Draft Assessment Report (DAR)

- public version -

Initial risk assessment provided by the rapporteur Member State United Kingdom for the existing active substance

POTASSIUM HYDROGEN CARBONATE

of the fourth stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC

Volume 1

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European Union

Programme for Inclusion of Active Substances in Annex I to Council Directive 91/414/EEC

(Articles 5 and 6 of Council Directive 91/414/EEC)

Bicarbonate, Salts of

(Potassium)

Volume 1

Draft Report and Proposed Decision

April 2006

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VOLUME 1

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FOREWORD

This monograph was generated in accordance with the *Guidelines and criteria for the evaluation of dossiers and for the preparation of reports to the European Commission by Rapporteur Member States relating to the proposed inclusion of active substances in Annex I of Directive 91/414/EEC* (Document 1654/VI/94, rev 7 of 22 April 1998). It was prepared on the basis of the dossier compiled and submitted by Brotherton Speciality Products Limited, Calder Vale Road, Wakefield, UK for the active substance Potassium hydrogencarbonate (Potassium bicarbonate). However, as the *Rapporteur Member State we* propose that not salts of bicarbonate are included in Annex I of Council Directive 91/414/EEC.

1 STATEMENT OF THE SUBJECT MATTER AND PURPOSE OF THE MONOGRAPH

1.1 Purpose For Which The Monograph Was Prepared

This application is to support the first inclusion of the substance potassium bicarbonate in Annex 1 of Council Directive 91/414/EEC in accordance with Article 8 of that Directive. [ref. Doc. A] Submission of dossier as part of re-registration at EU level according to Directive 91/414/EEC, Regulation 1112/2002. Potassium bicarbonate is included in List 4A.

1.2 Summary Of The Assessment Of The Steps Taken To Collectively Present The Dossier.

Brotherton Speciality Products Limited is the only notifier of potassium bicarbonate on the 4th stage of EU Regulation 1112/2002.

1.3 Identity Of The Active Substance. [Ref. Doc. F]

1.3.1 Name and address of the applicant. {Annex IIA 1.1} .

Address: Brotherton Speciality Products Limited,
Calder Vale Road,
Wakefield,
West Yorkshire,
WF1 5PH,
England.

[redacted] [redacted]

1.3.2 Common name and synonyms. {IIA 1.3}

ISO common name:	Potassium bicarbonate
Synonyms:	Potassium hydrogen carbonate
	Carbonic acid, monopotassium salt
	Potassium acid carbonate

1.3.3 Chemical name {IIA 1.4}

IUPAC:	Potassium hydrogen carbonate
CA:	Carbonic acid, monopotassium salt

1.3.4 Manufacturers development code number {IIA 1l.5}

Active substance is referred to as potassium bicarbonate. No code number is available.

Formulation name:	Armicarb 85SP
Formulation code number:	Fungicide 2346-102 (used in acute toxicity studies)

In the USA, Armicarb 85SP is registered under the following names: Armicarb 100, Agricure, MilStop, FirstStep, Remedy.

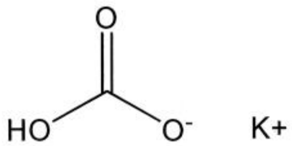
1.3.5 CAS, EU and CIPAC numbers {IIA 1.6}

CAS:	298-14-6
EEC:	206-059-0 (EINECS)
CIPAC:	Not applicable

1.3.6 Molecular and structural formula, molecular mass

Molecular formula: $KHCO_3$

Structural formula:



Molecular mass: 100.12 g/mol

1.3.7 Manufacturer of the active substance {IIA 1.2}

Address of manufacturer: [redacted]

Telephone: [redacted]

Location of manufacturing plants: [redacted]

1.3.8 Method of manufacture. {IIA 1.8.} [See document J]

Due to the confidential nature of this information, the manufacturing process for Potassium bicarbonate is described in **Annex C**.

1.3.9 Specification of the purity of the Active substance {IIA 1.9}

995.0 g/kg minimum.

1.3.10 Identity of the isomers, impurities and additives. {IIA 1.10}

[redacted]

[redacted]

1.3.11 Analytical profile of batches {IIA 1.11}

This information is confidential and is provided in **Annex C**.

1.4 Identity Of Plant Protection Products {Annex IIA 3.1: IIIA 1} [Dossier Documents J, K-II, L-II, K-III, L-III]

1.4.1 Current, former and proposed trade names and development code numbers {Annex IIIA 1.3}

Trade name:	Armicarb 85SP
Brotherton Code number:	None

1.4.2 Manufacturer or manufacturers of the plant protection product. {Annex IIIA 1.2}

Present manufacturer of the preparation:

Company: [redacted]
Address: [redacted]
Telephone: [redacted]

[redacted]

Company: [redacted]
Address: [redacted]
Telephone: [redacted]

Location of the manufacturing plant:

[redacted]

1.4.3 Type of the preparation and the code {Annex IIIA 1.5}

Water Soluble Powder: (Code SP).

1.4.4 Function {Annex IIA 3.1, Annex IIIA 1.6}

Fungicide. Armicarb 85SP is a potassium bicarbonate-based, broad-spectrum foliar fungicide for the curative and preventative control of powdery mildew, scab and other diseases.

1.4.5 Composition of the preparation Armicarb 85SP {Annex III, 1.4}

Component	% w/w	g/l	Chemical name	CAS no.	Function
Potassium bicarbonate	85.0	850.0	Potassium bicarbonate	298-14-6	Active substance
A detailed specification, which includes details of the formulants in the preparation, is provided in **Annex C**.					

1.5 Uses Of The Plant Protection Product {Annex IIA 3.1 - 3.4, Annex IIIA 3.1 - 3.7, 3.9 and 12.1} {Dossier documents C, D, E and F}

Armicarb 85SP, based on 85% potassium bicarbonate, acts as a contact fungicide able to control several diseases such as vine powdery mildew (*Uncinula necator*) and apple SCAB (*Venturia inaequalis*). Armicarb 85SP should be used as a preventative treatment, although it is also effective if applied just after onset of infection, especially on powdery mildew.

Recommended application rate for the formulated material is 2.5 to 6 kg/ha, in 200 to 600 litres/ha on grapes and from 500 to 1000 litres/ha on apple trees. Treatment is applied using commercial air-blast orchard sprayer. Interval between applications should be 10-12 days depending on rainfall, pest pressure and crop development. Maximum number of applications is limited to 8.

Armicarb 85SP will be marketed in 2.2 to 25 kg polyethylene bags. The bags are themselves sealed into polyethylene tubs to maintain the integrity of packaging.

1.5.1 Field of use {Annex IIIA 3.1}

Field use, such as agriculture, horticulture and viticulture.

1.5.2 Effects on harmful organisms {Annex IIA 3.2 and Annex IIIA 3.2}

Potassium bicarbonate mainly inhibits fungus mycelium development. Its mode of action is linked with osmotic pressure, pH and specific bicarbonate/carbonate ion effects. As a consequence of such mode of action it has to be applied preventively.

1.5.3 Summary of intended uses {Annex IIA 3.4: Annex IIIA 3.3 to 3.7 and 3.9 }

Table 1.5.3.1

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests Controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg/ as/hl min max	water L/ha min max	kg as/ha min max		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)	(min)				(l)	(m)
Use pattern : foliar application															
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.

Remarks :	(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)	(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment must be indicated
	(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(i) g/kg or g/l
	(c) e.g. bittin and sucking insects, soil born insects, foliar fungi, weeds	(j) Growth stage at least treatment (BBCH monograph, growth stages of plants, 1997 Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	(d) e.g. vegetable powder (WP), emulsifiable concentrate (EC), granule (GR)	
	(e) GCPF Codes - GIFAP Technical Monograph N°2, 1989	(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
	(f) All abreviations used must be explained	
	(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drenching	(l) PHI - minimum Pre-Harvest Interval
		(m) Remarks may include : extent of use/economic importance/restrictions

Table 1.5.3.2 Harmful Organisms Controlled By The Product.

Crop	PATHOGENS.		Region.
Vine	Vine powdery mildew	*Uncinula necator*	EU
Apples	Apple scab	*Venturia inaequalis*	EU

1.5.4 Information on authorisations in other EU member states {Annex IIIA 12.1}

Table 1.5.4.1 Authorisation And Registration In The EU

Country	Type of Authorisation	Crops/Uses	Authorisation Details
There are no registered uses as a plant protection product in Europe. Potassium bicarbonate has been used as a fungicide on many fruit, vegetable and ornamental crops for more than 30 years.			

Note:

The same product as Armicarb 85SP is registered under the name of Armicarb 100 in the USA. A product containing 94% potassium bicarbonate as the active ingredient (Ecocarb) is registered in Australia.

2. REASONED STATEMENT OF THE OVERALL CONCLUSIONS DRAWN BY THE RAPPORTEUR MEMBER STATE

2.1 Identity, Physical And Chemical Properties, Details Of Uses And Further Information, Classification And Labelling

2.1.1 Identity[1].

Please see volume 1 (level 1), volume 3 (data on application and further information) and volume 4 (Annex C).

2.1.2 Physical and chemical properties

Active substance:

The test for explosive properties was not carried out instead a reasoned statement was given as to why potassium bicarbonate is not explosive (Report no: ARM001, Laurence Guillossan, 9th May 2005). The statement was deemed to be acceptable. The test for oxidising properties was also not carried out instead a reasoned statement was given as to why potassium bicarbonate is not considered to possess oxidising properties (Report no: ARM003, Laurence Guillossan, 9th May 2005). The statement was deemed to be acceptable.

Potassium bicarbonate is a white[1,2], odourless[1], water-soluble (33.2 g/100g at 20°C)[1,4], non-volatile, non-explosive, non-oxidizing solid routinely used as a fire extinguishing ingredient. Potassium bicarbonate does not melt, but decomposes spontaneously above 156ºC to potassium carbonate, carbon dioxide and water[1]. Potassium bicarbonate is stable to photolysis but will rapidly dissociate to potassium and bicarbonate ions in water. Potassium bicarbonate does not classify from a physical/chemical point of view.

Information on the physical/chemical properties of potassium bicarbonate are sourced from chemical handbooks[1,2,3] and reference books[1,2,3]. No particular studies were generated to derive the chemical or physical properties of this molecule. This source of information was considered to be acceptable for what is a simple commodity chemical.

Plant protection product:

Armicarb 85SP is a Water Soluble Powder (SP) containing 85% potassium bicarbonate of declared purity 99.5% minimum. It is not explosive, oxidizing, corrosive or flammable, and has a minimum shelf life of 2 years. Storage under normal warehouse conditions in the original packaging is recommended. Neither of the two co-formulants classify from a physical/chemical point of view. The plant protection product will therefore not classify from a physical/chemical point of view.

A two year storage stability study was carried out on Armicarb 100 which is equivalent to Armicarb 85SP (CD 0897-1, Scott Weaver, 21st December 1999). There was no statistical change in the concentration of the active substance or degradation of either type of packaging material. During the course of the study, Armicarb 100 exhibited a slight crusting and yellowing and the formation of clumps. A short-term storage stability study was also carried out, 30 days at 50°C and 50% relative humidity (CD 0697-2, Jeff Stoudt, 29th August 1997). There was no significant change in the concentration of the active substance during storage. During the course of the study, Armicarb 100 exhibited a slight crusting and yellowing and the

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1 [1] "ArmicarbTM. A Safe and Efficacious Pest Management Alternative". Church & Dwight Co., Inc. April 1994.
"Review of the Carcinogenic Risk of Bicarbonates and Carbonates" by Dr. Samuel Cohen, University of Nebraska. Church & Dwight Co., Inc. Princeton, NJ 08843, April 1994.
2."Food Chemicals Codex – Fourth Edition. Effective July 1st, 1996". Committee on Food Chemicals Codex, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences.
3."Potassium bicarbonate Handbook". Armand Products Company.
4."Handbook of Chemistry – 10th Edition". N. A. Lange.

formation of clumps. There were no visual or palpable differences in the cardboard packaging after storage. The plastic bag packaging had changed from a loose-fitting material around the test substance to that of a tight fitting material, which clung to the Armicarb 100.

The notifier indicates that only one product Armicarb 85SP will be marketed in the short term. The technical properties of Armicarb 85SP indicate that no particular problems are to be expected when it is stored and used according to recommended use instructions.

2.1.3 Details of uses and further information

Armicarb 85SP, based on 85% potassium bicarbonate, acts as a contact fungicide able to control several diseases such as vine powdery mildew (*Uncinula necator*) and apple SCAB (*Venturia inaequalis*). Armicarb 85SP should be used as a preventative treatment, although it is also effective if applied just after onset of infection, especially on powdery mildew.

2.1.4 Classification and labelling

Potassium bicarbonate and the plant protection product Armicarb 85SP will not classify from a physical/chemical viewpoint.

2.2 Methods Of Analysis

2.2.1 Analytical methods for analysis of the active substance as manufactured

Two analytical methods have been provided and validated. The first is used to determine the content of potassium bicarbonate by way of acid base titration. The second is to determine the content of potassium ions by flame atomic absorption. These methods are considered to be adequate to deal with the data requirements for this simple commodity chemical.

2.2.2 Analytical methods for formulation analysis

The analytical methods supplied for the analysis of potassium bicarbonate and its impurities in the technical active substance apply to the formulation as well.

2.2.3 Analytical methods for residue analysis

Food of plant origin:

A waiver was requested for residue analysis methods for the following reasons:

Potassium and bicarbonate ions are naturally occurring in all environmental compartments including plant tissues and it is not possible to distinguish between the use of potassium bicarbonate for plant protection reasons and its natural occurring presence in the environment. Potassium bicarbonate is an approved food additive in the EU (E501) and is also listed as a food additive by CODEX Alimentarius (See Document K Point IIA 2.4.1). Potassium bicarbonate is Generally Regarded As Safe (GRAS) by the US FDA. It is impossible to differentiate between potassium and bicarbonate ions produced from the use of Armicarb 85SP and those occurring naturally in the crop.

The wavier was accepted.

Food of animal origin:

See food of plant origin above.

Soil:

See food of plant origin above.

Water:

See food of plant origin above.

Air:

See food of plant origin above.

Residues in body fluids and tissue:

See food of plant origin above.

2.3 Impact on animal and human health

2.3.1 Effects having relevance to human and animal health arising frm exposure to the active subatance or to impurities contained in the active substance or to their transformation products.

Toxicokinetics and metabolism

Very little data exist on the specific toxicokinetics of potassium bicarbonate and potassium carbonate (because volumes have been written on potassium itself and the bicarbonate-carbonate buffer system of the mammalian organism).

Sodium bicarbonate is rapidly absorbed in both humans and animals after oral, intravenous or intraperitoneal administration.

Acute toxicity

Potassium bicarbonate is of low acute toxicity (oral, dermal and inhalation). No dermal reactions were noted after application of potassium bicarbonate to the skin of rabbits. Significant conjunctival irritation occurred in the rabbit eye which reversed within 7 days. In a Buehler test, no skin sensitisation was observed.

Parameter	Species	Result	Classification	Reference
Acute oral toxicity	Rat	LD_{50} = 3 706 mg/kg (♂) LD_{50} = 2 064 mg/kg (♀) LD_{50} = 2 825 mg/kg (combined)	Not required	Glaza S. M. (1993)
Acute dermal toxicity	Rabbit	LD_{50} : > 2 000 mg/kg	Not required	Glaza S. M. (1993)
Acute inhalation toxicity	Rat	LC_{50}–4 hour : > 4.88 mg/L	Not required	Shapiro R. (1993)
Skin irritation	Rabbit	Non irritant	Not required	Glaza S. M. (1993)
Eye irritation	Rabbit	Moderate, reversible irritation	Not required	Glaza S. M. (1993)
Skin sensitisation (Buehler test)	Guinea-pigs	Not sensitising	Not required	Glaza S. M. (1993)

Genotoxicity, chronic and sub-chronic toxicity

It was reported in the review documents supplied that potassium carbonate was not mutagenic in Ames test conducted with Saccharomyces cereviseae, (strain D4) and Salmonella typhimurium, (strains TA-92, TA-1535, TA-100, TA-1537, TA-94, TA-137, or TA-1538), with and without liver microsome fraction and several of the studies were also conducted with activation assays prepared from liver, lungs and testes of mice, rats and monkeys.

Negative results were also obtained in the in vitro Chinese chromosomal aberration test.

All studies resulted in lack of any evidence of mutagenic potential for potassium bicarbonate.

A number of documents were supplied which outlined the human physiology of potassium bicarbonate. Some sub-chronic and chronic data on exposure of experimental animals (rats) were also supplied. It was reported that sodium and potassium salts of various anions including sodium saccharin, sodium ascorbate, sodium bicarbonate, potassium bicarbonate and potassium carbonate have been shown to be non-genotoxic promoters of bladder carcinogenicity in the male rat. The experimental data demonstrated that potassium bicarbonate could act as a weak initiator of bladder tumours in the rat. These results are consistent with the known nongenotoxic mechanism of bladder carcinogenesis in the rat.

The RMS can agree with the conclusion of the notifier that based upon a review of the toxicology, pathology, and related studies, food grade potassium bicarbonate does not represent a carcinogenic risk to humans from the pesticidal use proposed.

Reproductive toxicity

No data specific to potassium bicarbonate has been submitted. A review of the status of sodium bicarbonate with respect to reproductive toxicity was considered relevant to this point. The current US FDA GRAS report (1975) was referred to in which a number of studies were considered. It was concluded that there was no risk to man from possible reproductive toxicity arising from pesticidal use of potassium bicarbonate.

Neurotoxicity

Neither in acute toxicity in rat nor in short term toxicity studies in poultry, indications for neurotoxicity were observed, so no complementary study was performed.

2.3.2 Acceptable Daily Intake (ADI)

Due to the medical usage of potassium bicarbonate, there is no need to set an Acceptable Daily Intake.

The Normal Daily Requirement for potassium, established by the medical authorities, is 3.5 g K/day for a 70 kg adult.

2.3.3 Acceptable Operator Exposure Level (AOEL)

No NOEL has been established in the studies reported in literature for potassium bicarbonate (Church & Dwight Co-Anonymous 1, 1994).

Since the active ingredient is rapidly disassociated in the mammalian organism to the cation and the anion, it is appropriate to set the AOEL at the Normal Daily Requirement of the most "critical" ion which is potassium (bicarbonates daily intakes are proportionally higher because sodium bicarbonate is widespread).

The Normal Daily Requirement for potassium, established by the medical authorities, is 3.5 g K/day for the adult.

As this Normal Daily Requirement for potassium is established in human, there is no need to apply a Safety Factor. Therefore the AOEL is proposed at 3.5 g Potassium/day, corresponding to 8.96 g Potassium Bicarbonate/day and to **128 mg potassium bicarbonate/kg/day.**

2.3.4 Acute Reference Dose (ARfD)

Due to the low acute toxic potential of potassium bicarbonate, the allocation of an ARfD was not considered relevant.

2.3.5 Drinking water limit

Groundwater naturally contains varying levels of sodium, potassium and bicarbonate, coexist with varying rock and mineral deposits, and groundwater movement. Potassium and bicarbonate ions are also presents in various quantities in mineral water.

Therefore a drinking water limit is not relevant.

2.3.6 Impact on human or animal health arising from exposure to the active substance or to impurities contained in it.

2.3.6.1 Operator Exposure

Recommended use rates, details on application, and calculation parameters

ARMICARB 85SP is intended for use on vines / powdery mildew and apples / scab.

The amount used is 2,125-5,100 grams of active ingredient/ha/treatment with a maximum of 8 applications, and spray interval of 10-12 days.
All the calculations are made using the maximum used dose i.e. 5,100 g of potassium bicarbonate/ha (i.e. 6 kg ARMICARB 85SP / ha).
Spray volumes used for calculations are those described in the French GAPs

Recommended use rate and details on application

Crop	Recommended use rate		Spray volume	Maximum in-use concentration of a.i.	Application technique
	kg product/ha	g a.i./ha	(L/ha)	(mg a.i./mL)	
Apples	6.0	5 100	500 to 1000 L	10.2	Tractor-mounted/trailed broadcast air-assisted sprayer
Vines	6.0	5 100	200 to 600 L	25.5	Tractor-mounted/trailed broadcast air-assisted sprayer, low volume

The calculation parameters (worst case) for APPLES and VINES are as follows :

Area treated per day	:	15 ha for the calculations using the German Model and the UK-POEM.
Work rate per day	:	6 hours
Application dose	:	5 100 g a.i./ha
Spray volume	:	500 L/ha for apples - Not relevant for the German model 200 L/ha for vines - Not relevant for the German model
Packaging	:	25 kg - Not relevant for the German model
Standard operator body weight	:	70 kg for the calculations using the German Model and 60 kg for the calculations using the modified UK-POEM.

Personal protective equipment (PPE)

The calculation of the estimated operator exposure is made for different scenarios with respect to personal protective equipment (PPE):

UK-POEM	no PPE	Mixing/loading	no gloves
		Application	no gloves
	PPE	Mixing/loading	gloves
		Application	no gloves
German Model	no PPE	Mixing/loading	no gloves
		application	no gloves
	PPE	Mixing/loading	gloves
		Application	no gloves

Absorption data

In absence of specific data, the UK model requires use of 10% percutaneous absorption default value and 1% default value for penetration through gloves (based on ARMICARB 85SP being a solid formulation), and a value of 100 % for dermal absorption from the formulation during mixing/loading and spraying.

Results of the model calculations
The predicted absorbed doses of ARMICARB 85SP according to the UK-POEM and German Model, and the calculations of the respective risk quotients (ratio of absorbed dose to AOEL) are summarised as follows:

Absorbed doses and risk quotients

Model taken for calculation	Personal Protective Equipment (PPE)	Total absorbed dose potassium bicarbonate (mg/kg/day)	AOEL potassium bicarbonate (mg/kg/day)	% of AOEL
Apple				
UK-POEM	no PPE	4.686	128	3.66
	PPE (gloves only during mixing loading)	2.969	128	2.32
German Model	no PPE	2.009	128	1.57
	PPE (gloves only during mixing loading and spraying)	1.360	128	1.06
Vines				
UK-POEM	no PPE	5.781	128	4.52
	PPE (gloves during spraying)	4.064	128	3.18
German Model	no PPE	2.009	128	1.57
	PPE (gloves only during mixing loading and spraying)	1.360	128	1.06

The risk to the operator is therefore acceptable, with or without the use of personal protective equipment

2.3.6.2 Bystander exposure
The potential routes of exposure for bystanders are via dermal and inhalation exposure to drift of spray material. Given the low vapour pressure of ARMICARB 85SP (soluble powder in water) exposure to vapour is likely to be negligible and bystander exposure will result primarily from dermal exposure to drift of spray material. Such exposure is likely to be brief and unlikely to occur repeatedly to the same individual.
Bystander exposure is considered to be lower than the exposure of the mixer/loader/applicator. Therefore it is concluded that there is no undue risk to accidental bystander exposure.

2.3.6.3 Worker exposure

As a standard rule treated areas should not be entered before the spray deposit on plant surfaces has dried, unless protective clothing is worn. The exposure of workers will be considerably lower than spray operators since the spray would have dispersed in the air or dried on the plants once the crops have been treated.

The worker exposure may be limited to dislodgeable residues, and can be assessed according to Hoernicke et al., 1998 on the basis of:

- a default value of 1 µg/cm² per kg a.s./ha for the Dislogeable Foliar Residue (DFR),
- a transfer factor (TF) for high crops of 30000 cm²/person/h,

and according to the following formula:

$$D = DFR \times AR \times TF \times WR \times P \times DABS$$

where:

- D is absorbed dose of active substance (µg a.s./person/day),
- DFR is the Dislogeable Foliar Residue (1 µg/cm² per kg a.s./ha),
- AR is the application rate in kg a.s./ha: 5.10 kg a.s./ha for ARMICARB 85SP
- TF is the transfer factor, 15000 cm²/person/h for vineyards, and 10000 for orchards (see justification below)
- WR is the work rate, 8 hours per day,
- P is the penetration factor of PPE, the worker is considered not to wear PPP, i.e., P = 1,
- DABS is the dermal absorption coefficient: 100% in absence of specific data for dermal absorption
  In absence of specific data, Hoernicke *et al*. (1998) propose to use a RFD of 1 µg/cm² x kg a.i./ha and a transfer factor (FT) of 30 000 cm²/person x duration of exposition (h), as a worst case.
  However, the transfer factor varies according to the activities, and the following table presents those proposed by the U.S. E.P.A.:

		Transfer factor (cm²/h)
Low potential of dermal transfer	Harvesting (hands)	2 500
	Research, watering	1 000
Medium potential of dermal transfer	Harvesting (hands)	10 000
High potential of dermal transfer	Harvesting (hands)	10 000
	Support, research, watering	4 000
Vineyards	Harvesting (hands), cutting	15 000
Orchards	All activities	10 000

The worst case is given by the vineyards transfer factor: 15000 cm^2/h

The dermal absorbed dose is therefore:

$$D = 1 \times 5.10 \times 15000 \times 8 \times 1 \times 1 = 612 \text{ mg a.s./pers./day}$$

On the basis of a worker body weight of 70 kg, D represents 8.74 mg/kg b.w./day equivalent to 6.83 % of the AOEL.

The results show that without any specific personal protection the risk of a contamination to workers is low when entering the treated areas directly after application. The maximum exposure derived from the model calculation, assuming a general dermal absorption of 100 % and without any protective equipment in vineyards (worst case), is 6.83 % of the AOEL.

2.4 Residues

2.4.1 Definition of Residue relevant to MRL,s.

Plants:

Not applicable.

Animals:

Not applicable.

2.4.2 Residues relevant to consumer safety

Residues due to use of the product are not considered to be relevant when compared to the natural levels present in the environment. Potassium bicarbonate is approved as a food additive and an ingredient in pharmaceutical preparations. The intake of potassium bicarbonate through use as a plant protection product will be negligible compared with that through normal consumption of food additive or pharmaceutical preparations.

2.4.3 Proposed EU MRL,s and compliance with existing MRL,s

Armand Products Company requested a waiver from the need for an MRL for potassium bicarbonate due to its very favourable toxicity profile, registered use as a food additive (E501), its natural presence in living organisms and the environment and the impossibility to differentiate analytically between naturally present potassium and bicarbonate ions and those from Armicarb 85SP. Potassium bicarbonate is also classified as GRAS by the US EPA and has been exempted form residue tolerances by the US EPA.

It would not be possible to establish or to enforce an MRL for potassium bicarbonate associated with its use as a plant protection product due to the natural occurrence of potassium bicarbonate and its breakdown compounds, potassium ion and carbon dioxide. The waiver was accepted.

2.4.4 Basis for differences, if any, in conclusions reached having regard to established of proposed CAC MRL's

Not relevant.

2.5 Fate and behaviour in the environment

2.5.1 Definition of the residue relevant to the environment

No residue definitions are proposed for potassium bicarbonate ($KHCO_3$) for all environmental compartments, as both K^+ and HCO_3^- (plus CO_3^{2-} and H_2CO_3) are naturally occurring in the environment. Indeed, the carbonate equilibria (a natural buffering system in the environment) will regulate concentrations of carbonic acid, bicarbonate or carbonate in aqueous solutions depending upon the system's pH. Therefore the relationships between dissolved carbonate species and pH are as follows: Undissociated acid $[H_2CO_3] > [HCO_3^-]$ for pH <6.4; $[H_2CO_3] < [HCO_3^-] > [CO_3^{2-}]$ for pH 6.4-10.3; $[CO_3^{2-}] > [HCO_3^-]$ for pH > 10.3. With regard to metabolites, the resultant weathering or chemical breakdown of $KHCO_3$ produces substances considered to be of no concern for groundwater. It is likely that any additional $KHCO_3$ input to the environment resulting from the application of Armicarb 85SP will be indistinguishable from naturally present $KHCO_3$.

2.5.2 Fate and behaviour in soil

SOIL METABOLISM

The route of breakdown of $KHCO_3$ in the soil compartment is dissociation to potassium and bicarbonate ions.

$$KHCO_3 \leftrightarrows K^+_{(aq)} + HCO_3^-{}_{(aq)}$$

Depending upon soil type and soil pH bicarbonate will either remain intact or transform to carbonate.

$$HCO_3^-{}_{(aq)} \leftrightarrows H^+ + CO_3^{2-}{}_{(aq)}$$

At low pH values bicarbonate anions will be reduced by free hydrogen ions that ultimately produce water and carbon dioxide that in turn will form carbonic acid. The further dissociation of carbonic acid will in turn release more bicarbonate.

$$HCO_3^-{}_{(aq)} + H^+ \leftrightarrows H_2O + CO_{2(aq)}$$

$$CO_{2(aq)} + H_2O \rightarrow H_2CO_3$$

$$H_2CO_3 \rightarrow H^+ + HCO_3^-{}_{(aq)}$$

In more alkaline soils the bicarbonate anion can remain as the anion or loosely associated with free cations like calcium, magnesium or potassium.

$$Ca^{2+}{}_{(aq)} + 2HCO_3^-{}_{(aq)} \leftrightarrows Ca(HCO_3)_{2(aq)}$$

Overall, bicarbonate anions form part of the natural buffering system in soils through the carbonate equilibria mechanism and, hence, influence the soil pH.

Free potassium (K^+) is an essential nutrient for both plants and soil microorganisms and has a natural cycle in the soil of uptake and utilization by biota. The release of potassium back into soil is from decomposition of dead organisms or the chemical weathering of associated mineral assemblages. In natural soils total potassium concentrations are typically between 10-20 g/kg, with up to 90-98% of total potassium in the soil is in mineral form with <0.2 to 2% of total soil potassium considered to be bioavailable (soluble) and exchangeable.[1] Between 1-10% of total potassium is fixed in the soil. Plants and microorganisms can only readily access the soluble and exchangeable portions of potassium in the soil, which is estimated to be between 150 and 800 mg/kg in agricultural soil. Furthermore, in agricultural soils, it is common practice to supplement natural potassium levels through the application of NPK-based fertilizers.

RATE OF DECLINE IN SOIL

Not relevant for environmental exposure assessment. Potassium bicarbonate dissociates in soil water.

MOBILITY IN SOIL

Not relevant for environmental exposure assessment. Both potassium and bicarbonate are naturally occurring ions in the environment. Indeed, the carbonate equilibria (a natural buffering system in the environment) will enhance the concentrations of carbonic acid, bicarbonate or carbonate in soil depending upon the system's pH, whilst potassium is an essential nutrient for both plants and soil microorganisms and has a natural cycle in the soil of uptake and utilization by biota. Up to 90-98% of potassium in the soil is mineral and approximately 1-10% of remaining potassium is fixed in the soil. Both $KHCO_3$ and its dissociation products are considered not to pose a risk to groundwater quality (WHO standard of 12 mg/L for drinking water) and it is considered a substance of no concern with respect to groundwater based on SANCO/221/2000-rev.10 (2003).

PEC IN SOIL

The supported GAP use of potassium bicarbonate formulated as Armicarb 85SP involves foliar spray applications to vine and apple crops. Potassium bicarbonate is used in the control of fungi, such as vine powdery mildew (*Uncinula necator*) and apple scab (*Venturia inaequalis*). The active substance dissociates in moist soils to liberate the potassium and bicarbonate ions. Plants and microorganisms can only readily access the soluble and exchangeable portions of potassium in the soil, which is estimated to be between 150 and 800 mg/kg in agricultural soil. Initial PECs for these species [potassium and bicarbonate ions] were calculated immediately after a lumped annual application of 40.8 kg a.s./ha [8 x 5.1 kg active substance/ha]. The highest PECs in soil for potassium and bicarbonate ions were 10.6 and 16.6 mg/kg respectively. This represents 1-7 % of the readily accessible portion of potassium in agricultural soil. The bicarbonate dissociation product can transform into other common natural products such as carbon dioxide, carbonate and water.

2.5.3 Fate and behaviour in water

ABIOTIC DEGRADATION

The route of breakdown of $KHCO_3$ in the aquatic compartment is dissociation to potassium and bicarbonate ions.

$KHCO_3 \leftrightarrows K^+_{(aq)} + HCO_3^-{}_{(aq)}$

Both bicarbonate and potassium are naturally occurring compounds that become part of the carbon and potassium cycles in the environment, respectively. Released bicarbonate ions will

[1] Barak, P., 2005, Essential Elements for Plant Growth. University of Wisconsin http://www.soils.wisc.edu/~barak/soilscience326/essentl.htm

participate in the natural carbonate buffering equilibria as outlined below and no further degradation will take place.

$$CO_3^{2-}{}_{(aq)} + 2H^+ \leftrightarrows HCO_3^-{}_{(aq)} + H^+ \leftrightarrows H_2CO_3 \leftrightarrows CO_{2(aq)} + H_2O$$

The pH status of a water body will determine and in turn be determined by the relative proportions of carbonic acid, bicarbonate and carbonate species in solution based on the equilibria of the carbonate system as illustrated by **Figure 2.5.3-1**. The relationships between dissolved carbonate species and pH are as follows: Undissociated acid $[H_2CO_3] > [HCO_3^-]$ for pH <6.4; $[H_2CO_3] < [HCO_3^-] > [CO_3^{2-}]$ for pH 6.4-10.3; $[CO_3^{2-}] > [HCO_3^-]$ for pH > 10.3.

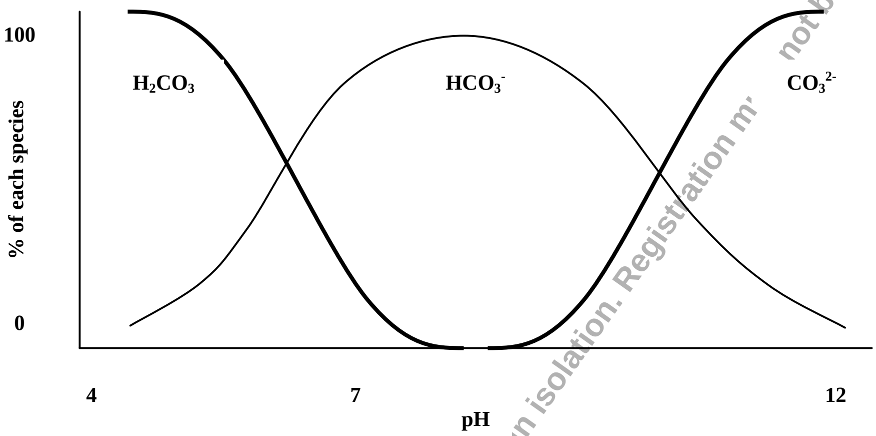


Figure 2.5.3-1: Relationship between dissolved carbonate species and pH in aquatic systems.

Free potassium (K^+) is an essential nutrient for both aquatic plants and microorganisms and has a natural cycle in the soil of uptake and utilization by biota. The release of potassium back into water is from decomposition of dead aquatic organisms or the abiotic weathering of associated minerals. Additional inputs of potassium to natural waters following application of Armicarb 85SP may occur from spraydrift or soil erosion. The typical concentration range of potassium in surface water (rivers) is between 0.5-4.0 mg/L.[2]

BIOLOGICAL DEGRADATION

Pure potassium bicarbonate, in its undissociated form, could be expected to be biodegradable, as based on the carbonate equilibria $KHCO_3$ will not be persistent in the aquatic environment under natural conditions. Therefore, in this sense, $KHCO_3$ may be considered readily biodegradable.

No adverse effects are expected to occur to microorganisms present in water treatment plants following the application of Armicarb 85SP.

PEC IN GROUNDWATER

The active substance may reach groundwater. However, it is highly unlikely to pose a risk to groundwater resources. Potassium bicarbonate dissociates in water to liberate the potassium and bicarbonate ions. The bicarbonate ion can then equilibrate with carbonate and carbonic acid to yield carbon dioxide and water. The other dissolution product, K^+, as previously

[2] Meybeck, M., 1980, Pathways of major elements from land to ocean through rivers. *Proceedings of the Review and Workshop on River Inputs to Ocean-Systems.* Ed. J.-M., Martin, J. D., Burton, and D. Eisma, pp. 18-30. Rome: FAO.

mentioned is an essential macronutrient for plants and microorganisms and has a well-known cycle via the food chain.

PEC IN SURFACE WATER

Given the nature of the active substance it was not considered appropriate to use the FOCUS model to determine PECs for surface waters. Instead, an estimation based on spray drift with no degradation between applications was used. The rate of application was 8 x 6 kg Armicarb 85SP/ha. As previously mentioned, the active substance dissolves in water to liberate potassium and bicarbonate ions. Maximum concentrations of these ions in surface water bodies arising from the use of Armicarb 85SP at a rate of 6 kg/ha (5.1 kg a.s/ha) with no loss of residues were determined to be 5.30 mg/L [potassium] and 8.30 mg/L [bicarbonate] assuming 100 % spray drift. In the presence of a 3 m buffer zone the amount of spray drift from an apple crop reaching a surface water body is reduced 1.55 mg/L [potassium] and 2.42 mg/L [bicarbonate]. In the presence of vine crops the loading to the surface water body was estimated to be lower. The absolute worse case PECs* refer to a static water system and in the case of potassium is comparable to levels observed in free flowing river and is lower than the WHO drinking water standard of 12 mg/L. In the unlikely event of direct overspray, the concentration of potassium ions arising from the use of active substance will be less in a free flowing river due to dilution effects. In addition, potassium is an essential plant and microbial nutrient that has a natural cycle in soil of uptake and utilisation by plants and microbes. Typical levels of bicarbonate in surface waters adjacent to agricultural land are between 100 to 500 mg/L.[3]

2.5.4 Fate and behaviour in air

$KHCO_3$ is not volatile. Carbon dioxide is the main component that would be released to the atmosphere from the dissociation of $KHCO_3$ and from the carbonate equilibria mechanism, which forms part of the natural carbon cycle. However, it is considered that the amounts of CO_2 released to the atmosphere would be minimal following the application of Armicarb 85SP when compared to the natural biological respiration process.

2.6 Effects on non-target species

Potassium and bicarbonate are widely occurring natural inorganic ions present in soils, sediments and water bodies.

Bicarbonate will either remain intact or transform into alkali earth metal carbonates, water and carbon dioxide, depending upon the soil type and acidity. Typical levels found in natural surface waters adjacent to agricultural land are between 100-500 mg/L.

Potassium is an essential macronutrient for plants and micro-organisms and has a well known cycle via the food chain. It is very abundant in soil, although most is not bioavailable. <0.1% is considered to be in solution, 0.1-2.0% exchangeable, 1-10% fixed and 90-98% mineral. Plants and microorganisms can only readily access the soluble and exchangeable portions, although some of the fixed can be released if soil water concentrations become depleted. Extractable potassium in agricultural soil is usually between 150 to 800 mg/kg.

Tests have shown potassium bicarbonate has very low toxicity to fish (LC_{50} 1400-1500 mg/L), *Daphnia* (LC_{50} = 1200 mg/L) and bees (LD50 >24 μg/bee). Although no acute data are

[3] Meybeck, M., 1979, *Concentrations des eaux fluviales en element majeurs et apports en solution aux oceans.* Rev. Geol. Dyn. Georgr. Phys., v. 21, p. 215-246.

available for birds, there is ample evidence that potassium bicarbonate is non-toxic to birds. For example, sodium bicarbonate (and to a lesser extent potassium bicarbonate) is frequently used as feed and drink additive for poultry. It is added at concentrations up to 1% (10,000ppm) without causing any adverse effects.

As potassium and bicarbonate ions are naturally present in the environment and in most living organisms at concentrations much higher than they could be through the use of Armicarb 85SP a waiver was accepted as regards conducting additional toxicity studies on birds, aquatic plants, earthworms, micro-organisms and beneficial organisms.
No adverse effects on the non target organisms within the ecosystems exposed to Armicarb at recommended use rates is considered likely and the environmental loading will not significantly alter natural balances.

APPENDIX 1 - STANDARD TERMS AND ABBREVIATIONS

Part 1 Technical Terms

A	ampere
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
AE	acid equivalent
AFID	alkali flame-ionization detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathie
BSP	bromosulfophthalein
Bt	bacillus thuringiensis
Bti	bacillus thuringiensis israelensis
Btk	bacillus thuringiensis kurstaki
Btt	bacillus thuringiensis tenebrionis
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degree Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DNA
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation

Cv	ceiling value
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DES	diethylstilboestrol
DFR	dislodgeable foliar residue
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic Acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days pot inoculation
DRES	dietary risk evaluation system
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
&	decadic molar extinction coefficient
EC_{50}	median effective concentration
ECD	electron capture detector
ECU	European currency unit
ED_{50}	median effective dose
EDI	estimated daily intake
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EPMA	electron probe micro analysis
ERC	environmentally relevant concentration
ERL	extraneous residue limit
F	field
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FIA	fluorescence immuno assay
FID	flame ionization detector
FOB	functional observation battery
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram
G	glasshouse
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionization detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism

GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPPP	good plant protection practice
GPS	global positioning system
GSH	glutathion
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value) (see also K)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionization detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilization concentration or median inhibitory concentration
ICM	integrated crop management
ID	ionization detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
iv	intravenous
IVF	*in vitro* fertilization
k	kilo
K	Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole) (see also H) [1]
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
kg	kilogram
L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC_{Lo}	lethal concentration low

LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LD_{Lo}	lethal dose low
LDH	lactate dehydrogenase
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
m	micrometer (micron)
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
g	microgram
mg	milligram
MHC	moisture holding capacity
min	minute(s)
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
mo	month(s)
mol	Mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
n	normal (defining isomeric configuration) or number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometer
NMR	nuclear magnetic resonance
no	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend

NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OM	organic matter content
op	organophosphorous pesticide
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the dissociation constant)
PNEC	predicted no effect concentration
po	by mouth
P_{OW}	partition coefficient between n-octanol and water
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	prothrombin time
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RBC	red blood cell
REI	restricted entry interval
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase

rpm	rotations per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
sq	square
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STMR	supervised trials median residue
t	tonne (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TC_{Lo}	toxic concentration, low
TID	thermionic detector, alkali flame detector
TD_{Lo}	toxic dose low
TDR	time domain reflectrometry
TER	toxicity exposure ration
TER_I	toxicity exposure ration for initial exposure
TER_{ST}	toxicity exposure ration following repeated exposure
TER_{LT}	toxicity exposure ration following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TOC	total organic carbon
Tremcard	Transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)

TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
$<$	less than
$\leq$	less than or equal to
$>$	greater than
$\geq$	greater than or equal to

Part 2 Organisations and Publications

ACPA	American Crop Protection Association
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
CA	Chemical Abstracts
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food
CE	Council of Europe
CIPAC	Collaborative International Pesticides Analytical Council Ltd
COREPER	Comite des Representants Permanents
EC	European Commission
ECB	European Chemical Bureau
ECCA	European Crop Care Association
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
ECLO	Emergency Centre for Locust Operations
ECMWF	European Centre for Medium Range Weather Forecasting
ECPA	European Crop Protection Association
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EHC (number)	Environmental Health Criteria (number)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GIEWS	Global Information and Early Warning System for Food and Agriculture
GRIN	Germplasm Resources Information Network

HRAC	Herbicide Resistance Action Committee
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
IBT	Industrial Bio-Test Laboratories
ICBB	International Commission of Bee Botany
ICBP	International Council for Bird Preservation
ICES	International Council for the Exploration of the Seas
ICPBR	International Commission for Plant-Bee Relationships
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
IRC	International Rice Commission
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides (WHO/FAO)
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)
NATO	North Atlantic Treaty Organisation
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Centre for Toxicological Research (USA)
NGO	non-governmental organization
NTP	National Toxicology Programme (USA)
OECD	Organization for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
PAN	Pesticide Action Network
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SCPH	Standing Committee on Plant Health
SETAC	Society of Environmental Toxicology and Chemistry
SI	Systeme International d'Unites
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UN	United Nations
UNEP	United Nations Environment Programme
WCDP	World Climate Data Programme
WCP	World Climate Programme
WCRP	World Climate Research Programme
WFP	World Food Programme
WHO	World Health Organization
WTO	World Trade Organization
WWF	World Wildlife Fund

APPENDIX 2 - SPECIFIC TERMS AND ABBREVIATIONS

Cont'd.	continued

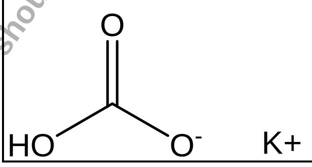
APPENDIX 3 - Listing Of Endpoints

Chapter 2.1 Identity, Physical and Chemical Properties, Details of Uses, Further.

Common name (ISO)	Potassium bicarbonate
Function	Fungicide

Rapporteur Member State	Ireland

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Potassium hydrogen carbonate
Chemical name (CA) ‡	Carbonic acid, monopotassium salt
CIPAC No ‡	*Not applicable*
CAS No ‡	298-14-6
EC No (EINECS or ELINCS) ‡	206-059-0 (EINECS)
FAO Specification (including year of publication) ‡	Not applicable
Minimum purity of the active substance as manufactured ‡	>99.5% minimum
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	*None*
Molecular formula ‡	$KHCO_3$
Molecular mass ‡	100.12 g/mol
Structural formula ‡	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Potassium bicarbonate does not melt (>99.5%)
Boiling point (state purity) ‡	Potassium bicarbonate does not boil (>99.5%)
Temperature of decomposition (state purity)	> 156ºC.
Appearance (state purity) ‡	White crystalline solid (>99.5%)
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 bicarbonate 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)	Historically, potassium bicarbonate and potassium carbonate have been identified and quantified by acid-base titration. The methods used are quick, accurate, precise, internationally approved and validated, precluding the need for developing spectroscopy-based analytical techniques. Therefore, no UV/Vis, IR, MS or NMR spectra are available.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	Not photolytically active.
Quantum yield direct phototransformation in water at λ > 290 nm	Not applicable. Potassium bicarbonate is not photolytically active.
Flammability ‡ (state purity)	Not flammable.
Explosive properties ‡ (state purity)	Not explosive.
Oxidising properties ‡ (state purity)	Not oxidizing.

Summary of intended uses supported by available data [Ref. Doc. D-1]
Summary of representative uses evaluated

Pesticide common name: Potassium bicarbonate
Trade name of PPP: Armicarb 85SP
Main use: Fungicide
Country: All European member states

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)	g as/hL min – max (l)	water L/ha min – max	g 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)	(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(i) g/kg or g/l
(c) e.g. biting or suckling insects, soil borne insects, foliar fungi, weeds	(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
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	
(e) GCFP Codes – GIFAP Technical monograph No 2, 1989	(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(f) All abbreviations used must be explained	(l) PHI – minimum pre-harvest interval
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drenching	(m) Remarks may include: Extent of use/economic importance/restrictions

Chapter 2.2 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)	None.
Plant protection product (analytical technique)	Acid-base titration

Analytical methods for residues (Annex IIA, point 4.2)

Food of plant origin		A waiver for analytical methods for residues is requested in view of physico-chemical, toxicological, ecotoxicological and environmental fate properties of active substance and formulated material. **Safety profile of potassium bicarbonate:** Potassium bicarbonate is approved for food use in Europe and has been assigned a food additive number of E501 (raising agent). Potassium bicarbonate is also listed for food use in the internationally recognized "Food Chemicals Codex" **Impossibility to differentiate analytically between synthetic potassium bicarbonate and naturally present potassium and bicarbonate:** Potassium bicarbonate is a natural component of soil and therefore cannot be distinguished from existing potassium and bicarbonate ions in the soil. Potassium bicarbonate 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 bicarbonate should not act any differently than the potassium bicarbonate already present in the environment.
Food of animal origin		See statement above
Soil		See statement above
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)	See statement above
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)	See statement above

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

	RMS/peer review proposal
Active substance	Potassium bicarbonate 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 ‡	Sexes combined: 2825 mg/kg bw/day Males: 3706 mg/kg bw/day Females: 2064 mg/kg bw/day	R22
Rat LD_{50} dermal ‡	>2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 4.88 mg/L (whole body)	
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 @ 2% and 4% of diet for 4- and 13-weeks in rats. Urinary bladder hyperplasia @ 2.5% and 5% of diet for 13 weeks in rats.	
Lowest relevant oral NOAEL / NOEL	Not relevant (2 dose study)	
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	Potassium bicarbonate is unlikely to be genotoxic	

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	Not relevant (2 dose study): 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 man	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	No data –not relevant	
Relavant parental NOAEL	No data –not relevant	
Relavant reproductive NOAEL	No data –not relevant	
Relavant offspring NOAEL	No data –not relevant	

Developmental toxicity

Developmental target / critical effect	Summary review only submitted. No developmental toxicity potential identified	
Relavant maternal NOAEL	-	
Relavant developmental NOAEL	-	

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data-not required	
Repeated neurotoxicity ‡	No data-not required	
Delayed neurotoxicity ‡	No data-not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	State which study that was performed and in what species and the outcome, if applicable also the NOAEL and LOAEL.
	No data – not 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 ‡	128 mg/kg bw/day	Based on the NDR (normal daily requirement) for potassium ion	Not required
AOEL ‡	128 mg/kg bw/day	Based on the RDA for potassium ion	Not required
ARfD ‡	128 mg/kg bw/day	Based on the RDA for potassium ion	Not required

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation: Armicarb 85 SP	No data – default values used: 10% dermal absorption from concentrate 1% for penetration through gloves 100% dermal absorption from spray dilution

Exposure scenarios (Annex IIIA, point 7.2)

Operator	The estimated exposure for Armicarb 85 SP according to the German model (application rate 5100 kg a.i./ha) was below the AOEL, with and without PPE . The estimated exposure for Armicarb 85 SP according to the UK POEM model (application rate 5100 kg a.i./ha) was below the AOEL with and without PPE.
Workers	No risk identified for proposed uses (German re-entry exposure estimate 6.83% of AOEL without PPE).
Bystanders	Acceptable for proposed uses

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

	RMS/peer review proposal
Potassium bicarbonate	**No Classification required.**

Chapter 4: Residues

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

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

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

Animals covered	Not appropriate and not scientifically appropriate. The use of the plant protection product is indistinguishable from naturally occurring residues present in any treated crop.
Time needed to reach a plateau concentration in milk and eggs	
Animal residue definition for monitoring	
Animal residue definition for risk assessment	
Conversion factor (monitoring to risk assessment)	
Metabolism in rat and ruminant similar (yes/no)	
Fat soluble residue: (yes/no)	

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

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

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

	Not relevant.
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no – if yes , specify the level.)	
Potential for accumulation (yes/no):	
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	
Muscle	
Liver	
Kidney	
Fat	
Milk	
Eggs	

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 or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
No critical residue data known for potassium bicarbonate.						

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 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)

ADI	
TMDI (% ADI) according to WHO European diet	Not applicable. The use of the plant protection product is indistinguishable from naturally occurring residues present in any treated crop.
TMDI (% ADI) according to national (to be specified) diets	Not applicable. The use of the plant protection product is indistinguishable from naturally occurring residues present in any treated crop.
IEDI (WHO European Diet) (% ADI)	Not required
NEDI (specify diet) (% ADI)	Not required
Factors included in IEDI and NEDI	Not required
ARfD	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

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Not required				

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

None required. The use of the plant protection product is indistinguishable from naturally occurring residues present in any treated crop

Chapter 2.5: Fate and Behaviour in the Environment

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

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

Soil adsorption/desorption
(Annex IIA, point 7.1.2)

	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)

	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 bicarbonate 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 average	Multiple application actual		Multiple application actual
			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 bicarbonate 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 bicarbonate 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 bicarbonate 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)

Direct photolysis in air	Not applicable. Potassium bicarbonate is not volatile and does not degrade in air.
Quantum yield of direct phototransformation at λ > 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 bicarbonate 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 bicarbonate is not volatile

List of studies submitted.

Waivers were requested by the notifier for potassium bicarbonate for all environmental fate studies. This was granted by the RMS as potassium bicarbonate is a natural component of the environment. Inputs from the use of Armicarb 85SP are expected to be negligible compared with natural background levels.

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)

Acute toxicity to mammals	2064 mg Armicarb/kg
Reproductive toxicity (2 generation) to mammals	No data

Effects on birds (Annex IIA, point 8.1, Annex IIIA, point 10.1)

Estimated maximum consumption of potassium bicarbonate by small insectivorous bird following worst-case applications of Armicarb 85SP.

Scenario	Dose kg a.s./ha	FIR /bw	RUD (90%)	ETE mg/kg insect	ETE* mg/kg bw/d
Acute	5.1	1.04	52	265	276
Short-term	5.1	1.04	29	148	154
Long-term	5.1	1.04	29	148	154

Given that food supplements were fed to chicken over long periods of time TER_{ST} and TER_{LT} based on 10,000 mg/kg diet concentration seem appropriate. Assuming the lowest weight of chickens fed the diet was 250g then the intake is equivalent to 2,500 mg/kg bw/d.

$$TER_{LT} = 2,500 / 154 = 16.2$$

In conclusion, the application of Armicarb 85SP is very unlikely to present a significant hazard to birds.

Toxicity data for aquatic species (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Laboratory tests				
Rainbow Trout	$KHCO_3$	Acute toxicity (96 h) – flow-through	LC_{50} (96 h)	1400
Bluegill Sunfish	$KHCO_3$	Acute toxicity (96 h) – flow-through	LC_{50} (96 h)	1500
Daphnia magna	$KHCO_3$	Acute toxicity (48h) – flow-through	EC_{50}(48 h)	1200

Toxicity/exposure ratios (TER_A) for the most sensitive aquatic organisms (Annex IIIA, point 10.2) (Annex IIA 8.2.1.1, Annex IIIA 10.2.1/01, Annex IIA 8.2.1.2, Annex IIIA 10.2.1/02; Annex IIA 8.3.1.1, Annex IIIA 10.2.1/03) where PEC_{sw} for overspray is 13.6 mg/L, Apples with a 3m buffer is 3.97 mg/L, and Vines with a 3m buffer is 1.088 mg/L

Category	Endpoint (mg a.s.'s/L)	TER_A overspray	TER_A 3m buffer apples	TER_A 3m buffer vines
Rainbow Trout	1400	103	353	1287
Bluegill Sunfish	1500	110	378	1379
Daphnia magna	1200	88	302	1103

Bioconcentration

No data

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

Test substance	Acute oral toxicity (LD50 µg/bee)	Acute contact toxicity (LD50 µg/bee)
$KHCO_3$	No data	>24

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

Exposure route	Test substance	Application - scenario	Maximum single application [kg as/ha]	LD_{50} [µg/bee]	Hazard quotient Q_{HO}/Q_{HC}	Q_H Annex VI trigger
Contact	$KHCO_3$	Apples and vines	5.100	>24	**212**	50

A slight risk to bees is indicated in this risk assessment since the test levels used did not allow determination of an LD_{50} value. In field studies reported no apparent adverse effects were observed on bees within treated fields.

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

Species	Test Substance	End point	Effect (LR_{50} g a.s./ha)
No Data			

Further laboratory and extended laboratory studies

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	% effect	Trigger value
No data					

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)

Test organism	Test substance	Time scale	End point
Earthworms			
No data			
Collembola			
No data			
Soil micro-organisms			
No data.			
Potassium and bicarbonates ions are natural soil components non toxic to soil micro-organisms. Worst case use of Armicarb 85SP will not significantly change the natural concentrations of potassium or bicarbonate in soils.			

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

Preliminary screening data

No data

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

Test type/organism	No data
Activated sludge	
End point - 3 hr EC 50	

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

	RMS/ proposal *
Potassium bicarbonate	No classification proposed

	RMS/ proposal *
Armicarb 85SP	No classification proposed

3 PROPOSED DECISION WITH RESPECT TO THE APPLICATION FOR INCLUSION OF THE ACTIVE SUBSTANCE IN ANNEX 1.

3.1 Background to the proposed decision

The fungicide, Potassium bicarbonate, has been supported for use as an agrochemical on two crops, apples and grapes. A full data package was presented which satisfies the data requirements necessary to support Annex I inclusion for Potassium bicarbonate. At this point there are no further data requirements.

Very little data exist on the specific toxicokinetics of potassium bicarbonate and potassium carbonate (because volumes have been written on potassium itself and the bicarbonate-carbonate buffer system of the mammalian organism).
Sodium bicarbonate is rapidly absorbed in both humans and animals after oral, intravenous or intraperitoneal administration.
Potassium bicarbonate is of low acute toxicity (oral, dermal and inhalation). No dermal reactions were noted after application of potassium bicarbonate to the skin of rabbits. Significant conjunctival irritation occurred in the rabbit eye which reversed within 7 days. In a Buehler test, no skin sensitisation was observed.
There is no evidence of gentoxic potential from any of the studies presented.
The RMS can agree with the conclusion of the notifier that based upon a review of the toxicology, pathology, and related studies, food grade potassium bicarbonate does not represent a carcinogenic risk to humans from the pesticidal use proposed.
A review of the status of sodium bicarbonate with respect to reproductive toxicity was considered relevant to this point. The current US FDA GRAS report (1975) was referred to in which a number of studies were considered. It was concluded that there was no risk to man from possible reproductive toxicity arising from pesticidal use of potassium bicarbonate.

Due to the medical usage of potassium bicarbonate, there is no need to set an Acceptable Daily Intake.
Due to the low acute toxic potential of potassium bicarbonate, the allocation of an ARfD was not considered relevant.
No NOEL has been established in the studies reported in literature for potassium bicarbonate (Church & Dwight Co-Anonymous 1, 1994).
Since the active ingredient is rapidly disassociated in the mammalian organism to the cation and the anion, it is appropriate to set the AOEL at the Normal Daily Requirement of the most "critical" ion which is potassium (bicarbonates daily intakes are proportionally higher because sodium bicarbonate is widespread).
The Normal Daily Requirement for potassium, established by the medical authorities, is 3.5 g K/day for the adult.
As this Normal Daily Requirement for potassium is established in human, there is no need to apply a Safety Factor. Therefore the AOEL is proposed at 3.5 g Potassium/day, corresponding to 8.96 g Potassium Bicarbonate/day and to **128 mg potassium bicarbonate/kg/day.**

Potassium bicarbonate dissociates in solution in terrestrial and aquatic compartments in the environment to potassium (K) and bicarbonate (HCO_3^-) ions. Both ions naturally occur in terrestrial, aquatic and atmospheric compartments and are associated with natural mineral cycling in the environment. K is present in the environment as either an inorganic mineral compound or as a charged cation (K^+), and with regard to agriculture is an essential mineral for both plants and animals. Released HCO_3^- participates in the carbonate equilibria (a natural buffering system in the environment) and will regulate concentrations of carbonic acid, bicarbonate or carbonate in aqueous solutions depending upon the system's pH ($CO_3^{2-}{}_{(aq)} + 2H^+ \leftrightarrows HCO_3^-{}_{(aq)} + H^+ \leftrightarrows H_2CO_3 \leftrightarrows CO_{2(aq)} + H_2O$). With regard to metabolites, the resultant

weathering or chemical breakdown of $KHCO_3$ produces substances considered to be of no concern for groundwater.
Overall, it is concluded that at the proposed level of use of potassium bicarbonate ($KHCO_3$) no adverse impacts are expected or anticipated for all environmental compartments.

Aquatic organisms may be exposed to Potassium bicarbonate via entry into surface water following spray drift, run-off and drainage from treated fields adjacent to the water body. The acute risk was assessedusing studies performed on Rainbow Trout, Bluegill Sunfish & *Daphnia magna*. All of the resulting TER values for aquatic organisms were higher than the relevant trigger values, indicating negligible acute risk to such organisms when the substance is used according to good agricultural practice.

Potassium bicarbonate has no unacceptable adverse effects on bees. A slight risk to bees is indicated in this risk assessment since the test levels used did not allow determination of an LD_{50} value. In field studies reported no apparent adverse effects were observed on bees within treated fields.
No effects are expected at the residue levels predicted in off-field areas, therefore, no buffer or use restrictions are required to provide adequate protection to the off-crop species.

The acute and chronic risk to earthworms and other soil non-target macro-organisms was also investigated, as well as the possible effects on organic matter breakdown in the field (litter-bag study). The results indicated that under practical use conditions in the field, the long-term risk to earthworms and other soil macro-organisms was considered acceptable and Potassium bicarbonate poses negligible risk to decomposition processes.

Potassium and bicarbonates ions are natural soil components non-toxic to soil micro-organisms. Worst case use of Armicarb 85SP will not significantly change the natural concentrations of potassium or bicarbonate in soils.

Potassium bicarbonate is not a herbicide so detrimental effects on non-target plants are not expected.

Overall, based on the data package submitted, it is concluded that at the proposed level of use, Potassium bicarbonate should not have any unacceptable adverse effects on non-target organisms. Therefore, no further data is required.

3.2. Proposed decision concerning inclusion in Annex I.

[redacted]

3.3. Rationale for the conditions and restrictions to be associated with a proposed inclusion in Annex I.

[redacted]

The information in sections 3.2 and 3.3 has been removed upon request by the EU Commission as it relates to risk management recommendations or proposals.

4 FURTHER INFORMATION TO PERMIT A DECISION TO BE MADE OR TO SUPPORT A REVIEW OF THE CONDITIONS AND RESTRICTIONS ASSOCIATED WITH THE PROPOSED INCLUSION IN ANNEX 1.

Overall comment

The applicant must submit a copy of all data, comments and clarifications, provided to the Rapporteur Member State, to all Member States, the EU Commission (DG SANCO) and to EFSA.

4.1 Identity of the active substance.

No data required.

4.2 Physical and chemical properties

4.2.1. Physical and chemical properties of the active substance.

No data required.

4.2.2. Physical and chemical properties of the plant protection product.

No data required.

4.3 Data on application and further information.

No data required.

4.4 Classification, packaging and labelling

No data required.

4.5. Methods of analysis.

No data required.

4.6 Toxicology and metabolism.

No data required.

4.7 Residue data.

No data required.

4.8 Environmental fate and behaviour

No data required.

4.9 Ecotoxicology

No data require