EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and biocides

COMMISSION STAFF WORKING DOCUMENT[1]

Basic Substance
sodium hydrogen carbonate
SANTE/10667/2015– rev. 3
7 October 2016[2]

Final Review report for the basic substance sodium hydrogen carbonate
Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 9 October 2015
in view of the approval of sodium hydrogen carbonate as basic substance in accordance with Regulation (EC) No 1107/2009

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of sodium hydrogen carbonate made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009[3] concerning the placing of plant protection products on the market, with a view to the possible approval of this substance as basic substance.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 26 March 2014 an application from the Danish Environmental Protection Agency, hereafter referred to as the applicant, for the approval of the substance sodium hydrogen carbonate as basic substance.

The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application, which was finalised in the new version of August 2014.

In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission required scientific assistance on the evaluation of the application to EFSA, who delivered its views on the specific points raised in the commenting phase.

EFSA submitted to the Commission the results of its work in the form of a technical report for sodium hydrogen carbonate on 12 December 2014[4].

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1 Does not necessarily represent the views of the Commission.

2 The Standing Committee on Plants, Animals, Food and Feed took note of revision 3 of the review report on 7 October 2016. The review report was amended to include the extension of use as a herbicide for use in greenhouses (see chapter 5 and Appendix II).

3 OJ L 309, 24.11.2009, p. 1-50.

4 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.

The Commission examined the application, the comments by Member States and EFSA and the EFSA Technical report on the substance together with the additional information and comments provided on it by the applicant, before finalising the current draft review report, which was referred to the Standing Committee on Plants, Animals, Food and Feed for examination. The draft review report was finalised in the meeting of the Standing Committee of 9 October 2015.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the EFSA technical report, and the comments and clarifications submitted (background document C), all these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed in support of the **Commission Implementing Regulation (EU) 2015/2069**[5] concerning the approval of sodium hydrogen carbonate as basic substance under Regulation (EC) No 1107/2009.

The review report will be made available for public consultation by any interested parties.

Without prejudice to the provisions of Regulation (EC) No 178/2002[6], in particular with respect to the responsibility of operators, following the approval of sodium hydrogen carbonate as basic substance, operators are responsible for using it for plant protection purposes in conformity with the legal provisions of Regulation (EC) No 1107/2009 and with the conditions established in the sections 4, 5 and Appendixes I and II of this review report.

EFSA will make available to the public all background documents and the final Technical Report of EFSA, as well as the application without the Appendixes and excluding any information for which confidential treatment is justified in accordance with the provisions of Article 63 of Regulation (EC) No 1107/2009.

Products containing exclusively one or more basic substances do not require authorisation in line with derogation set under Article 28 of Regulation (EC) No 1107/2009. As a consequence, no further assessment will be carried out on such products. However, the Commission may review the approval of a basic substance at any time in conformity with the provisions of Article 23(6) of Regulation (EC) No 1107/2009.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion based on the application, including the results of the evaluation carried out with the scientific assistance of EFSA, is that there are clear indications that it may be expected that sodium hydrogen carbonate fulfils the criteria of Article 23.

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5 OJ L 301, 18.11.2015, p. 42–44.

6 OJ L 31, 1.2.2002 p. 1-24 - 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.

Sodium hydrogen carbonate fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002.

Considering the EFSA conclusions on the basic substance application for sodium hydrogen carbonate, the rate of application and the conditions of use which are described in detail in Appendix I and II, it is concluded that the use of sodium hydrogen carbonate would not lead to concerns for human health. Furthermore, the conditions of use are not expected to lead to the presence of residues of concern in food or feed commodities.

Sodium hydrogen carbonate does not have an inherent capacity to cause endocrine disrupting (according to the interim criteria in Regulation (EC) No 1107/2009), neurotoxic or immunotoxic effects and is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Finally, it is not placed on the market as a plant protection product.

It can be concluded that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment when used in accordance with the supported uses as described in Appendix II.

In fact, these indications were reached within the framework of the uses which were supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this review report) and therefore, they are also subject to compliance with the particular conditions and restrictions in sections 4 and 5 of this report.

Extension of the use pattern beyond those described above will require an evaluation at Community level in order to establish whether the proposed extensions of use can still satisfy the requirements of Article 23 of Regulation (EC) No 1107/2009.

4. Identity and biological properties

The main properties of sodium hydrogen carbonate are given in Appendix I.

The active substance shall have a purity as food grade.

It has been established that for sodium hydrogen carbonate as notified by the applicant, no relevant impurities are considered, on the basis of information currently available, of toxicological, ecotoxicological or environmental concern.

5. Particular conditions to be taken into account in relation to the uses as basic substance of sodium hydrogen carbonate

Sodium hydrogen carbonate must be identified by the specifications given in Appendix I and must be used in compliance with conditions of supported uses as reported in Appendixes I and II.

The following conditions for use deriving from assessment of the application have to be respected by users:

- Only uses as basic substance being a fungicide or herbicide are approved.

Use of sodium hydrogen carbonate must be in compliance with conditions specified in the Appendixes I and II of this review report.

On the basis of the proposed and supported uses (as listed in Appendix II), no particular issues have been identified.

The identification of sodium hydrogen carbonate as food ingredient implies that the Regulation (EC) No 178/2002 on food safety applies.

On 7 October 2016, on the basis of the application submitted on 1 July 2016 by Agriculture and Horticulture Development Board, the Appendix II of the current review report has been amended to include the use as a herbicide on potted plants in greenhouses to control liverwort. Such extension of use has been evaluated and it has been established that it can still satisfy the requirements of Article 23 of Regulation (EC) No 1107/2009.

6. List of studies to be generated

No further studies were identified which were at this stage considered necessary.

7. Updating of this review report

The information in this report may require to be updated from time to time to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, as appropriate, in connection with any amendment of the approval conditions for sodium hydrogen carbonate in Part C of Annex of the Regulation (EC) No 540/2011.

8. Recommended disclosure of this review report

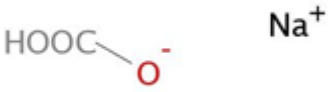
Considering the importance of the respect of the approved conditions of use and the fact that a basic substance will be not placed on the market as plant protection product, hence, no further assessment will have to be carried out on it, it is very important to inform not only applicants but also potential users on the existence of this review report.

It is therefore recommended that the competent authorities of Member States will make available such report to the general public and operators by means of their national relevant websites and by any other appropriate form of communication to ensure that the information reaches potential users.

APPENDIX I

Identity and biological properties

SODIUM HYDROGEN CARBONATE

Common name	Sodium hydrogen carbonate
Chemical name (IUPAC)	Sodium hydrogen carbonate
Chemical Name. (CA)	Sodium hydrogen carbonate
CAS No	144-55-8
CIPAC No and EEC No	Not available.
FAO SPECIFICATION	Not available.
Purity	Food grade as described in Directive 2000/63 amending Directive 96/77/EC.
Molecular formula	$NaHCO_3$
Relevant impurities	Not applicable.
Molecular mass and structural formula	 Molecular mass: 84.01 g mol^{-1}
Mode of Use	Sodium hydrogen carbonate as specified above to be used in water solution or as dry powder depending on application as listed in Appendix II.
Preparation to be used as a water solution	Sodium hydrogen carbonate to be diluted in compliance with rate of application reported in Appendix II.
Preparation to be used as a dry powder	Direct application of dry powder form of sodium hydrogen carbonate using a shaker pot.
Function of plant protection	Fungicide. Herbicide.

APPENDIX II

SODIUM HYDROGEN CARBONATE

Crop and/ or situation (a)	**F G or I** (b)	**Pests or group of pests controlled** (c)	**Formulation**		**Application**				**Application rate**			**PHI** (days)	**Remarks**
			Type (d-f)	Conc. of a.i. g/kg (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l) or concentration recommended		
Vegetables Soft fruit Ornamentals	F G	Mildews *(Sphaerotheca* spp, *Oidium* spp*)*	SP	990 g/kg	Broad cast using field spray or green house spray	BBCH 12 to 89	1-8	10 days	333-1000	300-600	2000-5000 0.33-1.0% Max 1% Dose adjusted depending on water volume	1	Different crops have different sensitivity. Check concentrations for phytotoxic effects before widely used.
Vitis vinifera {Vine}	F	*Uncinula necator* {Vine powdery mildew}	SP	990 g/kg	Broadcast using air blast orchard sprayer	BBCH 12 to 89	1-8	10 days	420-2000	200-600	2500 to 5000 0.42-2.0%	1	Volumes and doses will vary according to crop canopy size. Conc. higher than 1-2% can be phytotoxic
Malus sylvestris {Apple}	F	*Venturia inaequalis* {Apple scab}	SP	990 g/kg	Broadcast using air blast orchard sprayer	BBCH 10 to 85	1-8	10 days	500-1000	500-1000	2500 to 5000 0.5-1.0%	1	Volumes and doses will vary according to crop canopy size. Conc. higher than 1-2% can be phytotoxic

Crop and/ or situation (a)	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate			PHI (days)	Remarks
			Type (d-f)	Conc. of a.i. g/kg (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l) or concentration recommended		
Fruit of different types (oranges, cherries, apples, papaya)	F I	Storage diseases like Blue mould (*Penicillium italicum*) and Green mould (*Penicillium digitatum*)	SP	990 g/kg	Dipping or surface treatment	Harvested fruit	1-2	10 days	1000 g-4000 g in 100 l water		1-4%	1	Dose rates between 1-4% has been tested
Potted plants	G	Liverwort/ Bryophyte (thallose *Lunularia cruciata*) Green thallus of liverwort plus fruiting bodies.	Dry (D)	990 g/kg	Direct application of powder	Post emergence late summer or winter	1				122 kg/ha		The product is used for post-emergence application. Phytotoxicity of this use was not tested, check on small number of plants before it is widely used.

(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* pests as biting and sucking insects, soil born insects, foliar fungi, weeds or plant elicitor
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the substance (according to ISO)
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval