ORGANIC INPUTS EVALUATION - AMENDMENT TO REG. 2092/91 - ANNEX II

FORM FOR APPLICATION **product: Potassium hydrogen carbonate**

Requested data	Applicant statement *Provide statement for each cell.*
General information	
Applicant details *Enter contact details which allow the expert panel to contact a representative of the applicant MS in case of need.*	Draft version prepared by Agchem Project Consulting Ltd., with advice from FiBL
Completion date	03 August 2006, amended 16 November 2006
Nature of request *Specify whether this is a request to include a new product, to withdraw an existing product or to change the specifications for an existing product. In the latter case, give details.*	Request to re-introduce Bicarbonate (in the new form of Potassium Bicarbonate).
Introduction to the product *Specify the product's use (fertilizer, soil conditioner, insecticide, fungicide etc), origin of the main component (plant, animal, microbial, mineral, other) and the commodities where it will be used (horticulture, fruit trees, grapevines, arable crops, fodder crops etc.).*	Product use: Fungicide Origin of the main component: Mineral Commodities where it will be used: horticulture, grapevines, vegetables, arable crops.
A 1.0 Identification	
A 1.0.1 Chemical name(s)	Potassium hydrogen carbonate
A 1.0.2 Other names *Give synonyms, including common names. Selected trade names may be given, if desired*	Potassium bicarbonate (ISO common name) Carbonic acid, monopotassium salt Potassium acid carbonate Selected trade name: Armicarb 85SP
A 1.0.3 CAS name and number(s) *Give CAS name and number(s), where appropriate*	CAS number: 298-14-6
A 1.0.4 IUPAC name *Give IUPAC name, where appropriate*	IUPAC name: Potassium hydrogen carbonate
A 1.0.5 Other identification codes *Give other identification codes, if available (e.g. EINECS number)*	EINECS number: 206-059-0
A 1 .1 Characterization	
A 1.1.1 Composition *List main ingredients of the product (impurities to be listed under A 1.1.9).*	Potassium bicarbonate
A 1.1.2 Concentration of main ingredients *Give concentration range of main ingredients (in g/litre or g/kg).*	Potassium bicarbonate: 995.0 g/kg minimum.
A 1.1.3 Analytical methods *Mainly for PPP. If substances are identified, there should be a validated method for analysis; if not identified, a method of analysis of any available marker. Methods of analysis of the substance in water, soil and air may be necessary if exposure of either compartment is likely, and contribution compared to background levels likely to be substantial. For toxic substances, relevant to human or animal health or environment, validated methods of analysis may be required.*	Methods for the analysis of potassium bicarbonate within formulations: Potassium: US EPA method SW 846 3010A (Digestion), US EPA method 7610 (Method for Chemical Analysis of water and Wastes, method 258.1, Flame Atomic Absorption) Bicarbonate: Acid-base titrimetry (American Chemical Society method, 8th Edition) Methods of analysis of potassium bicarbonate in water, soil and air are not relevant: * 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". In the USA potassium bicarbonate is "generally recognized as safe" (GRAS) by the Food and Drugs Administration. * Potassium bicarbonate is naturally present in humans, other animals, plants and virtually all living organisms. Under environmental conditions, potassium bicarbonate dissociates completely to potassium and bicarbonate ions. It is impossible to differentiate analytically between potassium and bicarbonate ions naturally present in biological systems and those of external origin.
A 1.1.4 Quality control *Describe the quality control measures used to ensure consistency of composition and performance.*	Armand Products Company manufactures potassium bicarbonate in their ISO 9002-certified facilities for use as a food and pharmaceuticals additive, with a minimum purity of 99.5%.
A 1.1.5 Nutrient contents *For F&SC, give the concentration range of macro-nutrients (N, P, K etc.); where appropriate, also of micronutrients. For fertilizers rich in N, indicate whether nitrogen is present as NO_3, NH_4, or N_{org} (organically bound nitrogen).*	The maximum application of Armicarb 85SP is 8 times 2 - 8 kg/ha. Given that Armicarb 85SP contains 85% $KHCO_3$, which contains 39% K, this is equivalent to 6.4 - 25.5 kg/ha K_2O. The average need for field vegetables is 185 kg/ha K_2O; for apples, it is 80 kg/ha. Thus, the maximum input of potassium from the worst-case usage of Armicarb varies from 3 - 14% of the need of field vegetables, and from 8 - 32% of the need of apples.
A 1.1.6 Physical form *Indicate whether solid, liquid, powder etc; give relative density, particle size for powders and other relevant information*	Description: White (colourless) crystalline powder. Relative density: (Bulk density) = 1 g/cm^3
A 1.1.7 Chemical properties	pH = 8.3 (pH of a 1% dilution Potassium bicarbonate)

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A 1.1.9 Impurities *List potentially dangerous impurities such as xenobiotics, microorganisms (identified to genus, species or strain level, according to what is possible) and heavy metals which may occur in the product, and indicate their concentration ranges.*	The manufacturing process of potassium bicarbonate precludes the possibility of synthetic impurities; there are no competing reactions or reaction by-product in the manufacture of potassium bicarbonate. The only impurities at levels equal to or greater than 0.1% (1 g/kg) are potassium carbonate (< 2.5 %) and water (< 0.3 %). These are beginning material impurities and are of no toxicological, ecotoxicological or environmental concern. No additives are added to the technical active substance, prior to the manufacture of formulated product to either preserve stability or facilitate ease of handling. Potassium bicarbonate is produced as a powder or granules and is easy to handle mechanically. Therefore, there is no need for additives to ease handling. Potassium bicarbonate complies with the Food Chemicals Codex specifications for heavy metals and loss on drying. Heavy metals (as Pb) : < 10 ppm There are no further impurities of toxicological, ecotoxicological or environmental concern in potassium bicarbonate.
A 1.1.10 Risk phrases *List all R-phrases relevant for the product, and possibly also for commercial products based on it.*	Not required.
A 1.1.11 Safety phrases *List all S-phrases relevant for the product, and possibly also for commercial products based on it.*	Standard S-phrases for a powder product: S22, S24/25, S26, S28, S38, S39
A 1.1.12 Low risk product *Is the product food or feed grade, or has it been affirmed GRAS (generally recognized as safe)? If so, give details.*	Potassium bicarbonate is approved for food use in Europe and has been assigned food additive number E501 (raising agent). Potassium bicarbonate is also listed for food use in the internationally recognized "Food Chemicals Codex". In the USA potassium bicarbonate is "generally recognized as safe" (GRAS) by the Food and Drugs Administration.
A 1.2 Legal status and status in organic farming standards	
A 1.2.1 Approval in EU *List EU Member States, where product is approved for use under relevant national regulations. States where approval is expected may be listed separately.*	Approval under Dir. 91/414 under way; DAR prepared by RMS Ireland. Applications for registration at member state level in Spain, France, Italy, Greece, the Netherlands and the United Kingdom under way.
A 1.2.2 Approval outside EU *Give a representative range of non-EU Member States, where product is approved for use under relevant national regulations*	The product is registered and approved for use in the USA. A registration dossier is in progress in Switzerland.
A 1.2.3 IFOAM status *State whether allowed by IFOAM Basic standards. If allowed, give category/type definition and any conditions of use and/or restrictions.*	Potassium bicarbonate is listed in the IFOAM Basic standards, Appendix 3, section II. Source: Final Revision Draft of the IFOAM Basic standards, Version 20th May, 2005.
A 1.2.4 Codex Alimentarius status *State whether allowed for organic farming by Alinorm GL 32. If allowed, give category/type definition and any conditions of use and/or restrictions.*	Non explicitly allowed as a fungicide for organic farming by Directive GL 32 - 1999, Rev. 1, 2001. Related uses which are allowed: sodium bicarbonate allowed for plant protection (Annex 2, Table 2); potassium carbonates allowed for food processing (Annex 2, Table 3).
A 1.2.5 Status in other organic standards *State whether allowed by non-EU national organic standards. If allowed, give category/type definition and any conditions of use and/or restrictions.*	Allowed for use under the US NOP. Not allowed under Japan organic standards. Source: Organic Materials Review Institute (OMRI), Generic Materials List.
A 1.2.6 Precedents in 2092/91 EEC *If appropriate, describe in which respect products already listed in Annex II of Reg. 2092/91 set a precedent for specific aspects of this application (e.g. the raw material, manufacture, use etc.)*	NA
A 1.3 Purpose & intended use	
A 1.3.1 Intended use category *Specify use category (fertiliser, soil conditioner, fungicide, insecticide, etc.)*	Fungicide
A 1.3.2 Intended specifications *Describe intended specifications/restrictions to be included in Annex II.*	Specifications: 99.5% purity, lead content < 10 ppm.
A 1.3.3 Organism(s) to be controlled *PPP only. The organism(s) to be controlled should be named (ideally at species level). Describe the damage done to the plant by the organism(s), and the degree of protection achieved with the product.*	Armicarb 85SP, based on 85% potassium bicarbonate, acts as a contact fungicide able to control several diseases: * Vine: powdery mildew (*Uncinula necator*), grey mould (*Botrytis cinerea*) * Pome fruit: scab (*Venturia inaequalis*), powdery mildew (*Podosphaera leucotricha*) * Stone fruit: brown rot (*Monilia laxa*) * Strawberry and soft fruits: powdery mildew (*Sphaerotheca macularis*), grey mould (*Botrytis cinerea*) * Vegetables: powdery mildew *(Sphaerotheca* spp), grey mould (*Botrytis cinerea*) * Arable crops: powdery mildew (*Erisyphe graminis*), septoria *(Septoria* spp), Helminthosporiose Degree of protection achieved: according to field trials carried out for the above uses, Armicarb 85SP shows comparable performance to standard reference products currently on the conventional agricultural market.
A 1.3.4 Mode of action *PPP only. Where known, specify how the substance achieves effect against the organism(s) identified in A 1.3.3.*	Potassium bicarbonate is a contact fungicide. It mainly inhibits fungus mycelium development. Its mode of action is linked with osmotic pressure, pH and specific bicarbonate/carbonate ion effects. The product needs to be applied preventively or at first appearance of the disease in order to be effective.
A 1.3.5 Crops *Specify the crop(s) on which the product will be used.*	Potassium bicarbonate will be used on vines, pome and stone fruits, strawberry and other soft fruits, vegetables and arable crops.
A 1.3.6 Application method *Specify application equipment and whether applied to the soil or the plant (see also A 1.3.6).*	Armicarb 85SP has to be applied by standard spray equipment. Good spray coverage is essential, which usually requires a minimum spray volume of 300 l /ha.
A 1.3.7 Plant parts *Specify plant parts where product is applied, and stage of plant development*	Armicarb 85SP is applied to stems, foliage and fruits.
A 1.3.8 Dosage and application rate *Specify range of dosage and application rates.*	Between 2 and 8 kg of active substance per hectare, depending on crop and disease pressure. Re-apply every 7 to 10 days. Use maximum 8 times per season.

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A 1.3.9 Phytotoxic side effects *Describe any phytotoxic side-effects observed.*	Armicarb 85SP shows good crop selectivity. Some high dose trials on vines and fruit trees have shown some phytotoxicity.
A 2 Origin	
A 2.01 Origin of materials *List the origin of all materials included in the product. Specify whether they are of plant, animal, microbial or mineral origin, or describe if other.*	Mainly CO_2. Please refer to point A 3.01
A 2.02 GMO origin *Are the materials of origin GMOs or not (see Abbreviations and Definitions for guidance)?*	The materials are not of origin GMOs.
A 2.03 Factory farming origin *Are the materials of origin from factory farming or not (see Abbreviations and Definitions for guidance)?*	The materials are not of origin from factory farming.
A 2.04 Origin of plant material *For products derived from plants, name species and origin, part(s) of plant used and growth stage. Indicate whether plants are wild harvested or cultivated.*	NA
A 2.05 Renewable sources *Indicate whether the product is derived from a renewable source. If not, the likely extent of resource depletion should be explained.*	CO_2 is a renewable resource. Please refer to point A 3.01
A 3 Manufacturing	
A 3.01 Manufacturing methods *Describe manufacturing methods and process; list physical, microbial and enzymatic and chemical treatments applied during manufacture*	The Armand Products Company manufactures anhydrous potassium carbonate (K_2CO_3) through a fluidized bed reactor utilizing heated carbon dioxide (CO_2) gas and potassium hydroxide (KOH). K_2CO_3 is further carbonated with CO_2 to produce anhydrous potassium bicarbonate ($KHCO_3$). Potassium hydroxide is formed by the electrolysis of potassium chloride. All equipment is dedicated to a specific potassium product. Armicarb 85SP is manufactured by Armand Products Company in their ISO 9002-certified facilities.
A 3.02 Use of GMOs *Does manufacture involve GMOs or products made from GMOs (see Abbreviations and Definitions for guidance)?*	No
A 4 Use and necessity	
A 4.01 Traditional use *State whether, where and for what purpose the substance has or has had a traditional use in organic farming.*	Sodium and potassium bicarbonate have been known to have fungicidal effects for many years, and are currently used by organic farmers, particularly in North America. Sodium bicarbonate was included on Annex IIB of Reg. 2092/91, when this Regulation entered into force. Later, it was deleted from this Annex, because it was not used as a plant protection product in EU Member States. However, it has continued to be used in plant strengtheners, which may also be used by organic farmers in Germany. More recently, the bicarbonate ion (=active ingredient), is preferentially formulated with potassium rather than sodium, and products based on potassium bicarbonate are expected to become more important, when its re-evaluation under the 4th stage is completed. In the context of Reg. 2092/91, the use of fungicides containing bicarbonate is not new, and this request can be seen as a **request for re-introduction of bicarbonate**, rather than for introduction of a new substance.
A 4.02 Alternative methods *State the methods at the level of the organic farming system (as described in Annex 1) that can control the problem for which it is proposed to introduce the substance. List plant breeding, husbandry or management practices and compare them with the proposed product.*	Potassium bicarbonate is effective against many diseases which can affect many crops from vegetables to top fruits. Its specific activity will complement the impact of alternative methods that are either not existing for all targeted crops or which are not totally effective, for example apple scab, vine and strawberry powdery mildews.
A 4.03 Alternative products *State the alternative products that can control the problem for which it is proposed to introduce the substance that are already authorized for organic farming and that have a comparable effect. Explain the specific advantages and disadvantages of the proposed product over these alternatives.*	Sulfur is authorized for organic farming (Annex IIB of 2092/91) and is widely used against powdery mildew in many crops, including vines, pome fruits, strawberries and vegetables. Copper is also authorized for organic farming under different forms, and is used as a wide spectrum fungicide on many fruit crops. Armicarb 85SP shows comparable efficacy to sulfur treatments, except in specific conditions where the vapor effect of sulfur allows a slightly superior efficacy. However, sulfur is subject to strict MRLs and the use of copper is increasingly restricted, whereas potassium bicarbonate is not subject to any limitation. Therefore, Armicarb 85SP can be used very late in the growth stage, even up to harvest, which is a great advantage for organic farmers. Moreover, sulfur treatment can form stains on the crop, whereas potassium bicarbonate has no such negative visual impact on the treated crop. The replacement of copper fungicides in organic farming is a declared goal of the EU (see Reg. 473/2002). The use of potassium bicarbonate as a fungicide presents extremely low risk of resistance due to the non site-specific mode of action.
A 4.04 Efficacy *Summarize the effect of the product on crop growth, yield or quality.*	Practical use in the United States and extensive field trials in Europe have demonstrated good efficacy against a range of plant diseases with no adverse effect of the product on crop growth, yield, or quality. Potassium bicarbonate, by controlling some key diseases will facilitate crop growth, improve yield and quality. An exemption for crop residue tolerances has been granted in the USA and is being requested in Europe. In addition it will not stain the treated crops. According to the results of field trials, efficacy of Armicarb 85SP used a fungicide is independent from soil conditions, climate, altitude, etc…
A 4.05 Economic importance *Provide an estimate of the economic importance of the product, as far as is practicable. Where possible, indicate variability due to region, altitude, climate, soil type, crop, traditional use, local specialities etc.. The claim for economic importance must take account of organic farming principles (see Abbreviations & Definitions), local conditions, traditional practices etc.*	Armicarb 85SP is expected to have a positive economic impact by providing effective disease control at reasonable cost without generating residues that could impact value and acceptability. Armicarb 85SP should provide organic farmers with an efficient solution against fungus pests in various crops, especially for late applications, for which fungicide solutions are scarce.
A 4.06 Likely extent of use *Provide a rough estimate of the likely extent of use, for example the number or proportion of organic farmers, or land area likely to be treated. This will depend on the crops (A 1.3.5) and the organisms to be controlled (A 1.3.3).*	Judging from the interest of the organic sector, potassium bicarbonate is likely to be used on a large proportion organic pears, apples and strawberries.

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A 4.07 Resistance *PPP only.* ***(1)*** *Describe the likelihood of pests or pathogens developing resistance against the product.* ***(2)*** *Can the product help to prevent resistance against other products? Where appropriate, describe measures to prevent resistance development.*	The mode of action of Armicarb 85SP 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. Armicarb 85SP treatments should ideally be integrated to pest management schemes.
A 5 Environmental impact ***Note:*** *All statements in section 5 should be consistent*	
A 5.01 Manufacturing *Does the manufacturing process (see A 3.0.1) risk polluting the environment? Evidence and/or reasoned argument should be provided to explain the environmental impact.*	The manufacturing process of potassium bicarbonate precludes the possibility of synthetic impurities. Potassium bicarbonate complies with the Food Chemicals Codex specifications for heavy metals and loss on drying. The manufacturing process of Armicarb 85SP does not include or produce any impurities, by-products or coformulant of toxicological, ecotoxicological or environmental concern. Therefore, the manufacturing process of Armicarb 85SP does not risk polluting the environment.
A 5.02 Environmental fate *Provide information on fate and behaviour in the environment (i.e. How fast does it break down, and into what? How mobile are the product and its metabolites, and do they accumulate somewhere in the environment?). Where appropriate, information on half life and potential for bioaccumulation (e.g. Kow) should be provided. If exposure of water, soil or air is likely to occur, available information from literature on natural background levels should be provided.*	Bicarbonate is a natural product, present in soil pore waters as a result of carbon dioxide liberated from the respiration of soil organism. In soils below pH 5.5, bicarbonate anions are reduced by free hydrogen ions to produce water and carbon dioxide. In more alkaline soils the bicarbonate can remain as the anion loosely associated with cations, like calcium and magnesium. When bicarbonate or carbonate is added to the soil (eg through irrigation water or use of Armicarb), limestone is formed. In this process, free calcium levels in the soil are decreased and the pH can rise. In fertile acidic soils, bicarbonates are essential to buffer excess acidity. Such soils are often augmented by the addition of alkali earth carbonates such as calcium and magnesium. Potassium (K) is an essential plant and microbial nutrient that has a natural cycle in soil of uptake and utilisation by plants and microbes, followed by release resulting from the decomposition of rotting organisms. In agricultural soils, it is common practice to supplement the natural K levels through the application of potash based fertilisers.
A 5.03 Use *Does the use of the product or its metabolites risk to pollute the environment? Evidence and/or reasoned argument should be provided to explain the environmental impact. Effects on animals, plants and soil to be detailed under A 5.06 - 5.08.*	Environmental impact: Potassium bicarbonate and its metabolites do not risk polluting the environment.
A 5.04 Effects of impurities *The release of the substances listed under A 1.1.9 must be considered at the likely application rate (see A 1.3.8).*	NA Please refer to A 1.1.9
A 5.05 Release of biocontrol agents *Describe impact of release, particularly for non-native biological control agents.*	NA
A 5.06 Effects on animals *Indicate whether effects on non-target animals are possible. If so, give details of effects (e.g. LD_{50} or LC_{50}, likelihood of exposure etc.). Mention particularly farm animals, bees, beneficial insects, wildlife and endangered species.*	Potassium and bicarbonate are extremely common in all natural systems, including water, soil, plant and animal tissues. Armicarb 85SP has extremely low toxicity in mammals. 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 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. 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 Potassium is an essential plant nutrient and is often applied to crops as both a soil and/or foliar fertiliser. 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.
A 5.07 Effects on plants *Indicate whether phyto-toxic or nutrient supply effects on non-target plants are possible. If so, give details of effects (e.g. cress toxicity test for compost). Mention particularly crops and native botanicals.*	No phyto-toxic or nutrient supply effects were noted. As potassium and bicarbonate are extremely common in all natural systems, including in plants, it is very unlikely that potassium bicarbonate will have unexpected negative effects on plants. The potassium fertilizing effect is considered minor, compared with fertilization (please refer to A 1.1.5).
A 5.08 Effects on soil *Indicate whether effects on soil (including soil fertility & erosion) or microorganisms are possible. If so give details. Where appropriate, give salinity index.*	No effects on soil fertility, soil erosion, or soil microorganisms were noted. Potassium bicarbonate is naturally present in soil. The potassium fertilizing effect is considered minor, compared with fertilization (please refer to A 1.1.5).
A 5.09 Hazardous properties to the environment *State the hazardous properties of the substance to the environment, and state the specific risk management measures appropriate to mitigate the environmental risks (see also A. 1.1.10).*	Potassium bicarbonate does not present hazardous properties to the environment. No specific risk management measures are needed (please refer to points A 5.01 to A 5.08).

Requested data	Applicant statement *Provide statement for each cell.*
A 6 Human health impact ***Note:*** *All statements in section 5 should be consistent*	
A 6.01 Impacts on human health *Summarize all available toxicological information on reported or possible adverse impacts on human health, including studies, publications, evaluations done in OECD countries, and where relevant also for uses other than as PPP or F&SC.*	Based upon a review of the toxicology, pathology, and related studies, food grade potassium bicarbonate, and potassium carbonate do not represent any risk to humans.
A 6.02 Risks of manufacturing process *Discuss human health risks of the manufacturing process, as described under A 3.01.*	The potassium bicarbonate present in Armicarb 85SP is manufactured by Armand Products Company in their ISO 9002-certified laboratories. We are unaware of any human safety issue at the production plant.
A 6.03 Risks of application *Discuss human health risks from application of the product, as described under A 1.3.*	An evaluation of the operator exposure to Armicarb 85SP was carried out using the UK POEM model and the German BBA model on worst case scenarios. The results showed that the risk to the operator is acceptable, with or without the use of personal protective equipment. The same type of evaluation was carried out for bystanders and workers, and reached the conclusion that there is no undue risk to accidental bystander exposure, and that without any specific personal protection the risk of a contamination to workers is low when entering the treated areas directly after application.
A 6.04 Residues *Summarise any residue data available. Use reasoned argument for likely presence or absence of residues in or on treated food and feed products. Where presence is likely, document concentration with analytical data.*	A waiver has been requested from conducting residue trials because of the natural occurrence of potassium bicarbonate, its very low toxicity and the difficulty to differentiate residues from naturally occurring nutrients in the crop.
A 6.05 Risks from residues *If residues may occur (see A 6.04), compare with tolerances from national registration or other approval. Where not available, compare with toxicological data. Discuss toxicological relevance.*	Potassium and bicarbonate ions are naturally occurring in all environmental compartments including plant tissues. It is impossible to differentiate between potassium and bicarbonate ions produced from the use of Armicarb 85SP and those occurring naturally in the crop. Bicarbonate is not harmful to humans unless consumed in extremely high quantities and is widely used as a buffering agent to reduce stomach acidity. It also readily reduces in the presence of free hydrogen to produce water and carbon dioxide, which are both key components of photosynthesis in plants. 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. Total inputs of potassium from the worst-case usage of Armicarb 85SP are also considerably lower than those resulting from the use of potash based liquid fertilizers. For all these reasons, we believe that any residues of potassium bicarbonate is crops present no risk to the consumers.
A 6.06 Hazardous properties to human health *State the hazardous properties of the substance to human health, and state the specific risk management measures appropriate to mitigate these risks (see also A. 1.1.10).*	The substance does not present hazardous properties to human health. No specific risk management measures are required.
A 7 Animal health & welfare impact	
A 7.01 Effect on animal health and welfare *Describe positive and negative impacts on animal health and welfare, or absence thereof.*	No adverse effect are to be expected.
A 7.02 Hazardous properties to animal health and welfare *State the hazardous properties of the substance to the animal health and welfare, and state the specific risk management measures appropriate to mitigate these risks (see also A. 1.1.10).*	None.
A 8 Socio-economic aspects	
A 8.01 Public perception: consumption-related views. *Summarize consumption-related issues of public perception, especially product quality, availablilty, storage, price etc. Where appropriate, indicate range of variability (note: such considerations may also be expressed by stakeholders other than consumers).*	Consumer perception of the use of potassium bicarbonate as a fungicide on fruit crops is expected to be positive. Registered as a food ingredient, used as a leavening agent in baking and in medicine, "Generally Recognised As Safe", potassium bicarbonate has a very safe profile. Moreover, unlike sulfur treatments, potassium bicarbonate treatments does not cause any stain on the crop, which makes it more acceptable to the consumer.
A 8.02 Public perception: farming practice-related views. *Summarise issues of public perception relating to farming practices and their perception by the farming community (organic and conventional). Consistency with organic farming principles (see Abbreviations & Definitions) provides guidance.*	Safe, efficient, unlikely to trigger resistance: both to organic and conventional farmers, potassium bicarbonate fungicide treatments should bring innovative solutions for horticulture. Therefore, the public perception from a farming practice point of view is expected to be positive. The partial replacement of copper fungicides by potassium bicarbonate seems positive.
A 8.03 Public perception: other stakeholder views. *Summarize other issues of public perception, particularly ethical aspects such as animal welfare, fair trade etc. and environmental impact.*	As potassium bicarbonate has been used for decades in medicine and everyday products- including processed food-, the public perception of potassium bicarbonate fungicide use on fruit crops is expected to be positive. No reasons for negative perception obvious.
A 8.04 Effects on rural development *Explain the possible effects on rural development and rural living conditions from the point of view of organic farming system development.*	None.
A 8.05 Social justice *State whether the substance will affect social justice, or the scope for fair trade through contributing to the development of organic systems.*	None.
A 8.06 Cultural, ethical, religious issues *Address cultural, ethical or religious concerns (e.g. for vegetarians, animal based products may be an issue; certain religions require specific slaughtering procedures or exclude some animal species).*	None.
A 9 Other relevant information	

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A 9.01 Other information **(1)** *Give any other information considered relevant to the application or to support specific statements made in the Application Form.* ***(2)*** *List numbered documents and attach to the complete Application.*	None.
A 10 Key issues	
A 10.01 Key issues in favour *Summarise the key issues in favour of the product.*	From the farmer's perspective, Armicarb 85SP shows good efficacy and selectivity on the tested crops. Any residues will not require regulation (exempt from MRLs/ tolerances). It does not leave visible deposits on the crops, and is very unlikely to trigger any resistance. It therefore represents a good alternative to the products currently on the market. From a safety perspective, potassium bicarbonate is naturally present in humans, other animals, plants and the environment. Potassium bicarbonate and its metabolites are of no toxicological, ecotoxicological or environmental concern. Potassium bicarbonate is approved for food use both by the EU and by FCC, as well as being "generally recognised as safe" by the US FDA. It therefore has a safe profile for operators, workers, consumers, as well as for non-target animals and the environment. The replacement of copper fungicides is a priority in organic farming, and potassium bicarbonate provides the possibility for partial replacement. It is used in organic farming in the USA, and sodium bicarbonate by organic farmers in Germany. It is very likely to receive a positive response from the public. .
A 10.02 Key issues causing concern *Summarise the key issues which cause concern*	Potassium bicarbonate is manufactured synthetically through simple chemical processes. Through its use, a small proportion of the total K need will be supplied with K from synthetic origin.