBCH 12–85**	**F BBCH 68–89**	**F Central Zone**	**F Southern Zone**	**F BBCH 60–69**	**F BBCH 84–87**	**F**	**Use for open field and walk-in tunnels**
		4.25 kg/ha	**2.55 kg/ha**	**2.55 kg/ha**	**5.0 kg/ha**	**12 kg/ha**	**12 kg/ha**	**6 kg/ha**	**6 kg/ha**	**7.5 kg/ha**	**7.5 kg/ha**	**7.5 kg/ha**	**15.0 kg/ha**	**3.0 kg/ha**	**5.0 kg/ha**
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														

		Apple	Strawberry	Strawberry	Strawberry	Wine grapes and table grapes	Wine grapes and table grapes	Wine grapes and table grapes	Wine grapes and table grapes	Pome fruits	Pome fruits	Stone fruits	Stone fruits	Ornamentals	Cucurbits
Representative use		**Open field**	**Field use and greenhouse not strictly closed (e.g. plastic tunnel)**	**Greenhouse strictly closed (permanent structure)**	**Use for open field and walk-in tunnels**	**F BBCH 12–85**	**F BBCH 68–89**	**F BBCH 12–85**	**F BBCH 68–89**	**F Central Zone**	**F Southern Zone**	**F BBCH 60–69**	**F BBCH 84–87**	**F**	**Use for open field and walk-in tunnels**
		4.25 kg/ha	**2.55 kg/ha**	**2.55 kg/ha**	**5.0 kg/ha**	**12 kg/ha**	**12 kg/ha**	**6 kg/ha**	**6 kg/ha**	**7.5 kg/ha**	**7.5 kg/ha**	**7.5 kg/ha**	**15.0 kg/ha**	**3.0 kg/ha**	**5.0 kg/ha**
Groundwater exposure to metabolites	Legal parametric value breached[(a)]														
	Parametric value of 10 µg/L[(b)] breached														
	Assessment not finalised														

(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.
(b): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003).

10. List of other outstanding issues

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

These data gaps refer only to the representative uses assessed and are listed in the order of the sections:

- A transparent description of the criteria for study relevance of the scientific peer-reviewed open literature search in the environmental fate and behaviour and ecotoxicology sections was not available (relevant for all representative uses, see open points 4.6 and 5.23 of the Evaluation Tables; EFSA, 2021).
- The content of one significant impurity in the five batches of applicant Biofa (relevant for all representative field uses of 'VitiSan', see Section 1).
- Validated analytical method(s) for the determination of arsenic in the technical material as well as the PPPs at the level required by the set limit (relevant for all representative uses, see Sections 1 and 2).
- Information to address the risk to bees from sublethal effects (relevant for all representative field uses, see Section 5).

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Abbreviations

λ	Wavelength
ADI	acceptable daily intake
AAOEL	acute acceptable operator exposure level
ARfD	acute reference dose
AUC	area under the blood concentration/time curve
CAS	Chemical Abstracts Service
CI	confidence interval
DM	dry matter
DT_{50}	period required for 50% dissipation (define method of estimation)

DT_{90}	period required for 90% dissipation (define method of estimation)
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemicals Agency
EEC	European Economic Community
EUROPOEM	European Predictive Operator Exposure Model
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
GM	geometric mean
HBGV	Health-based guidance value
HQ	hazard quotient
HR	hazard rate
IESTI	international estimated short-term intake
IUPAC	International Union of Pure and Applied Chemistry
iv	Intravenous
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
LC_{50}	lethal concentration, median
M/L	mixing and loading
M&K	Maximisation test of Magnusson & Kligman
mm	millimetre (also used for mean measured concentrations)
MRL	maximum residue level
MS	mass spectrometry
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PIE	potential inhalation exposure
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
r^2	coefficient of determination
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
RBC	red blood cells
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue

TWA	time-weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor
UV	ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WBC	white blood cell
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – Consideration of cut-off criteria for potassium hydrogen carbonate according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

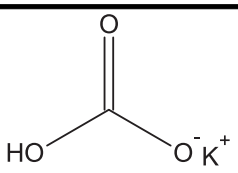
Properties		Conclusion[(a)]
CMR	Carcinogenicity (C)	Potassium hydrogen carbonate is not considered to be carcinogenic, mutagenic or toxic for reproduction.
	Mutagenicity (M)	
	Toxic for Reproduction (R)	
Endocrine-disrupting properties		Potassium hydrogen carbonate is not considered to meet the criteria for endocrine disruption for human health and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605.
POP	**Persistence**	Potassium hydrogen carbonate is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	
	Long-range transport	
PBT	**Persistence**	Potassium hydrogen carbonate is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	
	Toxicity	
VPvB	**Persistence**	Potassium hydrogen carbonate is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	

(a): Origin of data to be included where applicable (e.g. EFSA, ECHA RAC, Regulation).

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

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2021.6593

Appendix C – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
potassium hydrogen carbonate	potassium hydrogen carbonate [K+].[O-]C(=O)O	

(a): The substance name in bold is the name used in the conclusion.
(b): ACD/Name 2018.2.2 ACD/Labs 2018 Release (File version N50E41, Build 103230, 21 July 2018).
(c): ACD/ChemSketch 2018.2.2 ACD/Labs 2018 Release (File version C60H41, Build 106041, 7 December 2018).