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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B 9. ECOTOXICOLOGY

Armicarb 85SP is a foliar fungicide for application to vines and apples. It contains 85% w/w potassium bicarbonate as the active ingredient. The worst case use recommendation (critical GAP) is **6 kg Armicarb/ha applied 8 times a season** with a minimum interval of 10 days. Applications can start from the first appearance of the foliage until just before harvest.

B9.1 Effects On Birds (Annex IIA, 8.1; Annex IIIA, 10.1)

Waivers are requested for standard avian toxicity studies due to the following reasons:

- Potassium and bicarbonate are extremely common in all natural systems, including water, soil, plant and animal tissues.
- Potassium bicarbonate and Armicarb 85SP have extremely low toxicities in mammals.
- Poultry are often fed bicarbonates (usually sodium bicarbonate) as a supplement at 0.2% (2,000 mg/kg) but it has been shown to have no negative effects at rates up to 1% (10,000 mg/kg) in the diet (see below).
- Bicarbonate is not harmful to animals unless consumed in extremely high quantities and is widely used as a buffering agent to reduce stomach acidity.
- Potassium is an essential plant nutrient and is often applied to crops as both a soil and/or foliar fertiliser.
- Potassium bicarbonate is an approved food additive in the EU (E501) and is also listed as a food additive by CODEX Alimentarius.
- Potassium bicarbonate is Generally Regarded As Safe (GRAS) by the US FDA.
- The recommended daily allowance for potassium is usually considered as being 3.5 g/d in humans.
- Total inputs of potassium from the worst-case usage of Armicarb are also considerably lower than those resulting from the use of potash based liquid fertilisers (please refer to Document M, Point IIA 6, point 8.1)

A report reviewing some studies on the use of sodium bicarbonate as a food additive is summarised below.

B9.1.1
Report:

Environ Corp.. (1993): Safety of Sodium Bicarbonate Supplementation of Animal Feeds.

Four different studies involving feeding sodium bicarbonate to chickens are reviewed.

Study 1:

Treatments involved 4 coccidiostats administered with or without sodium bicarbonate added at 0.2% in the diet. Sodium bicarbonate produced no significant effects on survival compared with the coccidiostats alone. Indeed, there was a significant increase in weights in some treatment groups fed sodium bicarbonate. In addition after 45 days feeding there was a significant reduction in mortality in birds fed the sodium bicarbonate supplements together with the coccidiostats. Sodium bicarbonate given alone had no effects on any measured parameter.

Study 2:

Sodium bicarbonate and 3 other sources of sodium were added at 0.2% to the diet alongside a coccidiostat (Coban) after challenging the chickens with coccidiosis. Controls received only Coban. All sodium sources caused an increase in body weights and a reduction in mortalities compared with Coban alone.

Study 3:

Compared addition at 0.2% of 3 sources of sodium, (including bicarbonate) to 2 different chicken diets. Sodium bicarbonate and chloride had significant effects on water intake and excretion and also significantly reduced mortality.

Study 4:

Sodium bicarbonate, potassium bicarbonate, ground trona and soda ash were added to the diet of chickens at 0.2% with either BioCox or Coban coccidiostats. Controls only received the coccidiostats. In general, all the mineral supplements significantly improved body weight, feed efficiency and survival.

In general, it can be concluded from the 4 studies that the addition of 0.2% sodium (or potassium bicarbonate) to chicken diet has a beneficial effect on weight gain, survival and the activity of coccidiostats. There is also other published literature referenced in the review that confirms the safety to chickens of adding up to 1% sodium bicarbonate in the diet[1].

Risk Assessment

Estimates of the maximum concentrations of the amount of potassium bicarbonate likely to be added to crops following the application of Armicarb 85SP have been made using the methodology proposed in the EU Guidance Document SANCO/4145/2000 for Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (see Table B.9.1.1). In this worst case estimation, it can be seen that the highest possible additional inputs of potassium bicarbonate are unlikely to represent the levels of sodium or potassium bicarbonate fed to chickens (i.e. 2,000 to 10,000 mg/kg food) as a feed supplement.

Table B9.1.1: Estimated maximum consumption of potassium bicarbonate by small insectivorous birds following worst-case applications of Armicarb 85SP

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

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B9.2 Toxicity To Aquatic Organisms (Annex IIA, 8.2; Annex IIIA, 10.2)
B9.2.1 Acute toxicity to fish
B9.2.1.1
B9.2.1.1/01

Report: Bettencourt, M.J.. 1993a. Potasssium Bicarbonate-Acute Toxicity To Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-through Conditions

GLP: yes

Guidelines: FIFRA Guideline 72-1

Material and Methods:

The purpose of the study was to estimate the acute toxicity (LC_{50}) of potassium bicarbonate to rainbow trout (*Oncorhynchus mykiss*) under flow through conditions.

Twenty fish, (ten per replicate) were exposed in duplicate test aquaria, to six concentrations of potassium bicarbonate and a dilution water control. The mean wet weight was 0.52 g and mean total length was 40 mm. During the test nominal potassium bicarbonate concentrations of 160, 260, 430, 720, 1200 and 2000 mg/L were maintained by introducing approximately 6.5 aquarium volumes per day of newly prepared test solution. Each replicate was sampled and analysed for potassium bicarbonate at 0h (test initiation) and at 96h (test termination).

Biological observations and observations on the physical characteristics of the test media were made at 0h and every 24h until test termination. Physical characteristics that were monitored were: dissolved O_2, pH, and temperature. Throughout the study no signs of undissolved material were observed at any time.

Findings:

Based on the water analyses the mean measured exposure concentrations were defined as 160, 270, 430, 690, 1200 and 1900 mg/L At 48h exposure all fish in the top dose (1900 mg/L) had died and at 96h there was 35% in the next highest dose of 1200 mg/L. No mortality was observed in any other test concentrations. Sub-lethal effects (partial loss of equilibrium, erratic swimming behaviour) were observed among two of the surviving fish in the 680 and 1200 mg/L treatment levels. The LC_{50}, corresponding 95% confidence limits and NOEC were estimated as follows:

Table B9.2.1-1: Results

LC_{50} mg/L (95% confidence limits) Measured concentration				NOEC (mg/L)
24h	48h	72h	96h	96h
1500 (1300-1700)	1400 (1200-1900)	1400 (1200-1900)	1400 (1200-1900)	430

B9.2.1.1/02

Report: Bettencourt, M.J.. 1993b. Potasssium Bicarbonate-Acute Toxicity To Bluegill Sunfish (*Lepomis macrochirus*) Under Flow-through Conditions

GLP: yes

Guidelines: FIFRA Guideline 72-1

Material and Methods:

The purpose of the study was to estimate the acute toxicity (LC_{50}) of potassium bicarbonate to the warm water fish species bluegill sunfish (*Lepomis macrochirus*) under flow through conditions. Twenty fish, (ten per replicate) were exposed in duplicate test aquaria, to six concentrations of potassium bicarbonate and a dilution water control. During the test nominal potassium bicarbonate concentrations of 160, 260, 430, 720, 1200 and 2000 mg/L were maintained by introducing approximately 6.5 aquarium volumes per day of newly prepared test solution.

Each replicate was samples and analysed for potassium bicarbonate at 0h (test initiation) and at 96h (test termination). Biological observations and observations on the physical characteristics of the test media were made at 0h and every 24h until test termination.

Physical characteristics that were monitored were: dissolved O_2, pH, and temperature Throughout the study no signs of un-dissolved material were observed at any time.

Findings:

Based on the analyses the mean measured exposure concentrations were defined as 150, 260, 430, 690, 1200 and 1900 mg/L. After 96h exposure 95% mortality was observed in the top dose level (1900 mg/L). In addition, sub-lethal effects were observed among fish surviving this treatment level. No mortality or sub-lethal effects were observed in any other test concentrations (150-1200 mg/L). The LC_{50}, corresponding 95% confidence limits and NOEC were estimated as follows:

Table B9.2.1-02: Results

LC_{50} mg/L (95% confidence limits) Measured concentration				NOEC (mg/L)
24h	48h	72h	96h	96h
>1900	1700 (1200-1900)	1600 (1200-1900)	1500 (1200-1900)	1200

B9.2.1.2 TERA for an aquatic insect species
A waiver is requested – see Section B9.3.1.2.

B9.2.1.3 TERLT for an aquatic insect species
A waiver is requested – see Section B9.3.2.2

B9.2.1.4 TER_A for an aquatic crustacean species
A waiver is requested – see Section B9.3.1.3.

B9.2.1.5 TER_{LT} for an aquatic crustacean species
A waiver is requested – see Section B9.3.1.3.

B9.2.1.6 TER_A for an aquatic gastropod species
A waiver is requested – see Section B9.3.1.4.

B9.2.1.7 TER_{LT} for an aquatic gastropod species
A waiver is requested – see Section B9.3.1.4.

B9.2.1.8 TER_{LT} for algae
A waiver is requested – see Section B9.4

B9.2.1.9 TER_{LT} for aquatic macrophytes
A waiver is requested – see Section B9.8.6

B9.2.1 10 Acute toxicity (aquatic) of the preparation
Based on the above results potassium bicarbonate will not be classified under GHS criteria for the aquatic environment.

B9.2.2.2 Acute toxicity of metabolites
Potassium bicarbonate dissociates into potassium and bicarbonate ions in water. Potassium cannot degrade any further but bicarbonate can form carbon dioxide, water, carbonate and carbonic acid. All of these compounds are commonly found in natural waters where they usually occur at levels much higher than those that might result from the use of Armicarb 85SP. In view of the above, no testing of metabolites is considered necessary.

B9.2.2.3 Chronic toxicity to fish

Testing of chronic toxicity in fish is considered unnecessary for the following reasons:

- Potassium and bicarbonate are very common in natural surface waters. The use of Armicarb 85SP is extremely unlikely to result in significant increases in these products.
- Both potassium and bicarbonate are essential constituents of living organisms, including fish
- Potassium bicarbonate has a very low toxicity to fish.
- Potassium bicarbonate is highly soluble in water and has very limited potential for bio-accumulation in fish.

B9.2.2.4 Chronic toxicity (28 day exposure) to juvenile fish

Not applicable. Please refer to point B9.2.2.3

B9.2.2.5 Fish early life stage toxicity test

Not applicable. Please refer to point B9.2.2.3

B9.2.2.6 Fish life cycle test

Not applicable. Please refer to point B9.2.2.3

B9.2.2.7 Bio-concentration potential in fish

Potassium bicarbonate is highly soluble in water and as a result has a very limited potential for bio-concentration. Specific tests to evaluate bio-concentration potential are therefore considered unnecessary.

B9.2.2.8 Aquatic bio-availability / bio-magnification and depuration

Not applicable. Please refer to point B.9.2.2.7

B9.3 Toxicity to species other than fish and aquatic field testing

B9.3.1 Acute toxicity to aquatic invertebrates

B9.3.1.1-1 Acute toxicity to *Daphnia magna*

B9.3.1.1/01

Report: Putt, A.E.. 1993. Potasssium Bicarbonate-Acute Toxicity To Daphnids (*Daphnia magna*) Under Flow-through Conditions

GLP: yes

Guidelines: FIFRA Guideline 72-2

Materials and Methods:

The purpose of the study was to estimate the acute toxicity (LC_{50}) of potassium bicarbonate to *Daphnia magna* under flow through conditions. Twenty daphnids, (ten per replicate) were exposed in duplicate test vessels, to five concentrations of potassium bicarbonate and a dilution water control. During the test nominal potassium bicarbonate concentrations of 310, 520, 860, 1400 and 2400 mg/L were maintained by introducing approximately 5.9 test chamber volumes per day of newly prepared test solution. Each replicate was sampled and analysed for potassium bicarbonate at 0h (test initiation) and at 48h (test termination). Biological observations and observations on the physical characteristics of the test media were made at 0h and every 24h until test termination. Physical characteristics that were monitored were: dissolved O_2, pH, and temperature Throughout the study a slight layer of un-dissolved test material was observed on the bottom of the pre-dilution mixing chamber, the chemical cells of the diluter system and in the test vessels of the highest dose (2500 mg/L).

Findings:

Based on the analyses of the test media the mean measured exposure concentrations were defined as 340, 460, 890, 1500 and 2500 mg/L. After 24h exposure 100% immobilisation was observed in the top dose level (2500 mg/L). At test termination (48h) 80% immobilisation was also observed in the 1500 mg/L treatment level. In addition, all of the mobile daphnids exposed to this treatment level exhibited erratic swimming. Immobilisation of 0, 0 and 5% was observed in the 340, 460 and 890 mg/L treatment levels. The LC_{50}, corresponding 95% confidence limits and NOEC were estimated as follows:

Table B9.3.1.1-1: Mean % mortalities of *Daphnia magna*

Measured mean conc. mg/L	24h	48h
Control	0	0
340	0	0
460	0	0
890	0	5
1500	75	80
2500	100	100

Table B9.3.1.1-2: **Results**

EC_{50} (95% confidence limits) mg/L Measured conc.		NOEC mg/L
24h	48h	48h
1300 (890 – 1500)	1200 (1100 – 1400)	460

Based on the above results potassium bicarbonate will not be classified for toxicity to aquatic invertebrates under GHS criteria for the aquatic environment.

B9.3.1.1-2 TER_{LT} for *Daphnia magna*
A waiver is requested – see B9.3.2.

B9.3.1.2 Acute toxicity for representative species of aquatic insects

No testing is considered necessary due to the following considerations:

Potassium and bicarbonate are very common in natural surface waters. The use of Armicarb 85SP is extremely unlikely to result in significant increases in these products.

Both potassium and bicarbonate are essential constituents of living organisms, including aquatic invertebrates

Potassium bicarbonate has a very low toxicity to *Daphnia magna*

B9.3.1.3 Acute toxicity for representative species of aquatic crustaceans

Not applicable – see B9.3.1.2

B9.3.1.4 Acute toxicity to a representative species of aquatic gastropod mollusc

Not applicable – see B9.3.1.2

B9.3.2 Chronic toxicity to aquatic invertebrates

Testing of chronic toxicity in aquatic invertebrates is considered unnecessary for the following reasons:

- Potassium and bicarbonate are very common in natural surface waters. The use of Armicarb 85SP is extremely unlikely to result in significant increases in these products.
- Both potassium and bicarbonate are essential constituents of living organisms, including aquatic invertebrates
- Potassium bicarbonate has a very low toxicity to *Daphnia magna*.
- Potassium bicarbonate is highly soluble in water and has very limited potential for bio-accumulation in fish.

B9.3.2.1 Chronic toxicity in *Daphnia magna*

Not applicable - see B9.3.2

B9.3.2.2 Chronic toxicity for representative species of aquatic insects

Not applicable - see B9.3.2

B9.3.2.3 Chronic toxicity to a representative species of aquatic gastropod mollusc

Not applicable - see B9.3.2

B9.3.2.4 Aquatic field testing

Aquatic field testing is considered unnecessary for the following reasons:

- Potassium and bicarbonate are very common in natural surface waters. The use of Armicarb 85SP is extremely unlikely to result in significant increases in these products.
- Both potassium and bicarbonate are essential constituents of living organisms.
- Potassium bicarbonate has a very low toxicity to fish and *Daphnia magna*.
- Potassium bicarbonate is highly soluble in water and has very limited potential for bio-accumulation in aquatic organisms.

B9.3.5 Effects on algal growth and growth rate

Tests on plants, including algae are considered unnecessary for the following reasons:

- Potassium and bicarbonate are very common in natural surface waters. The use of Armicarb 85SP is extremely unlikely to result in significant increases in these materials.
- Both potassium and bicarbonate are essential nutrients of plants, including algae.
- Concentrations of potassium and bicarbonate naturally present in algal tissues are much higher than any that could be obtained from exposure to surface waters treated with Armicarb 85SP.
- Application as a fungicide to many crops and ornamental species has confirmed the selectivity of potassium bicarbonate to plants in general.
- Potassium bicarbonate is highly soluble in water and has very limited potential for bio-accumulation in aquatic organisms.

B9.3.6 Effects on sediment dwelling organisms

Tests on sediment dwelling organisms are considered unnecessary for the following reasons:

- Potassium and bicarbonate are very common in natural surface waters. The use of Armicarb 85SP is extremely unlikely to result in significant increases in these products in the sediment.
- Both potassium and bicarbonate are essential constituents of living organisms.
- Potassium bicarbonate has a very low toxicity to fish and *Daphnia magna*.
- Although most of the potassium is likely to partition into sediments it will generally be tightly bound by negatively charged micelles and therefore not readily available to organisms.
- Potassium bicarbonate is highly soluble in water and has very limited potential for bio-accumulation in aquatic organisms.

B9.3.7 Effects on aquatic plants

Not applicable – see B9.3.6

B9.3.8 Risk assessment

Acute toxicity tests with potassium bicarbonate were carried out on rainbow trout (*Oncorhynchus mykiss),* bluegill sunfish (*Lepomis macrochirus)* and *Daphnia magna.*

Table B9.3.8-1: Toxicity end points for aquatic species

Test Species	Test Duration	Test Conc.	LC_{50} (mg/L)	Reference
Oncorhynchus mykiss	96h	measured	1400	M J Bettencourt (1993)
Lepomis macrochirus	96h	measured	1500	M J Bettencourt (1993)
Daphnia magna	48h	measured	1,200	A.E. Putt (1993)

The worst case initial PECs for surface water following 8 applications at the maximum dose (6 kg Armicarb/ ha), no degradation between applications and a shallow water body (0.3m deep) are shown in Table B9.3.8-2.

Table B9.3.8-2: Worst case PEC_{sw} for potassium bicarbonate

Crop	**Buffer Zone (m)**	**% spray drift**	**PEC_{sw} (mg / L)**
Overspray	0	100	13.6
Apples	3	29.2	3.97
Vines	3	8.0	1.08

On the basis of the worst case $PEC_{sw,}$ and overspray scenario the TER_A for both species of fish demonstrates that the use of potassium bicarbonate presents no hazard when applied in vines and apples (Table B9.3.8-3). A slight risk to Daphnia is indicated in the overspray scenario (TER_A <100) which is removed for the two crop scenarios by including a 3m buffer zones.

Table B9.3.8-3: TER_A values for aquatic organisms using worst case initial PECsw for potassium bicarbonate

Fish Species	Overspray (0m)	3m Buffer apples	3m Buffer vines
Oncorhynchus mykiss	103	353	1296
Lepomis macrochirus	110	378	1389
Daphnia magna	88	302	1111

This risk assessment is extremely conservative and in normal good plant protection spray practice overspray of adjacent water bodies will not arise. Given the multiplication of worst case factors and the unlikely event of accumulation of all residues from 8 sprays, it is anticipated that no buffer zone will be required

B9.4 Effects on terrestrial vertebrates other than birds

A waiver is requested from conducting any studies and risk assessment for the following reasons:

- Potassium and bicarbonate are extremely common in all natural systems, including water, soil, plant and animal tissues.
- Potassium bicarbonate and Armicarb 85SP have extremely low toxicities in mammals with the lowest acute oral LD_{50} being 2,064 mg/kg in female rats (see Doc. M Section AII, point 3, 5.2.1).
- Bicarbonate is not harmful to animals unless consumed in extremely high quantities and is widely used as a buffering agent to reduce stomach acidity.
- Potassium is an essential plant nutrient and is often applied to crops as both a soil and/or foliar fertiliser.
- Potassium bicarbonate is an approved food additive in the EU (E501) and is also listed as a food additive by CODEX Alimentarius.
- Potassium bicarbonate is Generally Regarded As Safe (GRAS) by the US FDA.
- The recommended daily allowance for potassium is usually considered as being 3.5 g/d in humans.
- Total inputs of potassium from the worst-case usage of Armicarb are also considerably lower than those resulting from the use of potash based liquid fertilisers (point 6, 10.11.1).

In terms of risk it is perhaps valuable to compare the likely worst case acute exposure with the acute oral LD_{50} to rat. From this the following end point can be estimated:

Acute oral LD_{50} = 2,064 mg/kg $KHCO_3$ = 8256 mg/kg bw/d

Worst case acute exposure can be estimated for a small herbivore as shown in Table B9.4-1.

Table B9.4-1: Estimated theoretical worst case exposures for potassium bicarbonate and a small herbivorous mammal

Crops	Scenario	FIR/bw	RUD mean	Dose kg a.s./ha	MAF	f_{twa}	ETE_A mg/kg bw
Apples & vines	Acute	1.39	85	5.1	1.6	n/a	964

$TER_A = 8256 / 964 = 8.56$

This value does not exceed the Annex VI trigger value of 10. However, if the mean toxicity for both sexes is taken into account:
Acute oral LD_{50} = 2,825 mg/kg $KHCO_3$ = 11300 mg/kg bw/d

$$TER_A = 11300 / 964 = 11.7$$

Thereby passing the trigger value indicating that exposure to potassium bicarbonate is of low risk to small herbivorous mammals. The risk to small mammals from exposure to potassium bicarbonate residues is considered to be of low significance since the crops treated with Armicarb will not generally provide food sources of dietary choice.

Given the very low toxicity and natural occurrence of potassium and bicarbonate a waiver is requested from conducting long-term exposure estimates and risk assessments for mammals. Under natural conditions much of the bicarbonate will be converted to CO_2 and potassium incorporated into plant tissues.

B9.5 Effects on bees

B9.5.1 Acute oral toxicity

A waiver from conducting oral toxicity test is requested because potassium and bicarbonate are extremely common in nature and exposure to bees in food and drink is common.

Natural waters often contain high concentrations of bicarbonate, so bees are exposed when they drink. Potassium is also present at relatively high quantities in nectar and honey (usually contains 200-2000 mg/kg) so bees are continually exposed when foraging and eating.

B9.5.2 Acute contact toxicity

Report: IIA 8.7.2 Maura K Collins 1999, Armicarb sodium bicarbonate – Acute contact toxicity test with honey bees. Report number 98-11-7553

Guidelines: FIFRA Guideline 141-1

GLP: Yes

Materials and methods:

The purpose of the study was to estimate the acute contact toxicity (LC_{50}) of Armicarb to honey bees (*Apis mellifera)*. Thirty bees, (ten per replicate) were exposed in triplicate test cages, to five concentrations of sodium bicarbonate plus a control blank and one containing 1% of the surfactant sodium lauryl sulphate. Sodium bicarbonate doses of 1.6, 3.1, 6.2, 13 and 25 µg/bee were applied in 1 µL aliquots by micro-pipette to the thorax of individual bees. Bees were then returned to the test cages where they were maintained for the next 48h (test termination). Duplicate samples of each test solution and control blank were analysed at test initiation for sodium bicarbonate content. Biological observations (mortalities, behavioural abnormalities) and measurements of temperature and humidity were carried out daily.

Findings:

Measured test concentrations were found to be equivalent to 1.6, 3.0, 6.0, 13 and 24 µg/bee. Less than 3% mortality occurred in any of the control or treatment groups. The LC_{50}, and NOEC were estimated to be >24 µg/bee which was the highest dose tested.

Based on the above results sodium bicarbonate has a very low contact toxicity to honey bees.

B9.5.3 Hazard quotients for bees

B9.5.3.1 Oral exposure Q_{HO}

No study was conducted for the acute oral toxicity - see B9.5.1 for the waiver argument.

B9.5.3.2 Contact exposure Q_{HC}

Exposure route	Dose g as/ha	LD50 µg/bee	Q_{HC}
Contact	5100	> 24	>212

The Q_{HC} is above the trigger value of 50 indicating a potential risk to honey bees. However, there was no toxicity observed in the laboratory test at the maximum rate tested of 24 µg/bee.

Potassium is naturally present in nectar and honey at levels of 200-2000 mg/kg without causing any harm to bees. Natural waters often contain high concentrations of bicarbonate, so bees are exposed when they drink.
Therefore it is very unlikely that there will be any effects of potassium bicarbonate under field conditions. Please refer to point B9.5.3.6 for further details.

B9.5.3.3 Acute toxicity of the preparation to bees

A waiver is requested in view of the very low toxicity of the active ingredient and the lack of toxicity with the formulants.

B9.5.3.4 Effects on bees of residues on crops

Not applicable.

There are no known residues, metabolites or reaction products of toxicological, ecotoxicological or environmental significance. Potassium does not degrade and bicarbonate can transform into abundant natural products such as carbon dioxide, carbonates and water.

B9.5.3.5 Cage tests

Not applicable

B9.5.3.6 Field tests

No field tests have been conducted, however Armicarb has been used for many years in the USA on flowering fruits and ornamentals without any reported incidence on bees. A letter from an entomologist in Cornell University (John Sanderson, 1998) is also available that describes trials undertaken with Armicarb and bumble bees (*Bombus impatiens*) foraging flowering strawberry plants inside a glasshouse. Armicarb was applied at 0.6% in approximately 1000 L/ha of spray solution. In total 6 sprays were applied at weekly intervals. During this time a hive containing 30 bumble bees was maintained in the glasshouse. The hive entrance was closed during spraying but opened to allow foraging either when the spray deposit was dry or the following morning. On no occasion were any adverse effects observed on the survival and foraging activity of the bumble bees. In addition, there were no adverse effects on pollination and fruit set.

In an experiment carried out by the North Mississippi Research & Extension Centre to test the efficacy of 5 fungicides including Armicarb 100 [potassium bicarbonate] they were applied at recommended rates for control of leaf diseases in pumpkins. Four hives of honey bees were placed within 0.4 kilometers of the plantings to assist with pollination and fruit set. Treatments were applied weekly from about 20d after emergence. No adverse effects were reported on honey bees although few pollinators were observed visiting pumpkins blooms during and immediately after treatment although healthy colonies of honey bees were situated near the experiment.

B9.5.3.7 Investigation of special effects

Not applicable.

B9.5.3.8 Tunnel tests on contaminated honey dew

No applicable.

B9.6.1 Effects on arthropods other than bees

No studies have been carried out, although there are no recorded issues regarding adverse effects of Armicarb on beneficial arthropods despite several years of usage in the USA, mostly in IPM and organic farming situations.

B9.7 Effects on earthworms

No studies have been conducted with potassium bicarbonate on earthworms. A waiver is requested for the following reasons:

- Potassium and bicarbonate are very common natural materials that are present in soils.
- The amount of potassium or bicarbonate added to the soil following the application of Armicarb 85SP will be negligible compared with the amounts of potassium or bicarbonate already present.
- Any potassium added to the soil will enter the mineral cycle driven by the equilibrium between soluble, extractable and bound potassium.
- Potassium bicarbonate demonstrates a low level of activity against all animals that have been tested.
- As a consequence, adverse effects on earthworms from the application of potassium bicarbonate are extremely unlikely.

B9.8 Effects on soil microbial activity

No studies have been conducted with potassium bicarbonate on soil microbial activity. A waiver is requested for the following reasons:

- Potassium and bicarbonate are very common natural materials that are present in soils.
- The amount of potassium or bicarbonate added to the soil following the application of Armicarb 85SP will be negligible compared with the amounts of potassium or bicarbonate already present.
- Any potassium added to the soil will enter the mineral cycle driven by the equilibrium between soluble, extractable and bound potassium.
- Potassium is an essential nutrient for soil micro-organisms.
- Potassium bicarbonate is effective against some foliar fungal pathogens through both pH and osmotic effects. Such modes of action will not be relevant in the soil due to the enormous buffering impact on pH and massive dilution factors.

As a consequence, adverse effects on soil microorganisms from the application potassium bicarbonate are extremely unlikely.

B9.9 Effects on terrestrial vascular plants

No studies have been conducted with potassium bicarbonate on terrestrial vascular plants. A waiver is requested for the following reasons:

- Potassium and bicarbonate are very common natural materials that are present in soils.
- The amount of potassium or bicarbonate added to the soil following the application of Armicarb 85SP will be negligible compared with the amounts of potassium or bicarbonate already present.
- Any potassium added to the soil will enter the mineral cycle driven by the equilibrium between soluble, extractable and bound potassium.
- Potassium is an essential nutrient for plants and is often present in plant tissues at very high levels.
- Potassium bicarbonate has been applied as a fungicide on a wide range of crops (vascular plants) for many years without any major incidents of selectivity.

As a consequence, adverse effects on terrestrial vascular plants from the application of potassium bicarbonate are extremely unlikely.

B9.11 Effects on other non-target organisms believed to be at risk

Not applicable. No other non-target organisms are believed to be at risk.

B9.12 Effects on biological methods of sewage treatment

A waiver from conducting tests is requested for the following reasons:

- Potassium and bicarbonate are very common natural materials that are present in soils, sediments and surface water. They would therefore be present at high levels in sewage sludges.
- Any potassium added to the soil will enter the mineral cycle driven by the equilibrium between soluble, extractable and bound potassium.
- Potassium is an essential nutrient for micro-organisms and would probably enhance activity in sewage sludges.
- Potassium bicarbonate is effective against some foliar fungal pathogens through both pH and osmotic effects. Such modes of action will not be relevant in sewage sludges due to the enormous buffering impact on pH and massive dilution factors.

As a consequence, adverse effects on biological methods of sewage treatment from the application of potassium bicarbonate are extremely unlikely.

B9.14 Other/special studies

Not applicable

B.9.15 Refereneces 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 protection claimed	Owner
Annex IIA 8.1 IIIA 10.1	Environ Corp.	1993	Safety of Sodium Bicarbonate Supplementation of Animal Feeds	no	Environ Corp.
Annex IIA 8.2.1.1 IIIA 10.2.1/01	Michael J.Bettencourt	1993a	Potassium Bicarbonate - Acute Toxicity To Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-through Conditions [redacted] Document No: 93-6-4812 GLP: Yes Published: No	yes	Armand products
Annex IIA, 8.2.1.2 IIIA 10.2.1/02	Michael J.Bettencourt	1993b	Potassium Bicarbonate - Acute Toxicity To Bluegill Sunfish (*Lepomis macrochirus*) Under Flow-Through Conditions [redacted] Document No. 93-5-4804 GLP: Yes Published: No	yes	Armand products
Annex IIA, 8.3.1.1 IIIA 10.2.1/03	Arthur E. Putt	1993	Potassium Bicarbonate - Acute Toxicity To Daphnids (*Daphnia Magna*) Under Flow-Through Conditions Springborn Laboratories, Inc. Environmental Sciences Division 790 Main Street Wareham, Massachusetts 02571 Document No: 93-6-4798 GLP: Yes Published: No	yes	Armand products

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 protection claimed	Owner
Annex II, 8.3.1.1 IIIA10.4.5	Maura K. Collins	1999	Lot #8F065 Armicarb® Sodium Bicarbonate – Acute Contact Toxicity test with Honey Bees Springborn Laboratories, Inc. 790 Main Street Wareham, Massachusetts 02571-1075 Document No. 98-11-7553 GLP: Yes Published: No	yes	Armand products
Annex IIA 8.1 IIIA 10.1	Environ Corp.	1993	Safety of Sodium Bicarbonate Supplementation of Animal Feeds	no	Environ Corp.
Annex IIA 8.1 IIIA 10.1	Silva AVF, Flemming JS, Franco SG	1994	Utilização de diferentes sais na prevenção do estresse calórico de frangos criados em clima quente. Revista do Setor de Ciências Agrárias 1994; 13:287-292	no	
Annex IIA 8.2.1.1 IIIA 10.2.1/01	Michael J.Bettencourt	1993a	Potassium Bicarbonate - Acute Toxicity To Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-through Conditions [redacted] Document No: 93-6-4812 GLP: Yes Published: No	yes	Armand products
Annex IIA, 8.2.1.2 IIIA 10.2.1/02	Michael J.Bettencourt	1993b	Potassium Bicarbonate - Acute Toxicity To Bluegill Sunfish (*Lepomis macrochirus*) Under Flow-Through Conditions [redacted] Document No. 93-5-4804 GLP: Yes Published: No	yes	Armand products

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Annex II, 8.3.1.1 IIIA10.4.5	Cushman K.E., M. Kenty, T.E. Horgan, D.M. Ingram, and C.E. Watson	2002	CoRoN enhancement of pumpkin fungicides. Annual Report of the North Mississippi Research & Extension Center, Miss. Agric. & For. Expt. Sta. Info. Bull. 386. pp. 284-285.	no	