European Food Safety Authority

EFSA supporting publication 2015:EN-719

TECHNICAL REPORT

Outcome of the consultation with Member States and EFSA on the basic substance application for sodium hydrogen carbonate for use in plant protection as a fungicide for the control of mildews on a range of horticultural crops, apple scab and for post-harvest control of storage diseases of various fruits[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for sodium hydrogen carbonate are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of sodium hydrogen carbonate as a basic substance for use in plant protection as a fungicide for the control of mildews on a range of horticultural crops, apple scab and for post-harvest control of storage diseases of various fruits. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

KEY WORDS

sodium hydrogen carbonate, basic substance, application, consultation, plant protection, pesticide, fungicide

[1] On request from the European Commission, Question No EFSA-Q-2014-00722, approved on 10 December 2014.

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Suggested citation: European Food Safety Authority, 2015; Outcome of the consultation with Member States and EFSA on the basic substance application for sodium hydrogen carbonate for use in plant protection as a fungicide for the control of mildews on a range of horticultural crops, apple scab and for post-harvest control of storage diseases of various fruits. EFSA supporting publication 2015:EN-719. 30 pp.

Available online: www.efsa.europa.eu/publications

SUMMARY

Sodium hydrogen carbonate is an active substance for which in accordance with Article 23(3) of Regulation (EC) No 1107/2009 the European Commission received an application from the Danish Environmental Protection Agency, Pesticides and Gene Technology Division for approval as a "basic substance". Regulation (EC) No 1107/2009 introduced the new category of "basic substances", which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013 the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in October 2014, EFSA was asked to organise a commenting on the basic substance application for sodium hydrogen carbonate, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a Reporting Table within 3 months of acceptance of the specific request.

A consultation on the basic substance application for sodium hydrogen carbonate, organised by EFSA, was conducted with Member States and EFSA via a written procedure in August – October 2014. Subsequently the applicant was invited to address the comments received in the format of a Reporting Table, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by EFSA on the basic substance application for sodium hydrogen carbonate and presents EFSA's scientific views on the individual comments received in the format of a Reporting Table.

Sodium hydrogen carbonate is intended to be used against mildews in vegetables, soft fruit and ornamentals, against *Uncinula necator* in vine, against *Venturia inaequalis* in apple and against storage diseases in fruit of different types.

Sodium hydrogen carbonate as specified in this application, approved as a food additive (E500) (Commission Regulation (EU) No 1130/2011) or complying with the requirements of the European Pharmacopoeia (2005 & 2014), fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 and shall be considered as a basic substance from the point of view of the identity and physical-chemical properties.

The information provided in the mammalian toxicology section support the proposal that sodium hydrogen carbonate is a basic substance devoid of effects of toxicological concern.

Considering that sodium hydrogen carbonate fulfils the criteria of a 'foodstuff' under Regulation (EC) No 178/2002, it is concluded that no residues of concern are expected to be present in food and feed commodities when sodium hydrogen carbonate is applied according to the proposed uses.

It is considered that the assessment of information provided relating to the environmental fate and behaviour of sodium and hydrogen carbonate ions is sufficient for the soil, water, sediment and air environmental exposure characterisation from the uses that have been assessed, considering that an EFSA conclusion (EFSA Journal 2012;10(1):2524) on a Draft Assessment Report prepared by Ireland, that considered similar uses, is available for the related substance potassium hydrogen carbonate that dissociates to potassium and hydrogen carbonate ions.

The available ecotoxicological information and assessments are considered sufficient to address the risk to non-target organisms (birds, mammals, aquatic organisms, honey bees, non-target arthropods, earthworms and soil macroorganisms other than earthworms).

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1107/2009[3] (hereinafter referred to as 'the Regulation') introduced the new category of "basic substances", which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as "basic" and used for plant protection purposes.

Sodium hydrogen carbonate is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from the Danish Environmental Protection Agency, Pesticides and Gene Technology Division for approval as a "basic substance" for use in plant protection against mildews in vegetables, soft fruit and ornamentals, against *Uncinula necator* in vine, against *Venturia inaequalis* in apple and against storage diseases in fruit of different types.

The European Food Safety Authority (EFSA) organised a consultation with Member States and EFSA on the basic substance application for sodium hydrogen carbonate, which was conducted via a written procedure in August – October 2014. The comments received were collated by EFSA in the format of a Reporting Table. Subsequently, the applicant was invited to address the comments in column 3 of the Reporting Table. The comments received and the response of the applicant thereon, together with the application submitted by the applicant, were considered by EFSA in column 4 of the Reporting Table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for sodium hydrogen carbonate and to present EFSA's scientific views on the individual comments received in the format of a Reporting Table.

The application and, where relevant, any update thereof submitted by the applicant for approval of sodium hydrogen carbonate as a "basic substance" in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (Danish Environmental Protection Agency, Pesticides and Gene Technology Division; 2014a, 2014b).

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

On 6 March 2013 the European Commission requested EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 10 October 2014, EFSA was asked to organise a commenting on the basic substance application for sodium hydrogen carbonate, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a Reporting Table.

To this end, a Technical Report containing the finalised Reporting Table is prepared by EFSA. The agreed deadline for providing the finalised report is 12 January 2015.

On the basis of the Reporting Table, the European Commission may decide to further consult EFSA to conduct a full or focussed peer review and to provide its conclusions on certain specific points.

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

EVALUATION

The comments received on the basic substance application for sodium hydrogen carbonate and the conclusions drawn by EFSA are presented in the format of a Reporting Table.

The comments received are summarised in column 2 of the Reporting Table. The applicant's considerations of the comments, where available, are provided in column 3, while EFSA's scientific views and conclusions are outlined in column 4 of the table.

The finalised Reporting Table is provided in the Appendix of this report.

DOCUMENTATION PROVIDED TO EFSA

1. Danish Environmental Protection Agency, Pesticides and Gene Technology Division, 2014a. Sodium hydrogen carbonate. Basic substance application submitted in the context of Article 23 of Regulation (EC) No 1107/2009. August 2014. Submitted by the Danish Environmental Protection Agency, Pesticides and Gene Technology Division. Documentation made available to EFSA by the European Commission.

2. Danish Environmental Protection Agency, Pesticides and Gene Technology Division, 2014b. Sodium hydrogen carbonate. Basic substance application update submitted in the context of Article 23 of Regulation (EC) No 1107/2009. November 2014. Submitted by the Danish Environmental Protection Agency, Pesticides and Gene Technology Division. Documentation made available to EFSA by the applicant.

REFERENCES

EFSA (European Food Safety Authority), 2012. Conclusion on the peer review of the pesticide risk assessment of the active substance potassium hydrogen carbonate. EFSA Journal 2012;10(1):2524. [37 pp.] doi:10.2903/j.efsa.2012.2524

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2013. Scientific Opinion on the safety evaluation of the active substances citric acid (E330) and sodium hydrogen carbonate (E500ii), used as carbon dioxide generators, together with liquid absorbers cellulose and polyacrylic acid sodium salt crosslinked, in active food contact materials. EFSA Journal 2013;11(4):3152. [10 pp.] doi:10.2903/j.efsa.2013.3152

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

Lippert, R., 1997. Cation exchange capacity and percent base saturation. Soil Testing. Clemson Extension. IL 67, December 1997.

UNEP, 1995. Water quality of world river basins. Global environment monitoring system (GEMS). UNEP Environment Library No 14: 1-37.

APPENDIX

COLLATION OF COMMENTS FROM MEMBER STATES AND EFSA ON THE BASIC SUBSTANCE APPLICATION FOR SODIUM HYDROGEN CARBONATE AND THE CONCLUSIONS DRAWN BY EFSA ON THE SPECIFIC POINTS RAISED

1. Purpose of the application

General				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

2. Identity of the substance/product as available on the market and predominant use

2.1. Identity and Physical and chemical properties of the substance and product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.1.5 Specification of the substance, p.7	EFSA: EFSA agrees that sodium hydrogen carbonate approved as a food additive (E500) (COMMISSION REGULATION (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients) and a feed ingredient, or meeting the requirements of the European Pharmacopoeia (2005) can be considered a basic substance from the point of view of the identity and physical-chemical properties.	No comments.	Addressed: EFSA agrees that sodium hydrogen carbonate, approved as a food additive (E500) (Commission Regulation (EU) No 1130/2011 of 11 November 2011)[4] or complying with the requirements of the European Pharmacopoeia (2005 & 2014), can be considered as a basic substance from the point of view of the identity and physical-chemical properties.
2(2)	2.1.7 Methods of analysis	DE: Analytical methods for the impurities of sodium hydrogen carbonate mentioned in chapters 2.1.5 and 2.1.6 should be described, too.	Analytical procedures for determination of the impurities mentioned in section 2.1.5 can be found in the European Pharmacopeia (2005) (provided already) and (Ph. Eur. 8.2) (as mentioned in that section. Reference to the Pharmacopeia will be inserted also in section 2.1.7.2. With regard to the impurities mentioned in	Addressed: Analytical methods for the impurities chlorides, sulphates, ammonium, As, Ca, heavy metals are described in the European Pharmacopeia (2005).

[4] Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients. OJ L 295, 12.11.2011, pp 178-204.

2.1. Identity and Physical and chemical properties of the substance and product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			section 2.1.6, the Danish EPA considers these to be natural and low-toxic substances appearing as impurities in typical products in concentrations so low that description of analytical methods is not relevant.	

2.2. Current Former and in case proposed trade names				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

2.3. Manufacturer of the substance/products				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

2.4. Type of preparation				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

2.5. Description of the recipe for the product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

2.6. Function on plant protection				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

3. Uses of the substance and its product

3.1. Field of use				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

3.2. Effects on harmful organisms or on plants				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)	3.2 Post-harvest treatment p.15	EFSA: small note: it is not correct to use the plural for sodium bicarbonate, as this is a unique substance	This typographical errors are corrected.	Addressed: the typos have been corrected.

3.3. Summary of intended uses				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(2)	3.3 Summary of intended uses, p.17	EFSA: it is rather strange to propose doses and intervals for application making reference to an "active substance" potassium hydrogen carbonate. Probably the way the two substances are treated, should be the same.	As sodium hydrogen carbonate is not predominantly being used for plant protection purposes (which is one of the prerequisites for being eligible as a basic substance), not much specific documentation is available on which to base recommendations on doses etc. for specific use areas. Therefore, the Danish EPA finds that use of such information from the similar potassium salt is relevant to qualify the choice of dose rates in the	Addressed: The proposed doses and intervals for the related active substance potassium hydrogen carbonate can be accepted.

3.3. Summary of intended uses				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			table in section 3.3, even though the potassium salt is approved as an active substance in EU.	
3(3)	3.3 Summary of intended uses	DE: It would be helpful for the assessment (and probably also for the user of the product) if the intended uses would be precisely described. The statement "Different crops have different sensitivity. Check concentrations for phytotoxic effects before widely used" do not lead to a precise risk assessment that can exclude harmful effects for non-target organisms.	The use of sodium hydrogen carbonate to control mildew is potentially relevant in several crop types of quite different character (vegetables, soft fruits, and ornamentals). Therefore, and because use as a PPP is not the predominant use of the substance (and, hence, actual efficacy trials have only been conducted to a very limited extent), it is recommended to check or test for phytotoxicity in crops for which no specific previous experience with use of the substance exist. This is considered to be a normal, sound practice.	Addressed: In crops, for which no specific previous experience with the use of sodium hydrogen carbonate exists (efficacy trials have not been conducted), it is recommended to check or test for phytotoxicity.

4. Classification and labelling of the substance

Classification and labelling of the substance				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
4(1)	5.3 (eye irritation)	DE: In the application, it is stated that several parties notified the compound as eye irritant (H319) to the CLP inventory. It is unclear why this self-classification is considered not relevant for the evaluated substance.	Only 36 out of a total of 2771 self-classifications by industry suggested a classification as an eye irritant. The Danish EPA assesses that as a majority do not classify the substance it is deemed that there is no justification for a H319 classification. This is also confirmed by the EFSA conclusion on the similar substance potassium hydrogen carbonate stating that potassium hydrogen carbonate is not eye irritant.	Addressed: Based on the available data the classification as H319 is not justified.

5. Impact on Human and Animal Health

5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)		EFSA: based on the available information it is agreed that sodium hydrogen carbonate is a basic substance.	No comments.	Addressed: Based on the available information it is agreed that sodium hydrogen carbonate is a basic substance.
5(2)	5 (impact on human and animal health)	DE: Among others, information/data created with other compounds than sodium hydrogen carbonate are presented (e.g., potassium salts or carbonates) throughout the toxicity chapter. The relevance of these different compounds for the evaluation of sodium hydrogen carbonate is unclear. Has the different identity (e.g., hydrogen carbonate vs. carbonate) an impact on the toxicological properties of the test compound?	The Danish EPA finds that it will not make a big difference in the toxicological properties of the substance if the salt differs from sodium to potassium. And further, no big differences are expected from potassium hydrogen carbonate to potassium carbonate.	Addressed: No significant differences are expected for different salts.
5(3)	5 (impact on human and animal health)	DE: It seems that only few original study reports are available. Most information was cited from older reviews. It is unclear whether these evaluations comply with current criteria.	As the substance has been authorised as a food additive and used e.g. as an antacid for many years, most of the references are fairly old and the studies therefore performed according to the standards from that time. But the Danish EPA finds that the studies are valid all the same and no serious effects have been found in the studies.	Addressed: The database is rather old, however the available information supports the proposal that sodium hydrogen carbonate is a basic substance.
5(4)	2.2 and 2.3	DE: From the information summarised in chapters 2.2 and 2.3, it is unclear, which specification is intended for the material	The Danish EPA proposes to approve as basic substance only the food grade quality as described in chapter 9.	Addressed: The food grade quality sodium hydrogen carbonate can be considered a basic

5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		to be authorised. Therefore, a toxicological evaluation is currently not possible. Is it intended to set the specification to that of pharmaceutical quality or food additive quality? Are there relevant differences between these two specifications?	Please see also EFSA comments in 2(1).	substance, based on the available data.

5.2. Toxicokinetics and metabolism in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.3. Acute toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.4. Repeated dose toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.5. Genotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(5)	5.5 (genotoxicity)	DE: It seems that the available information/data on the genotoxic properties of the compound are very limited and of limited validity, only.	It is correct that the available information on genotoxic properties are of limited validity, but all the studies are negative. Furthermore, sodium hydrogen carbonate is naturally present in cells and the structure does not indicate a genotoxic potential. Therefore, the Danish EPA agrees with the OECD evaluation (2002) that sodium hydrogen carbonate is considered not to be genotoxic. In addition, the substance is authorised as a food additive.	Addressed: The available information, although limited, indicates that sodium hydrogen carbonate is not genotoxic.

5.6. Long-term toxicity and carcinogenicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.7. Reproductive toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.8. Neurotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.9. Toxicity studies on metabolites				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.10. Medical Data: adverse effects reported in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.11. Additional Information related to therapeutic properties or health claims				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(6)	5.11 (Information related to therapeutic properties)	DE: It is questioned, whether a human drug which is used therapeutically should be authorised as basic substance.	No comments.	Addressed: According to the legislation (Regulation (EC) No 1107/2009) sodium hydrogen carbonate, intended for use in plant protection, fulfils the requirements as a basic substance.

5.12. Additional information related to use as food				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(7)	5.12	DE: It is noted, that EFSA's CEF panel evaluated a use where "direct contact between the substance and the food is excluded". Hence, it is unclear whether the panel's evaluation covers the uses described for the basic substance. Even for the use as food additive a limit was set: "quantum satis". Is a recent EFSA opinion available on the safety of the food additive uses?	The opinion of the CEF panel (EFSA, 2013) only concerns citric acid and sodium hydrogen carbonate used in combination as carbon dioxide generators in food contact materials. In this case, citric acid reacts with sodium hydrogen carbonate in the packaging materials generating carbon dioxide in the package. EFSA states that as the mixture of substances is placed in liquid absorbent pads not in contact with food, no safety concerns are raised. EFSA does not say that safety concerns can occur if the substances should be in contact with the food. Sodium hydrogen carbonate is authorised as a food additive (E500) COMMISSION REGULATION (EU)	Addressed: The EFSA CEF Panel opinion (EFSA CEF Panel, 2013) concerns citric acid and sodium hydrogen carbonate used in combination.

5.12. Additional information related to use as food				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			No 1130/2011 of 11 November 2011. [See point 2.1]	

5.13. Acceptable daily intake, acute reference dose, acceptable operator exposure level				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.14. Impact on human and animal health arising from exposure to the substance or impurities contained in it				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(8)	5.14, p. 31	DE: At least a statement on the expected risk for humans (and animals) from exposure during/after application should be given.	A statement of the expected risk to operators, workers and bystanders will be included in 5.14. The highest dose of sodium hydrogen carbonate used for spraying vines and apples is 5,000 kg/ha. It is the same dose as for potassium hydrogen carbonate use. Based on exposure calculations from that substance, the exposure for operators is around 40 mg/kg/day without PPE. As an intake of up to 4 g sodium hydrogen carbonate per day as an antacid is without adverse effects, no risk for operators is expected from use of sodium hydrogen carbonate as a plant protection product.	Addressed: The non-dietary exposure to sodium hydrogen carbonate is expected to be lower than the dietary.

5.14. Impact on human and animal health arising from exposure to the substance or impurities contained in it				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			There are no calculations of exposure from the use of post-harvest treatment or exposure to workers and bystanders, but the exposure is estimated to be low compared to exposure from intake of sodium hydrogen carbonate via food or as antacid.	

6. Residues

Residues				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)		EFSA: No comments.		

7. Fate and Behaviour in the environment

Fate and Behaviour in the environment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	Annex I-List of references relied on Section 7 page 52	EFSA: The DAR for potassium hydrogen carbonate and OECD 2002 SIDS documents (both being third party evaluations) are referenced in chapter 7, with the DAR not being listed as having been relied upon, is this an omission? If the applicant considers that the DAR has been relied upon, pertinent underlying references used in this assessment of that DAR, are not needed as this was a 'European evaluation' as defined in the basic substances articles of the 1107 regulation. In contrast the OECD SIDS document is a third party evaluation which is not a 'European evaluation'. Consequently the underlying references cited in the SIDS needed to be supplied and they do not appear to be available.	The DAR for potassium hydrogen carbonate is now included in the list of references for Chapter 7. The OECD reference is now changed to the reference UNEP (1995): "Water quality of world river basins" and the reference has been submitted.	The DAR for potassium hydrogen carbonate, Ireland (2006), has been appropriately added to the references supporting the evaluation in section 7. The reported aqueous solubility of 96 g/L at 20°C and negligible solubility (page 34 of the updated application dated November 2014), now cited as having an origin in a supplied UNEP (1995) reference, are not contained in the reference. Therefore these quoted properties cannot be tracked back to any observation or measurement using the information in the application. The supplied UNEP (1995) reference does contain the presented information on natural levels of sodium and hydrogen carbonate in natural surface waters.
7(2)	Annex I-List of references relied on Section 7 page 52	EFSA: The reference Lippert, 2000 has not been included in the documentation available to EFSA that was uploaded to CIRCABC. The hyperlink to the document on the web in the reference list appears broken, so EFSA is unable to understand the nature of the information that might be in this reference.	The reference, Lippert (2000), has now been changed to Lippert (1997), which contains the same information and which has now been supplied.	The supplied reference Lippert (1997) contains the statements that sodium levels higher than 15 % on the exchange site can result in soil dispersion, poor water infiltration and possible sodium toxicity to plants. However, it is now apparent that the reference is just a document providing practical advice to growers and it is not the source of any observation or measurement

Fate and Behaviour in the environment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				that supports the statement. This of course does not preclude that the statement is accurate.

8. Effects on non target species

8.1. Effects on terrestrial vertebrates				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	8.1 Effects on terrestrial vertebrates	DE: In section 5.6 "Long-term toxicity and carcinogenicity" bladder carcinogenesis promoting properties of sodium hydrogen carbonate are described as well as growth retardation in rats after feeding on a diet with $NaHCO_3$. In section 8.1 is not described whether the doses proposed for the intended uses possibly induce these unwanted effects in terrestrial vertebrates.	Evidently, the effects referred to in section 5.6 occurred after long term exposure to high dosages which will not occur as a result of the (short term) use of sodium hydrogen carbonate in crops.	On the basis of the available information the risk to terrestrial vertebrates is considered to be appropriately addressed and it is considered to be low.

8.2. Effects on aquatic organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(2)	Effects on aquatic plants/algae	DE: An increasing algal standing crop for a concentration of 45 mg/L of sodium hydrogen carbonate as well as a possible growth reduction at very high concentrations (> 1 g/L) of sodium hydrogen carbonate is described. Both could lead to unwanted effects on the composition of the aquatic biocoenosis. Possibly risk minimising measures should be considered.	The PEC for surface water (section 7.3) mentions a "worst case" concentration of 5.3 mg/l sodium and 8.3 mg/l hydrogen carbonate resulting from 8 annual applications of 5.1 kg a.s./ha and 100% drift. This concentration is considerably lower than the 45 mg/l mentioned and a natural level in many rivers throughout the world. Therefore, the Danish EPA does not consider risk minimising measures to	On the basis of the available information the risk to aquatic organisms is considered to be appropriately addressed and it is considered to be low.

8.2. Effects on aquatic organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			be necessary.	
8(3)	Effects on aquatic plants / algae	EFSA: In the application it is stated that:' A further addition of sodium hydrogen carbonate will increase the growth of the algae, while a growth reduction (osmotic effect) will probably be found at very high concentrations (>1 g/l). These potential effects would need to be further clarified as these could lead to potential adverse effects on the aquatic ecosystem.	See response above.	On the basis of the available information the risk to aquatic organisms is considered to be appropriately addressed and it is considered to be low.

8.3. Effects on bees and other arthropods species				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(4)	Effects on bees	EFSA: Potential adverse effects on bees by contact exposure need to be further clarified. It has also to be noted that for Potassium Hydrogen carbonate a critical area of concern was identified with regard to the contact toxicity to bees.	Following confirmatory data on acute and oral toxicity of potassium hydrogen carbonate to honey bees evaluated e.g. by The Netherlands and Germany, no critical area of concern was identified for potassium hydrogen carbonate in connection with national authorisations of Armicarb 85 SP and VitiSan. The Danish EPA suggests that bridging to potassium hydrogen carbonate is accepted. Therefore, the Danish EPA does not	On the basis on the available data on sodium hydrogen carbonate a high acute contact risk to honey bees cannot be excluded for the intended uses of sodium hydrogen carbonate. However, data for formulations containing potassium hydrogen carbonate were reported in the application, indicating a low risk to honey bees. An extrapolation from potassium hydrogen carbonate to sodium hydrogen carbonate could be considered as reasonable. Therefore, although pertinent information on sodium hydrogen carbonate was not available, the risk to honey bees can be considered as low based on weight of

8.3. Effects on bees and other arthropods species				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			consider risk minimising measures to be necessary.	evidence.

8.4. Effects on earthworms and other soil macroorganisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

8.5. Effects on soil microorganisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

8.6. Effects on other non-target organisms (flora and fauna)				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

8.7. Effects on biological methods of sewage treatment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

9. Overall conclusions with respect of eligibility of the substance to be approved as basic substance

Overall conclusions with respect to eligibility of the substance to be approved as basic substance				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)	9. Overall conclusion, p.47	EFSA agrees that sodium hydrogen carbonate specified as under 2.1.5 of this application fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 and shall be considered as a basic substance from the point of view of the identity and physical-chemical properties and human toxicology.	The Danish EPA is of the opinion that sodium hydrogen carbonate in all respects qualify for eligibility as basic substance.	Sodium hydrogen carbonate specified under 2.1.5 of this application fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002[5].

[5] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, pp. 1-24.

10. Other comments

Other comments				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

ABBREVIATIONS

°C	degree Celsius (centigrade)
a.s.	active substance
CEF	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CLP	classification, labelling and packaging of substances and mixtures
DAR	Draft Assessment Report
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency (Denmark)
EU	European Union
g	gram
ha	hectare
kg	kilogram
L	litre
mg	milligram
OECD	Organisation for Economic Co-operation and Development
PPE	personal protective equipment
PPP	plant protection product
UNEP	United Nations Environment Programme