CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance potassium hydrogen carbonate[1]

European Food Safety Authority[2]

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SUMMARY

Potassium hydrogen carbonate is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[3], as amended by Commission Regulation (EC) No 1095/2007[4].

Potassium hydrogen carbonate was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation') and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[5], in accordance with Commission Implementing Regulation (EU) No 540/2011[6], as amended by Commission Implementing Regulation (EU) No 541/2011[7]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[8], the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Ireland being the designated rapporteur Member State submitted the DAR on potassium hydrogen carbonate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 2 May 2006. The peer review was initiated on 16 May 2008 by dispatching the DAR for consultation of the Member States and the original notifier Brotherton Speciality Products Limited (the notifier subsequently changed and is now Church & Dwight UK Ltd). Following consideration of the comments received on the DAR, it was concluded that there was no need to conduct an expert consultation and EFSA should deliver its conclusions on potassium hydrogen carbonate.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of potassium hydrogen carbonate as a fungicide on apple and grapevines, as

[1] On request from the European Commission, Question No EFSA-Q-2009-00256, approved on 16 December 2011.
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[3] OJ L 379, 24.12.2004, p.13
[4] OJ L 246, 21.9.2007, p.19
[5] OJ L 309, 24.11.2009, p.1
[6] OJ L 153, 11.6.2011, p.1
[7] OJ L 153, 11.6.2011, p.187
[8] OJ L 37, 10.2.2010, p.12

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proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

Data gaps were identified for the section on physical and chemical properties of the formulation.

No critical areas of concern or data gaps were identified in the toxicology section.

Metabolism and residue studies were considered not necessary and not relevant for the evaluation, due to the nature and properties of the active substance. The setting of MRLs for potassium hydrogen carbonate associated with its use as a plant protection product is considered not necessary and a quantitative consumer risk assessment was not conducted.

Potassium hydrogen carbonate is a naturally occurring inorganic compound that dissociates to K^+ and HCO_3^- in the presence of water. A data gap has been identified for studies or peer reviewed scientific literature to support the naturally occurring levels of potassium proposed by the notifier.

Based on the limited data set available, the risk to birds and to biological methods of sewage treatment was assessed as low for the representative uses. Several data gaps were identified in relation to the assessments for non-target terrestrial vertebrates, for aquatic organisms, for honeybees, for non-target arthropods, for soil non-target organisms and for terrestrial non-target plants. Based on the available data, a high risk for honeybees was identified as a critical area of concern

KEY WORDS

Potassium hydrogen carbonate, peer review, risk assessment, pesticide, fungicide

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BACKGROUND

Potassium hydrogen carbonate is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[9], as amended by Commission Regulation (EC) No 1095/2007[10].

Potassium hydrogen carbonate was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[11], in accordance with Commission Implementing Regulation (EU) No 540/2011[12], as amended by Commission Implementing Regulation (EU) No 541/2011[13]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[14] the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Ireland being the designated rapporteur Member State submitted the DAR on potassium hydrogen carbonate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 2 May 2006 (Ireland, 2006). The peer review was initiated on 16 May 2008 by dispatching the DAR to the notifier original Brotherton Speciality Products Limited (the notifier subsequently changed and is now Church & Dwight UK Ltd), and on 24 February 2011 to the Member States, for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 20 June 2011. On the basis of the comments received and the RMS's evaluation thereof it was concluded 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, and additional information to be submitted by the notifier, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions 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 took place with Member States via a written procedure in November – December 2011.

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 uses as a

[9] OJ L 379, 24.12.2004, p.13
[10] OJ L 246, 21.9.2007, p.19
[11] OJ L 309, 24.11.2009, p.1
[12] OJ L 153, 11.6.2011, p.1
[13] OJ L 153, 11.6.2011, p.187
[14] OJ L 37, 10.2.2010, p.12

fungicide on apple and grapevines, as proposed by the notifier. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, 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 (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (21 June 2011),
- the Evaluation Table (12 December 2011),
- the comments received on the assessment of the points of clarification,
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of December 2011 containing all individually submitted addenda (Ireland, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Potassium bicarbonate is the ISO common name for potassium hydrogen carbonate (IUPAC).

The representative formulated product for the evaluation was 'Armicarb 85SP', a water soluble powder (SP), containing 850 g/kg potassium hydrogen carbonate.

The representative uses evaluated comprise spray applications to apple and grapevines as a fungicide against vine powdery mildew and apple scab. Full details of the GAP can be found in the list of end points in Appendix A.

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/3030/99 rev.4 (European Commission, 2000) and SANCO/825/00 rev. 7 (European Commission, 2004a).

The minimum purity of potassium hydrogen carbonate is 995 g/kg. No FAO specification exists.

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 10 mg/kg of lead and 3 mg/kg of arsenic (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 formulation, however, data gaps were identified for the wettability and foam persistence of the formulation. The main data regarding the identity of potassium hydrogen carbonate and its physical and chemical properties are given in Appendix A.

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

The need for methods of analysis for monitoring this compound in food of plant and animal origin and in the environment have been waived due to the nature of the compound. A method for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

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/222/2000 rev. 7 (European Commission, 2004b) and SANCO/10597/2003 – rev. 8.1 (European Commission, 2009).

Lead and arsenic are considered relevant impurities their maximum content being 10 mg/kg and 3 mg/kg respectively.

In experimental animals low acute toxicity of potassium hydrogen carbonate is observed in rats via the oral, dermal and inhalation routes. It is neither a skin nor an eye irritant nor a skin sensitizer. In rats, alkalogenic diets have been associated with adverse effects in adrenals (hyperthrophy of zona glomerulosa) and urinary bladder (hyperplasia, papiloma and carcinoma) through well-recognised mechanisms not considered relevant for humans.

No suitable data are available to set reference values. However, it should be taken into account that potassium hydrogen carbonate is a major constituent of normal human physiology. The recommended

daily intakes for potassium are in the order of 3.5 g/adult/day. Potassium hydrogen carbonate is food grade, as per Food Chemical Codex, and it is used in over-the-counter antacid preparations for humans.

A quantitative risk assessment has been performed by the RMS comparing the non-dietary exposure to potassium hydrogen carbonate arising from the use as a plant protection product with normal dietary intakes of potassium (3.5 g/adult/day, equivalent to 128 mg potassium hydrogen carbonate/kg bw/day) indicating that predicted estimates for operators, workers and bystanders will not impact on potassium balance in the human body.

3. Residues

The assessment in the residue section below is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999), and the JMPR recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports.

Metabolism and residue studies were not considered relevant for the evaluation of the active substance potassium hydrogen carbonate, which dissociates in plants in the presence of water to produce the ions K^+ and HCO_3^-, which are naturally occurring in all environmental compartments, including plant tissues. It is therefore not possible to distinguish between the residues arising from the use of potassium hydrogen carbonate as a plant protection product and its natural presence in plants.

Moreover potassium hydrogen carbonate is approved as bicarbonate as a food additive in the EU (E501) and is also registered as an ingredient in pharmaceutical preparations. The intake of potassium hydrogen carbonate through use as a plant protection product will be negligible compared with that through normal consumption of the food additive or pharmaceutical preparations.

Consequently, the setting of MRLs for potassium hydrogen carbonate associated with its use as a plant protection product is considered not necessary and a quantitative consumer risk assessment was not conducted. Potassium hydrogen carbonate could be considered a candidate for the inclusion in Annex IV of Commission Regulation (EC) No 396/2005[15].

4. Environmental fate and behaviour

No studies on the fate and behaviour of potassium bicarbonate in the environment are available in the dossier.

Potassium hydrogen carbonate is a naturally occurring inorganic compound that dissociates to K^+ and HCO_3^- in the presence of water. The notifier proposed a waiver for additional fate studies on the basis of the naturally occurring background levels of K^+ and HCO_3^- in soil and water. Whereas the levels of HCO_3^- have been documented with scientific peer reviewed literature, the levels of K^+ have been provided from an internet link that does not contain references to any scientific peer reviewed study. Therefore, a data gap has been identified for studies or peer reviewed scientific literature to support the naturally occurring levels of potassium proposed by the notifier.

Worst case initial PEC soil and PEC SW have been calculated for the representative uses taking into account the maximum application rate of 5.1 kg a.s./ha. These PECs have been used in the ecotoxicological risk assessment.

[15] OJ L 70, 16.3.2005, p. 16

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission 2002a, 2002b and 2002c.

To support the risk assessment for **birds**, toxicological endpoints only from study summaries from the open literature could be derived. In these long-term feeding studies, where chickens were fed with high concentrations of sodium hydrogen carbonate or potassium hydrogen carbonate in the diet, no adverse effects were observed. It is noted that poultry are often fed with sodium hydrogen carbonate at a typical dietary concentration of 0.2 %. The available risk assessments for wild birds are based on the endpoint derived from one of the studies conducted with sodium hydrogen carbonate and contain several assumptions and extrapolations, and therefore include some uncertainties. It was however concluded that the risk to birds from the use of potassium hydrogen carbonate as a plant protection product based on the representative uses is low. Only acute endpoints were available for the risk assessment for **mammals**. These first tier assessments indicated a high risk to wild mammals. No higher tier data and assessments (e.g. refinements of the standard exposure scenarios) were available. However the peer-review considered that the acute risk to non-target vertebrates, such as wild mammals, arising from the representative use of potassium hydrogen carbonate is low. For this conclusion a weight of evidence approach was used considering the nature of the active substance and that its dissociation products are widespread elements of the environment, therefore wildlife will often be exposed to them. Moreover the available toxicity data on vertebrates (mammals and birds) and the risk assessments on birds were also taken into consideration. No risk assessments for long-term scale were available. Since repeated and long-term exposure of wild mammals arising from the representative uses, a data gap was identified for long-term risk assessment for wild mammals.

Risk assessments for **aquatic organisms** based on the available acute data for fish and daphnia, and considering a worst case approach via spray drift exposure of the aquatic environment, resulted in a low risk. No chronic data and long-term risk assessments were available. It is noted that the background concentrations of the dissociation products of potassium hydrogen carbonate in natural aquatic systems was assumed to be relatively high compared to the predicted concentrations arising from the application of the active substance, although there is a data gap identified for data to support the high background concentrations of K^+ (see section 4). If the background levels are confirmed to be higher than the exposure from the representative uses then the long-term risk could be considered as low, however, a data gap to re-consider the risk assessment has been identified pending the availability of the necessary data in section 4. No data and no associated risk assessments were available for algae therefore a data gap was identified to address these assessments. No data were available for the representative formulation, which contains relatively toxic co-formulants and is therefore likely to pose a higher risk to aquatic organisms when compared with the active substance. A data gap was therefore identified for appropriate risk assessments for the representative formulation and aquatic organisms.

No data for acute oral toxicity to **honeybees** were available. Considering however that the dissociation products of potassium hydrogen carbonate are common elements of the environment, the peer-review agreed that no risk assessments for the oral exposure of bees are necessary. Risk assessments for the contact route of exposure (e.g. over spraying of the honeybees) resulted in a high risk. No reliable higher tier data were available therefore a data gap was set to further address the risk assessment for honeybees. This was identified as a critical area of concern. No data were available for the representative formulation therefore a data gap was set for appropriate risk assessments for the representative formulation to honeybees.

No data or risk assessments were available for non-target arthropods, earthworms, soil macro- and micro- organisms or for terrestrial non-target plants. It is noted that the background concentrations of the dissociation products of potassium hydrogen carbonate in soil was assumed to be relatively high compared to the predicted concentrations arising from the application of the active substance, although there is a data gap identified for data to support the high background concentrations of K^+ (see section

4). If the background levels are confirmed to be higher than the exposure from the representative uses then the risk could be considered as low, however, a data gap to re-consider the risk assessments has been identified pending the availability of the necessary data in section 4.

The risk to the biological methods for sewage treatments for the representative uses of potassium hydrogen carbonate was considered to be low.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Potassium hydrogen carbonate	Naturally occurring inorganic compound applied at levels assumed to be in the range of natural occurrence. Data gap identified for the natural background levels of K^+.	No data or risk assessment is available for non-target soil organisms. Data gap pending on the information on the background level of K^+.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)[(a)]	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Potassium hydrogen carbonate	Not assessed. Naturally occurring inorganic compound applied at levels assumed to be in the range of natural occurrence. Data gap identified for the natural background levels of K^+.	Not assessed. Naturally occurring inorganic compound applied at levels assumed to be in the range of natural occurrence. Data gap identified for the natural background levels of K^+.	Yes	Not assessed.	No data were available for long-term scale for aquatic organisms. Data gap pending on the information on the background level of K^+. The acute risk for fish and daphnia was assessed as low.

(a): EFSA's reading of the Council Directive 98/83/EC[16] on the quality of drinking water intended for human consumption is that, as an inorganic fungicide, potassium hydrogen carbonate or the relevant ions that are formed from it, are not considered a pesticide under this directive, so the parametric drinking water limit of 0.1µg/L for pesticides, usually used as a decision making criteria regarding groundwater exposure, does not apply. 'Chemical parameters' or 'indicator parameters' levels (as defined in this directive) have not been prescribed for potassium or carbonate ions.

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Potassium hydrogen carbonate	No data were available for long-term scale for aquatic organisms. Data gap pending on the information on the background level of K^+. The acute risk for fish and daphnia was assessed as low.

6.4. Air

Compound (name and/or code)	**Toxicology**
Potassium hydrogen carbonate	LC_{50} inhalation > 4.88 mg/L (whole body, 4 1/2 hours)

[16] OJ L 330, 5.12.1998, p.32

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Wettability and foam persistence of the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- The background level of K^+ in natural soils and surface waters needs to be reported from a study or a peer reviewed scientific reference (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- Appropriate long-term risk assessments for wild mammals (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- The long-term risk assessments for aquatic organisms should be re-considered once the information on the background levels of K^+ is available, see data gap identified in section 4 (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- Algal toxicity data and related risk assessments for algae (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that a new study is already available, but not peer-reviewed; see section 5).
- Appropriate risk assessments for the representative formulation and aquatic organisms. For the risk assessment toxicological studies might need to be conducted (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- Higher tier risk assessments for honeybees (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- Appropriate risk assessments for the representative formulation to honeybees (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that a new study is already available to support the risk assessment, but the study is not peer-reviewed; unknown; see section 5).
- Appropriate risk assessments for non-target arthropods to be provided once the information on the background levels of K^+ is available. For the risk assessments toxicological studies might need to be conducted (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that new studies are already available, but not peer-reviewed; see section 5).
- Appropriate risk assessments for soil non-target organisms to be provided once the information on the background levels of K^+ is available, see data gap identified in section 4 (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- Appropriate risk assessments for non-target terrestrial plants to be provided once the information on the background levels of K^+ is available, see data gap identified in section 4(relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).

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

None.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where 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 of Annex VI to Directive 91/414/EEC and where 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).

1. The environmental risk assessment for soil and water can not be finalised until the naturally occurring background levels assumed for potassium are confirmed by studies or peer reviewed scientific literature. Consequently, the long-term risk assessment for aquatic organisms, and the risk assessments for non-target arthropods, soil non-target organisms and terrestrial non-target plants could not be finalised.

2. There were some indications that the representative formulation is more toxic to aquatic organisms than the active substance. Therefore further data and assessments are necessary to finalise the risk assessments.

3. There were some indications that the representative formulation is more toxic to honeybees than the active substance. Therefore further data and assessments are necessary to finalise the risk assessments.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude 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 where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude 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.

4. Based on the available data, a high risk to honeybees was identified.

9.3. Overview of the concerns 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 this table.)

Representative use		**Fungicide on grapevine** (8x 5100 g a.s./ha)	**Fungicide on apple** (8x 5100 g a.s./ha)
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
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	X[4]	X[4]
	Assessment not finalised	X[1,3]	X[1,3]
Risk to aquatic organisms	Risk identified		
	Assessment not finalised	X[1,2]	X[1,2]
Groundwater exposure active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure metabolites	Legal parametric value breached		
	Parametric value of 10µg/L[(a)] breached		
	Assessment not finalised		
Comments/Remarks			

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information. A column is greyed out if there is a concern for that specific use.

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

REFERENCES

EFSA (European Food Safety Authority), 2011. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance potassium hydrogen carbonate.

European Commission, 1999. Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev.2, 10 June 1999.

European Commission, 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3030/99 rev.4, 11 July 2000.

European Commission, 2002a. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev.2 final, 17 October 2002.

European Commission, 2002b. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001 rev 4 (final), 17 October 2002.

European Commission, 2002c. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC. SANCO/4145/2000.

European Commission, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 - final, 25 February 2003.

European Commission, 2004a. Guidance document on residue analytical methods. SANCO/825/00 rev. 7, 17 March 2004.

European Commission, 2004b. Guidance Document on Dermal Absorption. SANCO/222/2000 rev. 7, 19 March 2004.

European Commission, 2008. Review Report for the active substance potassium hydrogen carbonate finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 8 October 2008 in view of the inclusion of potassium hydrogen carbonate in Annex I of Directive 91/414/EEC. SANCO/2625/08 – rev. 1, 04 July 2008.

European Commission, 2009. Guidance Document on the Assessment of the Equivalence of Technical Materials of Substances Regulated under Council Directive 91/414/EEC. SANCO/10597/2003 – rev. 8.1, May 2009.

Ireland, 2006. Draft Assessment Report (DAR) on the active substance potassium hydrogen carbonate prepared by the rapporteur Member State Ireland in the framework of Directive 91/414/EEC, April 2006.

Ireland, 2011. Final Addendum to Draft Assessment Report on potassium hydrogen carbonate, compiled by EFSA, December 2011.

JMPR, 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–29 September 2004, Report 2004, 383 pp.

JMPR, 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Geneva, Switzerland, 18–27 September 2007, Report 2007, 164 pp.

APPENDICES

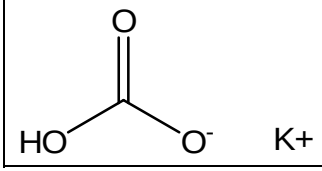
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Potassium bicarbonate
Function (*e.g.* fungicide)	Fungicide

Rapporteur Member State	Ireland
Co-rapporteur Member State	Not applicable.

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	potassium hydrogen carbonate
Chemical name (CA) ‡	carbonic acid, monopotassium salt
CIPAC No ‡	853
CAS No ‡	298-14-6
EC No (EINECS or ELINCS) ‡	206-059-0 (EINECS)
FAO Specification (including year of publication) ‡	None
Minimum purity of the active substance as manufactured ‡	minimum 99.5%
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Pb: max. 10 mg/kg As: max. 3 mg/kg
Molecular formula ‡	$KHCO_3$
Molecular mass ‡	100.12 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Decomposes without melting at 156 °C (>99.0%)
Boiling point (state purity) ‡	Decomposes at 156 °C (>99.0%)
Temperature of decomposition (state purity)	> 156 ºC (>99.0%)
Appearance (state purity) ‡	Pure material: White crystalline solid (>99.5%)
	Technical material: No information.
Vapour pressure (state temperature, state purity) ‡	Not applicable.
Henry's law constant ‡	No Henry's law constant.
Solubility in water (state temperature, state purity and pH) ‡	332 g/L at 20ºC
Solubility in organic solvents ‡ (state temperature, state purity)	Almost insoluble in alcohol.
Surface tension ‡ (state concentration and temperature, state purity)	Not applicable.
Partition co-efficient ‡ (state temperature, pH and purity)	No information provided. Not considered relevant.
Dissociation constant (state purity) ‡	Not applicable. Potassium hydrogen carbonate completely dissociates to its respective ions when dissolved in water: $KHCO_3 \rightarrow K^+ + HCO_3^-$ HCO_3^- is amphoteric and will then naturally participate in natural carbonic acid equilibria: $CO_3^{2-} + 2H^+ \leftrightharpoons HCO_3^- + H^+$ ($pKa_1 = 10.377$) $HCO_3^- + H^+ \leftrightharpoons H_2CO_3$ ($pKa_2 = 6.381$) $H_2CO_3 \leftrightharpoons CO_2 + H_2O$
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	No UV/Vis, IR, MS or NMR spectra are available.
Flammability ‡ (state purity)	Not flammable.
Explosive properties ‡ (state purity)	Not explosive.
Oxidising properties ‡ (state purity)	Not oxidizing.

Summary of representative uses evaluated (Potassium hydrogen carbonate)

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL min–max (l)	water L/ha min – max	kg as/ha min–max (l)		
Vitis vinifera VITVI {Vine}	All EU	Armicarb 85SP	F	*Uncinula necator* {Vine powdery mildew}	SP	850 g/kg	Broadcast using air blast orchard sprayer	BBCH 12 to 89	1 to 8	10 days	0.30 - 0.72	200-600	2.125 to 5.100	1	Volumes and doses will vary according to crop canopy size.
Malus sylvestris MABSD {Apple}	All EU	Armicarb 85SP	F	*Venturia inaequalis {Apple SCAB}*	SP	850 g/kg	Broadcast using air blast orchard sprayer	BBCH 10 to 85	1 to 8	10 days	0.34 – 0.51	500-1000	2.125 to 5.100	1	Volumes and doses will vary according to crop canopy size.

(a) For crops, the Codex and EU (or other) classifications should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) e.g. biting or suckling insects, soil borne insects, foliar fungi, weeds

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCFP Codes – GIFAP Technical monograph No 2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drenching

(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

(j) Growth stage at last treatment (BBCH Monograph, Growth Stage 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) PHI – minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	Acid-base titration
Impurities in technical as (analytical technique)	Acid-base titration USP Limit tests 231 & 211
Plant protection product (analytical technique)	Acid-base titration

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		A residue definition is not required and therefore has not been set. **Safety profile of Potassium hydrogen carbonate:** Potassium hydrogen carbonate is approved for food use in Europe and has been assigned a food additive number of E501 (raising agent). Potassium hydrogen carbonate is also listed for food use in the internationally recognized "Food Chemicals Codex"
Food of animal origin		See statement above
Soil		A residue definition is not required Potassium hydrogen carbonate is a natural component of soil and therefore cannot be distinguished from existing potassium and bicarbonate ions in the soil. Potassium hydrogen carbonate is a natural component of the environment, including aquatic bodies such as streams, rivers, lakes and ponds. A discussion is provided in the environmental section to substantiate that manufactured potassium hydrogen carbonate should not act any differently to the potassium hydrogen carbonate already present in the environment.
Water	surface	See statement above
	drinking/ground	See statement above
Air		See statement above

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	A waiver for analytical methods for residues is agreed in view of physico-chemical, toxicological, ecotoxicological and environmental fate properties of active substance and formulated material.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	See statement above
Soil (analytical technique and LOQ)	See statement above

Water (analytical technique and LOQ)	See statement above
Air (analytical technique and LOQ)	See statement above
Body fluids and tissues (analytical technique and LOQ)	Not required

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	Potassium hydrogen carbonate and the P.P.P. Armicarb 85SP will not classify from a physical/chemical viewpoint.

Chapter 2.3 Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Rapidly absorbed, approximately 100%
Distribution ‡	Widespread
Potential for accumulation ‡	Not relevant
Rate and extent of excretion ‡	Not relevant
Metabolism in animals ‡	Normal homeostasis maintained through well known mechanisms
Toxicologically relevant compounds ‡ (animals and plants)	K+ ion
Toxicologically relevant compounds ‡ (environment)	-

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	Females: 2064 mg/kg bw/day	
Rat LD_{50} dermal ‡	>2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 4.88 mg/L (whole body, 4 1/2 hours)	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Moderate, reversible	
Skin sensitisation ‡	Non-sensitising (M & K)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Altered urinary pH/hypertrophy of adrenal zona glomerulosa/increased potassium exretion. Urinary bladder hyperplasia (rats)	
Lowest relevant oral NOAEL / NOEL	4- and13-week rat-LOAEL: 2%	
Lowest relevant dermal NOAEL / NOEL	No data - not required	
Lowest relevant inhalation NOAEL / NOEL	No data - not required	

Genotoxicity (Annex IIA, point 5.4)

Genotoxicity	Data available of limited validity. No further data required.	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect	Growth retardation, ↑ serum potassiumin, ↑urinary potassium, ↑ urinary pH and volume, hypertrophy of adrenal zona glomerulosa;	
Lowest relevant NOAEL / NOEL	Neoplasia at 4% of diet and pre-neoplastic alterations at 2%.	
Carcinogenicity	Hyperplasia, papilloma and carcinoma of urinary bladder in rats through well-recognised mechanism, not considered relevant to humans	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	No data available. No data required.	
Relavant parental NOAEL		
Relavant reproductive NOAEL		
Relavant offspring NOAEL		

Developmental toxicity

Developmental target / critical effect	Data available of limited validity. No further data required.	
Relavant maternal NOAEL	-	
Relavant developmental NOAEL	-	

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available. No data required.	
Repeated neurotoxicity ‡	No data available. No data required.	
Delayed neurotoxicity ‡	No data available. No data required.	

Other toxicological studies (Annex IIA, point 5.8) Mechanism studies ‡	No data available. No data required.

Medical data ‡ (Annex IIA, point 5.9)

Overdose : Confusion; irregular or slow heartbeat; numbness or tingling in hands, feet or lips; shortness of breath or difficult breathing; paralysis of arms and legs, blood pressure drop; convulsions, coma, cardiac arrest.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	No suitable data available. Not needed.		
AOEL ‡	No suitable data available. Not needed		
ARfD ‡	No suitable data available. Not needed		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation: Armicarb 85 SP	100% (in the absence of data)

Exposure scenarios (Annex IIIA, point 7.2)

Operator	German and UK POEM models (application rate 5100 g a.s./ha): Exposure estimates to potassium hydrogen carbonate as a plant protection product are below the normal dietary intake of potassium (3.5 g/adult/day equivalent to 128 mg potassium hydrogen carbonate /kg bw/day) with and without PPE.
Workers	Exposure estimates to potassium hydrogen carbonate as a plant protection product are below the normal dietary intake of potassium (3.5 g/adult/day equivalent to 128 mg potassium hydrogen carbonate /kg bw/day) with and without PPE.
Bystanders	Exposure estimates to potassium hydrogen carbonate as a plant protection product are below the normal dietary intake of potassium (3.5 g/adult/day equivalent to 128 mg potassium hydrogen carbonate /kg bw/day)

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	peer review proposal
Potassium hydrogen carbonate	**None**

Residues:

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Not required. The residue arising from the use of the plant protection product is indistinguishable from naturally occurring residues present in any treated crop.
Rotational crops	Not provided and not required
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable
Processed commodities	Not provided and not required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Not proposed and not required
Plant residue definition for risk assessment	Not proposed and not required
Conversion factor (monitoring to risk assessment)	Not applicable

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Not provided and not required
Animal residue definition for monitoring	Not applicable
Animal residue definition for risk assessment	Not applicable
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Not applicable
Fat soluble residue: (yes/no)	Not applicable

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Not applicable. The residue arising from the use of the plant protection product is indistinguishable from naturally occurring residues present in any treated crop.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

Not provided and not required

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Not relevant.	Not relevant.	Not relevant.
Potential for accumulation (yes/no):	Not relevant.	Not relevant.	Not relevant.
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Not relevant.	Not relevant.	Not relevant.
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	Not relevant.	Not relevant.	Not relevant.
Liver	Not relevant.	Not relevant.	Not relevant.
Kidney	Not relevant.	Not relevant.	Not relevant.
Fat	Not relevant.	Not relevant.	Not relevant.
Milk	Not relevant.		
Eggs		Not relevant.	

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern Southern Region, field or glasshouse,	Trials results relevant to the representative uses (a)	Recommendation/comments	**MRL** estimated from trials according to representative use	**HR** (c)	**STMR** (b)
Residue trials for potassium hydrogen carbonate not provided and not required.						

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.15, 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)[7]

ADI	Not proposed and not required.
TMDI (% ADI) according to WHO European diet	Not required
TMDI (% ADI) according to national (to be specified) diets	Not required.
IEDI (WHO European Diet) (% ADI)	Not required.
NEDI (specify diet) (% ADI)	Not required.
Factors included in IEDI and NEDI	Not required.
ARfD	Not proposed and not required.
IESTI (% ARfD)	Not required.
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not required.
Factors included in IESTI and NESTI	Not required.

[7] To be done on the basis of WHO guidelines and recommendations with the deviations within the EU so far accepted (especially diets).

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Numberof studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor [8]	Yield factor [8]	
Not provided and not required.				

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

No MRL proposed	Not required. The residue arising from the use of the plant protection product is indistinguishable from naturally occurring residues present in any treated crop

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

Chapter 2.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil
(Annex IIA, point 7.1.1.1.1)

Potassium hydrogen carbonate completely dissociates to potassium and bicarbonate ions in the presence of water.

Route of degradation in soil - Supplemental studies
(Annex IIA, point 7.1.1.1.2)

None available.

Rate of degradation in soil
(Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Not applicable: Potassium hydrogen carbonate completely dissociates to potassium and bicarbonate ions in the presence of water.

Soil adsorption/desorption
(Annex IIA, point 7.1.2) It should be noted that no data was presented for this section nor was any data requested.

Potassium is strongly bound in soil and a rapid equilibrium is observed between soluble and exchangeable forms.

Mobility in soil
(Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2) It should be noted that no data was presented for this section nor was any data requested.

Potassium has a very low mobility in soil due to cation binding to negatively charged soil components.

PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation	Calculations were based on a lumped application of 40.8 kg a.s./ha corresponding to the maximum number of recommended doses and the highest rate of application in a season. Potassium hydrogen carbonate spontaneously dissociates to potassium and bicarbonate ions in moist soils. Consequently initial PECs were calculated for the potassium and bicarbonate ions.
Application rate	*% plant interception:* 50 *Crops:* Apples & vines. *Number of applications:* 1 lumped application of the active substance. That is, the active substance is applied eight times per season with no loss of residues. *Application rate*: 40.8 kg a.s./ha per season [8 x 5.10 kg a.s/ha]

PEC_S mg /kg soil	Single application Actual	Single application Time weighted	Multiple application actual	Multiple application actual

		average	K^+	HCO_3^-	$KHCO_3$
Initial	Only the PEC soil used in the risk assessment is included in the list of end points[EPCO Manual E4-rev. 4 September 2005].		10.6	16.6	27.2

Route and rate of degradation in water
(Annex IIA, point 7.2.1)

Not applicable: Potassium hydrogen carbonate completely dissociates to potassium and bicarbonate ions in the presence of water. Bicarbonate is produced from various natural sources, particularly carbonate based rocks and respiration of aquatic plants during the hours of darkness. Typical levels found in natural surface waters adjacent to agricultural land are between 100-500 mg/L. Potassium is an essential nutrient for aquatic plants and micro-organisms and has a well known cycle via the food chain.

PEC (surface water)
(Annex IIIA, point 9.2.3)

Method of calculation	Given the nature of the active substance it was not considered appropriate to use the FOCUS model to determine the PEC of potassium hydrogen carbonate in surface waters. Instead, an estimation based on spray drift with no degradation between applications was used.
Application rate	40.8 kg a.s ha[8 x 5.10 kg a.s./ha]
Main route of entry	Spray drift [100 %]

PEC_{SW} mg as/L	Single application Actual		Single application Time weighted average	Multiple application actual	Multiple application Time weighted average		
	K^+	HCO_3^-			K^+	HCO_3^-	$KHCO_3$
Initial (100% spray drift)	-	-	-	-	5.30	8.30	13.6
Apple crop [3 m buffer zone]	-	-	-	-	1.55	2.42	3.97
Vine crop [3 m buffer zone]	-	-	-	-	0.42	0.66	1.088

PEC (groundwater)

Method of calculation and type of study (e.g. modelling, monitoring, lysimeter) Application rate PEC_{GW} Maximum concentration Average annual concentration	Not calculated. The dissolution products of Potassium hydrogen carbonate are naturally occurring in the environment. For example, bicarbonate is produced from various natural sources, particularly carbonate-based rocks: $CaCO_{3(S)} \leftrightarrows Ca^{2+}_{(aq)} + CO_3^{2-}{}_{(aq)}$ $CO_3^{2-}{}_{(aq)} + H_2O_{(l)} \leftrightarrows HCO_3^{-}{}_{(aq)} + OH^{-}{}_{(aq)}$ and respiration of aquatic plants during the hours of darkness. Potassium is an essential nutrient for aquatic plants and micro-organisms and has a well known cycle via the food chain.

Fate and behaviour in air

(Annex IIA, point 7.2.2, Annex III, point 9.3) It should be noted that no data was presented for this section nor was any data requested.

Direct photolysis in air	Not applicable. Potassium hydrogen carbonate is not volatile and does not degrade in air.
Quantum yield of direct phototransformation at □ > 290 nm	Not applicable
Photochemical oxidative degradation in air	Not applicable
Volatilisation	Not applicable

PEC (air)

Method of calculation	Not applicable

PEC_A

Maximum concentration	Not applicable

Definition of the Residue

(Annex IIA, point 7.3)

Relevant to the environment	Not applicable, Potassium hydrogen carbonate is naturally present in the environment.

Monitoring data, if available

(Annex IIA, point 7.4)

Soil (indicate location and type of study)	Not applicable, potassium and bicarbonate ions are naturally present in the environment.
Surface water (indicate location and type of study)	Potassium and bicarbonate ions are naturally present in sediments in surface water.
Ground water (indicate location and type of study)	Potassium and bicarbonate are naturally present in groundwater.
Air (indicate location and type of study)	Not applicable: Potassium hydrogen carbonate is not volatile

List of studies submitted.

Waivers were requested by the notifier for potassium hydrogen carbonate for all environmental fate studies. This was accepted by the RMS as potassium hydrogen carbonate is a natural component of the environment. Inputs from the use of 'Armicarb 85SP' are expected to be negligible compared with natural background levels. A data gap has been identified for studies or peer reviewed scientific literature to support the naturally occurring levels of potassium proposed by the notifier.

Chapter 2.6 Effects on Non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Standard tests not available. Not required.				
Chicken	$NaHCO_3$*	Acute	>8,075*	10 000
Chicken	$NaHCO_3$*	Short-term	>8,075*	10 000
Chicken	$NaHCO_3$*	Long-term	>8,075*	10 000
Mammals				
Rat	$KHCO_3$	Acute	2064	-
Long-term and additional higher tier studies				
Not available				

*: endpoint is based on summaries of long-term feeding studies where chickens were fed with high concentration of sodium bicarbonate in the standard feed and no adverse effects were observed. 1.04 kg feed /kg bw/day was assumed to be consumed by the chickens. The value is expressed as HCO_3, therefore refers only to bicarbonate.

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Crop and application rate: Apples & grapevines, 8 x 5100 g a.s./ha

Indicator species	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
representative insect eating bird	Acute	276	>29	10
representative insect eating bird	Short-term	154	>52	10
representative insect eating bird	Long-term	154	>52	5
Higher tier refinement (Birds)				
Not required				
Tier 1 (Mammals)				
Rat	Acute	964	2.1	10
Long-term and higher tier refinement (Mammals)				
Not available – data gap				

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Rainbow Trout	$KHCO_3$	96 hr (flow-through)	Mortality,LC_{50}	>1200 ($_{nom}$)
Bluegill Sunfish	$KHCO_3$	96 hr (flow-through)	Mortality,LC_{50}	>1200 ($_{nom}$)
Aquatic invertebrate				
Daphnia magna	$KHCO_3$	48 hr (flow-through)	Mortality, EC_{50}	>860 ($_{nom}$)
Sediment dwelling organisms				
Not available. Not required				
Algae				
Not available - data gap				

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Higher plant				
Not available. Not required				
Microcosm or mesocosm tests				
Not available. Not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Worst-case PEC_{SW} of $KHCO_3$ following a lumped dose of 8 applications at the maximum recommended dose rate of Arimcarb 85SP: PEC_{SW} for overspray is 13.6 mg/L; Apples (3m from edge of field) is 3.97 mg/L; Vines (3m from edge of field) is 1.088 mg/L.

Organism	Toxicity end point (mg/L)	TER_A overspray	TER_A 3m from apples	TER_A 3m from vines	Annex VI Trigger
Fish	LC_{50} 1200	> 88	> 302	> 1103	100
Aquatic invertebrates	EC_{50} 860	> 63	> 217	> 790	100

Bioconcentration
No data. Not required

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
$KHCO_3$	No data. Not required.	>24
Field or semi-field tests		
No data. Not required.		

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Test substance	Exposure Route	Dose g a.s./ha	LD_{50} µg/bee	Hazard quotient Q_{HC}	Annex VI Trigger
$KHCO_3$	Contact	5100	>24	<212	50

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

No data - data gap

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Earthworms
No data - data gap
Other soil macro-organisms
No data - data gap

Soil micro-organisms
No data - data gap

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

No data - data gap

Effects on biological methods for sewage treatment (Annex IIA 8.7)

No data. Not required

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Potassium hydrogen carbonate

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS proposal
Active substance	No classification proposed

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram

GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on 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)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level

NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
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
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year