

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**

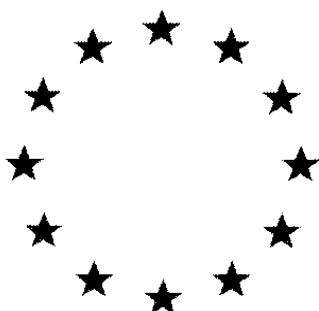
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European Union

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 3 Annex B

to the Draft Report and Proposed Decision

Rapporteur Member State's summary, evaluation and
assessment of the data and information

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Pesticide Control Service
Department of Agriculture and Food Laboratories
Backweston Campus
Young's Cross, Celbridge,
Co. Kildare, Ireland

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B RAPPORTEUR MEMBER STATE'S SUMMARY, EVALUATION AND ASSESSMENT OF THE DATA AND INFORMATION SUBMITTED.

B.1 IDENTITY

B.1.1 Identity Of The Active Substance. {Annex IIA 1 And 3.1}

This was addressed in Level 1.

Common name and synonyms:

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

Chemical name

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

Manufacturers development code number None

Active substance

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

Formulations

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

CAS, EU and CIPAC numbers {IIA 1.6}

CAS:	298-14-6
EEC:	206-059-0 (EINECS)
CIPAC:	not available
ELINCS:	not available

B.1.2 Identity Of The Plant Protection Products. {Annex IIIA 1}

This was addressed in Level 1.

B.1.3 References Relied On.

None.

B.2 PHYSICAL AND CHEMICAL PROPERTIES.

B.2.1 Physical And Chemical Properties Of The Active Substance {Annex IIA, 2}

See Volume 1

B.2.2 Physical, Chemical And Technical Properties Of The Plant Production Products {IIIA 2}

See Volume 1

B.2.3 Evaluation And Assessment

B.2.3.1 Active substance.

See Volume 1 & Volume 4

B.2.3.2 Plant protection properties.

See Volume 1 & Volume 4

B.2.4 References Relied On

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., GLP status (where relevant) published or not	Data protect. claimed	Owner

B.3 DATA ON APPLICATION AND FURTHER INFORMATION

B.3.1 Further Information On The Active Substance

B.3.1.1 Mode of Action

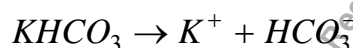
Fungicide. Potassium bicarbonate mainly inhibits fungus mycelium development. Its mode of action is linked with osmotic pressure, pH and specific bicarbonate/carbonate ion effects. As a consequence of such mode of action it has to be applied preventively.

B.3.1.2 Biochemical and physiological mechanism(s) and biochemical pathways involved

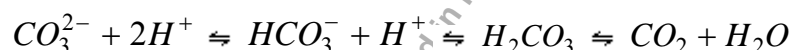
Not relevant.

B.3.1.3 Formation of Active Metabolites

Potassium bicarbonate spontaneously dissociates to its respective ions when dissolved in water:



HCO_3^- is amphoteric and will then participate in natural carbonic acid equilibria:



B.3.1.4 Information on the possible occurrence of the development of resistance or cross-resistance

The mode of action of Armicarb is not site specific and is therefore very unlikely to result in the development of resistance and/or to be cross resistant with other currently registered active ingredients (Grove, G, Nelson, M & Xiao, C-L. 2005 – Stewardship of powdery mildew fungicides in perennial crops.). However, in order to avoid any risk of resistance, it is proposed to rotate Armicarb with fungicides with other modes of action (e.g. sulphur, copper, triazoles etc) during the same season.

B.3.2 Data On Application And Further Information On The Plant Protection Product

B.3.3 Summary Of Data On Application

B.3.4 Further Information On The Active Substance

B.3.5 Further Information On The Plant Protection Products {Annex III A 4.1}

B.3.5.1 Packaging (type, materials, size etc.), compatibility on the preparation with proposed packaging materials (Annex IIIA 4.1)

B.3.5.1.1 Description of the packaging:

Polyethylene bags into sealed polyethylene tubs.

Armicarb is not currently marketed in the EU and packaging size and type have not been decided yet.

B.3.5.1.2 The suitability of the packaging, including closures

Potassium bicarbonate has been shipped for decades in polyethylene bags for numerous industrial markets without incident. The polyethylene bag will not react with potassium

bicarbonate. Over-packaging the polyethylene bag into a sealed polyethylene tub prevents tearing of the bag and contamination/reaction of potassium bicarbonate with other substances.

B.3.5.1.3 The resistance of the packaging material to its contents

See above.

B.3.5.2 Procedures for cleaning spray equipment and protective clothing

At the end of the application, spray until empty on the treated plot. Fill up with clean water, agitate and spray until empty again. Check for solid residues. Rinse the equipment several times with clean water and properly dispose of rinse water, preferably on the treated plot. Periodically check for blocked filters. Clothes can be washed in normal water and soap.

B.3.5.3 Re-entry and withholding periods

B.3.5.3.1 Withholding period between application and harvest:

Given the safety profile of potassium bicarbonate, the minimum pre-harvest interval, i.e. 1 day, is requested.

Re-entry period (in days) for livestock, to areas to be grazed:

Not applicable: Armicarb 85SP is not intended for use on areas to be grazed.

B.3.5.3.2 Re-entry period (in hours or days) for man to crops, buildings or spaces treated:

Given the safety profile of potassium bicarbonate, a zero-day re-entry period is requested for man.

B.3.5.3.3 Withholding period (in days) for animal feedingstuffs:

Not applicable. Armicarb 85SP is not intended for use on animal feeding crops.

B.3.5.3.4 Waiting period (in days) between application and handling treated products:

Given the safety profile of potassium bicarbonate, a zero-day waiting period is requested. Treated products can be handled as soon as spray mist has dried.

Waiting period between application and sowing or planting of succeeding crops:

Not applicable as approval is sought for perennial crops only.

B.3.5.3.5 Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used:

The action of Armicarb 85SP on pest fungi is one of contact. As the active ingredient (KHCO_3) is highly soluble in water, it should not be applied when rain is expected. Avoid wind drift onto neighboring crops.

B.3.5.4 Recommended methods and precautions concerning: handling, storage, transport or fire

B.3.5.4.1 Handling and storage

B.3.5.4.1.1 Warehouse storage:

Keep containers tightly closed in a dry, cool and well-ventilated place, away from food or feed. Product is slippery when wet. Direct exposure to prolonged high humidity or other moist/damp conditions may cause product to cake.

Please refer to Safety Data Sheet (Document H)

B.3.5.4.1.2 User-level storage:

Keep containers tightly closed in a dry, cool and well-ventilated place, away from food or feed. Product is slippery when wet. Direct exposure to prolonged high humidity or other moist/damp conditions may cause product to cake.

Please refer to Safety Data Sheet (Document H)

B.3.5.4.1.3 Hazards identification: None**B.3.5.4.1.4 Protective Equipment:****B.3.5.4.1.4.1 Protective clothing:**

Storage & transport – not applicable.

Fire fighting – normal fire-fighting clothing

B.3.5.4.1.4.2 Respiratory equipment:

Storage & transport – not applicable.

Fire fighting – normal fire-fighting equipment.

B.3.5.4.1.5 Information on combustion products likely to be generated in the event of a fire:

Armcarb 85SP contains 85 % potassium bicarbonate, a non-flammable substance which will not react with fire. The remaining 15 % consist of substances, which may release harmful substances such as the following gases in the event of a fire:

- Carbon dioxide
- Sulfur oxides
- Potassium oxide

Firefighters should wear fire-fighting gear (full Bunker gear), including approved self-contained breathing apparatus with full-face piece operated in the pressure demand or other positive pressure mode.

B.3.5.4.1.6 Procedures to minimize the generation of waste:

Always calculate the appropriate quantity required to treat a crop. Do not prepare too much diluted spray. Dispose of leftover diluted spray by spraying onto a suitable plot of land, if possible on the treated crop.

Dispose of packaging according to local / regional / national procedures after having made it unusable.

B.3.5.4.2 Transport

Armcarb 85SP is not classified as dangerous in the meaning of transport regulations.

B.3.5.4.3 Fire

Armcarb 85SP is not classified as flammable. Armcarb 85SP does not burn. Use extinguishing media appropriate for surrounding fire.

B.3.5.5 Emergency measures in case of an accident

Cover powder spill with plastic sheet or tarpaulin to minimize spreading and dust generation. Scoop up or vacuum into a container for reclamation or disposal. Avoid stirring up dust. Flush area thoroughly with water. Prevent flushing water from entering drains or contaminating surface water. Solutions may create slippery surfaces. Make sure surface is slip-free before reopening to traffic.

Dispose of in landfill according to local environmental regulations.

Inhalation exposure:

Remove from exposure to fresh air. Treat symptomatically.

Skin contact:

Remove contaminated clothing. Flush skin with large amounts of water. Obtain medical attention if irritation develops.

Eye contact:

Irrigate immediately with water for 10 - 15 minutes. Obtain medical attention if irritation persists.

Ingestion:

If swallowed, do not induce vomiting. If person is conscious, give water to drink. Never give anything orally to an unconscious person. Seek medical attention.

B.3.5.6 Procedures for destruction or decomposition of the plant protection product and its packaging**B.3.5.6.1 Packaging:**

Armcarb 85SP is packaged in polyethylene bags, which can be incinerated under, controlled conditions

B.3.5.6.2 Adsorbents:

Armcarb 85SP is a solid and does not require adsorbing materials in the event of spillage. Scoop up or vacuum into a container for reclamation or disposal. Dispose of as non-hazardous waste.

B.3.5.6.3 Other materials:

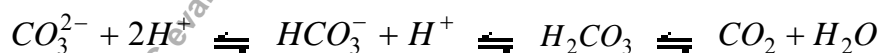
Armcarb 85SP is not acutely toxic and can be safely rinsed out with water and soap. In the event of damage, please wash the damaged item with soap and water prior to disposal according to the item's disposal regulations.

B.3.5.6.4 Possibility of neutralization

Not applicable.

Armcarb 85SP contains 85% potassium bicarbonate. In case of dry spill, scoop up or vacuum into a container for reclamation or disposal. Dispose of as non-hazardous waste or according to local / regional / national regulations.

Potassium bicarbonate is soluble in water and will rapidly dissociate to K^+ and HCO_3^- which will then equilibrate spontaneously with free hydrogen ions present in water and become part of the natural carbon cycle:



Potassium bicarbonate is mildly alkaline, with strong buffering properties. pH will be locally buffered at around 8 – 9 until dilution effects return it to normal.

These procedures also apply to large spills.

B.3.5.6.5 Controlled incineration

B.3.5.6.6 Detailed instructions for safe disposal of the plant protection product and its packaging

Armcarb 85SP contains potassium bicarbonate which, if disposed of as received, is a non-hazardous waste. Local disposal laws and regulations will determine the proper waste disposal / recycling / reclamation procedure.

Armcarb 85SP can be disposed of in landfill.

Packaging can be incinerated.

B3.5.7 Safety data sheet

See document H

B.3.5.7.1 Pyrolytic behaviour of the active substance, Potassium bicarbonate under controlled conditions 800°C and the content of polyhalogenated dibenzo-p-dioxins in the products of pyrolysis

Above 156°C, potassium bicarbonate spontaneously decomposes to potassium carbonate, carbon dioxide and water. Potassium bicarbonate does not contain halogenated compounds or aromatic cycles. Controlled incineration will not result in the production of dioxins or furans. Other ingredients in Armcarb 85SP do not contain halogenated compounds however they may release sulfur oxides.

B.3.5.7.2 Methods other than controlled incineration for disposal of the active substance, contaminated packaging and contaminated materials

See B.3.5.6. above

B.3.6 References Relied On

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., GLP status (where relevant) published or not	Data protect. claimed	Owner

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B.4 PROPOSALS FOR CLASSIFICATION AND LABELLING**B.4.1 Proposals For The Classification And Labelling Of The Active Substance** (Annex IIA 10)**Physical/Chemical Effects**

Hazard symbol: None
 Indication of danger: None
 Risk phrases: None
 Safety phrases: None

Toxicological effects:

Hazard symbols: None
 Indication of danger: None
 Risk phrases: None
 Safety phrases: S2, 13, 39, 46,

Ecotoxicological Effects:

Hazard symbol None
 Indication of danger None
 Risk phrases None
 Safety phrases S61

B.4.2 Proposals For The Classification And Labelling Of Preparations (Annex IIIA 12.3 and 12.4)**Armcarb 85SP :**

Hazard symbol: None
 Indication of danger: None
 Risk phrases: None
 Safety phrases: S2, 13, 39, 46,

B.4.3 References Relied On

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
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B.5 METHODS OF ANALYSIS

B.5.1 Analytical Methods For Formulation Analysis. (Annex II 4.1, Annex IIIA 5.1)

B.5.1.1 Analytical methods for the determination of the pure active substance in the active substance as manufactured. (Annex IIA, 4.1)

See Volume 4 Annex C

B.5.1.2 Determination of isomers and toxicologically and ecotoxicologically significant impurities in the a.s. (IIA 4.1)

None.

B.5.1.3 Analytical methods for the determination of impurities present in the active substance as manufactured.

See Volume 4 Annex C.

B.5.1.4 Analysis of active substance in plant protection products (Annex IIIA 5.1)

See Volume 4 Annex C.

B.5.2 Analytical Methods (Residues) For Food And Feed (Annex IIA 4.2.1; Annex IIIA 5.2.1)

B.5.2.1 Food of plant origin

A waiver was requested for residue analysis methods.

B.5.2.2 Food of animal origin

A waiver was requested for residue analysis methods.

B.5.3 Soil

A waiver was requested for residue analysis methods.

B.5.4 Water

A waiver was requested for residue analysis methods.

B.5.5 Air

A waiver was requested for residue analysis methods.

B.5.6 Residues In Body Fluids And Tissue

A waiver was requested for residue analysis methods.

B.5.7 Evaluation And Assessment

See Volume 1.

B.5.8 References Relied On

Annex point/reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., GLP status (where relevant) published or not	Data protect. claimed	Owner

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company name, Report No., GLP status (where relevant) published or not	Data protect. claimed	Owner
IIA 4.2.1/03	Anonymo us	2004	The United States Pharmacopoeia 1511/Official Monographs/Potassium No report number Not GLP Published	N	Public
IIA 4.2.1/04	Anonymo us	2004	The United States Pharmacopoeia 2202/Limit Tests/Arsenic/{211} No report number Not GLP Published	N	Public
IIA 4.2.1/05	Anonymo us	2004	The United States Pharmacopoeia 2204/Limit Tests/Heavy Metals/{231} No report number Not GLP Published	N	Public
IIA 4.2.1/02	Church & Dwight Company Inc.	1994	Product chemistry: Armicarb™ Potassium Bicarbonate F.C. Church & Dwight Company Inc. No report number Not GLP Unpublished	Y	Armand Products Compan y
IIA 4.2.1/01	Olexa S	1997	Validation of the Analytical Method for the Quantitation of Potassium Bicarbonate Active Ingredient Benchmark Analytics, Center Valley, PA, USA Report number CD0497-1 GLP Unpublished	Y	Armand Products Compan y