Appendix to:

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Appendix A – List of end points for the active substance and the representative formulation

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

| Active substance (ISO Common Name) | Sodium hydrogen carbonate (ISO common name not required) |
|------------------------------------|--------------------------------------------------------|
| Function (e.g. fungicide)          | fungicide                                               |
| Rapporteur Member State            | Austria                                                 |
| Co-rapporteur Member State         | none                                                    |

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

| Chemical name (IUPAC)              | sodium hydrogen carbonate                              |
|------------------------------------|--------------------------------------------------------|
| Chemical name (CA)                 | monosodium carbonate                                    |
| CIPAC No                           |                                                        |
| CAS No                             | 144-55-8 (formerly 19621-68-9, 199723-76-7, 26180-97-2) |
| EC No (EINECS or ELINCS)           | 205-633-8 (EINECS)                                      |
| FAO Specification (including year of publication) | none as food additive (FAO, 2006): INS no 500 (ii) (not assigned as active substance) |
| Minimum purity of the active substance as manufactured | 990 g/kg |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | As: max. 3 mg/kg Pb: max. 2 mg/kg Hg: max. 1 mg/kg |
| Molecular formula                  | NaHCO₃                                                  |
| Molar mass                         | 84.01 g/mol                                             |
| Structural formula                 | ![Structural formula](image)                            |
## Physical and chemical properties

*(Regulation (EU) N° 283/2013, Annex Part A, point 2)*

| Property                                           | Description                                                                                                                                  |
|----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Melting point (state purity)                       | decomposes without melting, decomposing starts >50 °C (releasing e.g. CO₂, H₂O and Na₂CO₃), total decomposition at 270 °C                |
| Boiling point (state purity)                       | decomposing starts >50 °C                                                                                                                   |
| Temperature of decomposition (state purity)        | decomposing starts >50 °C (>98 %) total decomposition at 270 °C (>98 %)                                                                      |
| Appearance (state purity)                          | technical and purified (>98 %): white crystalline powder, without odour                                                                     |
| Vapour pressure (state temperature, state purity)  | not applicable                                                                                                                                |
| Henry’s law constant (state temperature)           | not applicable                                                                                                                                |
| Solubility in water (state temperature, state purity and pH) | 103 g/L at 25 °C (purity not addressed)                                                                                                       |
| Solubility in organic solvents (state temperature, state purity) | no data provided, insoluble in organic solvents, sodium hydrogen carbonate is a salt and an ionic compound (highly soluble in water) |
| Surface tension (state concentration and temperature, state purity) | not applicable                                                                                                                                |
| Partition coefficient (state temperature, pH and purity) | no data provided, considered not relevant                                                                                                    |
| Dissociation constant (state purity)               | Sodium hydrogen carbonate completely dissociates to its respective ions when dissolved in water: NaHCO₃ → Na⁺ + HCO₃⁻  |
|                                                    | HCO₃⁻ is amphoteric and will then naturally participate in natural carbonic acid equilibria:  
|                                                    | \[
|                                                    | \[CO₃^{2-} + 2H^+ \Leftrightarrow HCO₃^- + H^+ (pK_{a1} = 10.33)\]
|                                                    | \[HCO₃^- + H^+ \Leftrightarrow H₂CO₃ (pK_{a2} = 6.33)\]
|                                                    | \[H₂CO₃ \Leftrightarrow CO₂ + H₂O\]                                                                                                          |
| UV/VIS absorption (max.) incl. \(\varepsilon\) (state purity, pH) | UV/VIS and IR spectra are available (unspecific), NMR and NIR spectra are not provided and considered as not relevant                        |
| Flammability (state purity)                        | not flammable                                                                                                                                |
| Explosive properties (state purity)                | not explosive                                                                                                                                |
| Oxidising properties (state purity)                | not oxidising                                                                                                                               |
Summary of representative uses evaluated, for which all risk assessments needed to be completed (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

| Crop and/or situation (a) | Member State | Product Name | FGI (b) | Pests or group of pests controlled (c) | Formulation | Application | Application rate per treatment | PHI (days) (l) | Remarks (m) |
|---------------------------|--------------|---------------|---------|-------------------------------------|-------------|------------|-------------------------------|---------------|------------|
| Vitis vinifera VITVI      | Southern Zone| NatriSan      | F       | Erysiphe necator UNCINE (powdery mildew) | SP 989      | Spray      | BBCH 12 to 89                 | 3 days        | 0.425-2.55 kg a.i./hl | max. 5.1 kg/ha | 1          |
| (wine grapes and table grapes) |              |               |         |                                     |             |            |                               |               | 200-1200        |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |

Representative use for table and wine grapes in the Southern Zone.
Volumes and doses will vary according to crop canopy size (if not applied according to the treated LWA).
Under dry and hot conditions, interval between applications should be extended up to 10 days.

| Crop and/or situation (a) | Member State | Product Name | FGI (b) | Pests or group of pests controlled (c) | Formulation | Application | Application rate per treatment | PHI (days) (l) | Remarks (m) |
|---------------------------|--------------|---------------|---------|-------------------------------------|-------------|------------|-------------------------------|---------------|------------|
| Vitis vinifera VITVI      | Central Zone | NatriSan      | F       | Erysiphe necator UNCINE (powdery mildew) | SP 989      | Spray      | BBCH 12 to 89                 | 3 days        | 1-6        | max. 12 kg/ha | 1          |
| (wine grapes and table grapes) |              |               |         |                                     |             |            |                               |               | 200-1200    |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |
|                           |              |               |         |                                     |             |            |                               |               |                          |                        |            |

Representative use for table and wine grapes in the Central Zone.
Volumes and doses will vary according to crop canopy size (if not applied according to the treated LWA).
- BBCH 12-60: 3 kg/ha
- BBCH 61-70: 6 kg/ha
- BBCH 71-74: 9 kg/ha
- BBCH 75-89: 12 kg/ha
Under dry and hot conditions, interval between applications should be extended up to 10 days.
For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

(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. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(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 active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. bentiavalicarb-isopropyl).
(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)
Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

| Central zone: | No minimum effective dose trials were carried out. |
|--------------|--------------------------------------------------|
|              | NatriSan has been tested in one GEP field trial. In this bridging trial, comparability of NatriSan to the plant protection product VitiSan (containing Potassium hydrogen carbonate) was demonstrated. |
|              | Across all seven efficacy trials (EPPO Maritime zone), Potassium hydrogen carbonate contained in the product VitiSan applied 8-12 times at 3-12 kg/ha reduced UNCINE quite well compared to the untreated control. Reduction was comparable to the use of the reference product (sulphur). The effectivenes of VitiSan on leaves was 74% and on bunches 79%. Neither the level of disease in the untreated control plots, nor the kind of assessment (severity or incidence) was indicated. |
| Southern zone: | One minimum effective dose trial was conducted to test Potassium hydrogen carbonate contained in the product VitiSan against UNCINE on wine grapes in France (Southern Zone, EPPO Maritime zone) in 2014. |
|              | In this trial Potassium hydrogen carbonate contained in the product VitiSan was applied at the target dose of 6.0 kg/ha and two reduced doses at 4.0 kg/ha and 2.0 kg/ha. Dose response was shown; the best effect was achieved at 6 kg/ha, applied 9 times. |
|              | In the same trial also efficacy of VitiSan was demonstrated: At low disease pressure (15.6 resp. 13.8 %, disease severity in leaves resp. bunches) VitiSan applied 6 times at 6 kg/ha achieved 81.5 resp. 77.3 % efficacy (disease severity, leaves resp. bunches). |

Based upon the bridging approach between sodium and Potassium hydrogen carbonate, efficacy is regarded to be sufficiently supported with data at the current level of active substance evaluation.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

| Crop safety of NatriSan (sodium hydrogen carbonate) was assessed in one single Maritime zone trial, all others were carried out with VitiSan (Potassium hydrogen carbonate). No phytotoxic symptoms were recorded at all. |
| Extrapolation of crop safety between different formulations (VitiSan and NatriSan), resp. different active substances (Potassium hydrogen carbonate and sodium hydrogen carbonate) is not possible. No data were presented addressing yield (quality, amount) as well as transformation processes. |
| Overall, the presented data are regarded to barely address crop safety of NatriSan both in the Central and the Southern zone. |
Observations on other undesirable or unintended side-effects (Regulation (EU) No 284/2013, Annex Part A, point 6.5)

| Activity                        | Description                                                                 |
|---------------------------------|-----------------------------------------------------------------------------|
| No observations (positive or negative) on living organisms or on the environment have been reported in the efficacy studies (one trial conducted with NatriSan, 8 trials conducted with VitiSan) |

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

| Activity against target organism | Description                                                                 |
|---------------------------------|-----------------------------------------------------------------------------|
| No data submitted, not required | (See Section 4)                                                             |
Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

| Category | Analytical Technique |
|----------|----------------------|
| Technical a.s. (analytical technique) | acid-base titration, ICP-OES |
| Impurities in technical a.s. (analytical technique) | ICP-OES (Pb, As), FIMS-AAS (Hg) |
| Plant protection product (analytical technique) | acid-base titration, ICP-OES |

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

| Category | Definition |
|----------|------------|
| Food of plant origin | A residue definition is not required |
| Food of animal origin | A residue definition is not required |
| Soil | A residue definition is not required |
| Sediment | A residue definition is not required |
| Water surface | A residue definition is not required |
| Drinking/ground water | A residue definition is not required |
| Air | A residue definition is not required |
| Body fluids and tissues | A residue definition is not required |

Monitoring/Enforcement methods

| Category | Method |
|----------|--------|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | not required |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | not required |
| Soil (analytical technique and LOQ) | not required |
| Water (analytical technique and LOQ) | not required |
| Air (analytical technique and LOQ) | not required |
| Body fluids and tissues (analytical technique and LOQ) | not required |

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

| Substance | Definition |
|----------|------------|
| Sodium hydrogen carbonate | |
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]:

Peer review proposal 2 for harmonised classification according to Regulation (EC) No 1272/2008:

| Sodium hydrogen carbonate and the plant protection product “NatriSan”: |
|-------------------------------------------------|
| A classification from the physico-chemical section is not required |

see statement above

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1 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

2 It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) No 283/2013, Annex Part A, point 5.1)

| Parameter | Description |
|-----------|-------------|
| Rate and extent of oral absorption/systemic bioavailability | Rapidly absorbed, approximately 100% |
| Toxicokinetics | Not relevant |
| Distribution | Widely distributed |
| Potential for bioaccumulation | Not relevant |
| Rate and extent of excretion | Not relevant |
| Metabolism in animals | Normal homeostasis maintained through well known mechanisms |
| In vitro metabolism | Not relevant |
| Toxicologically relevant compounds (animals and plants) | Na⁺ ion |
| Toxicologically relevant compounds (environment) | - |

Acute toxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.2)

| Parameter | Description |
|-----------|-------------|
| Rat LD₅₀ oral | > 2000 mg/kg bw |
| Rat LD₅₀ dermal | > 2000 mg/kg bw |
| Rat LC₅₀ inhalation | > 4.74 mg/L air /4h (not clear if nose only or whole body) |
| Skin irritation | Slightly irritating |
| Eye irritation | Slightly irritating |
| Skin sensitisation | Not-Sensitising (Buehler Test with Potassium hydrogen carbonate, 3 inductions) |
| Phototoxicity | Not required |

Short-term toxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.3)

| Parameter | Description |
|-----------|-------------|
| Target organ / critical effect | Potassium hydrogen carbonate: Altered urinary pH/hypertrophy of adrenal zona glomerulosa/increased potassium excretion. Urinary bladder hyperplasia (rats) |
| Relevant oral NOAEL | Potassium hydrogen carbonate: 4- and13-week rat LOAEL: 2% |
| Relevant dermal NOAEL | No data - not required |
| Relevant inhalation NOAEL | No data - not required |

Genotoxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.4)

| Parameter | Description |
|-----------|-------------|
| In vitro studies | AMES: negative |
Chromosomal aberration (Chinese hamster fibroblasts): negative
DNA damage and repair assay in E.coli: negative

In vivo studies
No data – not required

Photomutagenicity
No data – not required

Potential for genotoxicity
Sodium hydrogen carbonate is unlikely to be genotoxic

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)
No effects up to 0.64 % NaHCO₃

Relevant long-term NOAEL
0.64 % NaHCO₃

Carcinogenicity (target organ, tumour type)
Hyperplasia, papilloma and carcinoma of urinary bladder in rats only in presence of inducer N-butyl-N-(4-hydroxybutyl)nitrosamine (BBN) and a possible promotor (o-phenylphenate) through well-recognised mechanism, not considered relevant to humans

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity
Reproduction target / critical effect
No data available, not required

Relevant parental NOAEL
No data available, not required

Relevant reproductive NOAEL
No data available, not required

Relevant offspring NOAEL
No data available, not required

Developmental toxicity

Developmental target / critical effect
Sodium hydrogen carbonate did not induce teratogenic effects when administered orally up to highest dose of 580 mg/kg bw per d (mice), 340 mg/kg bw per d (rats) and 330 mg/kg bw per d (rabbits)

Relevant maternal NOAEL
No data available, not required

Relevant developmental NOAEL
No data available, not required

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity
No data available, not required

Repeated neurotoxicity
No data available, not required

Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)
No data available, not required
Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

| Study                                                                 | Outcome                                                                 |
|----------------------------------------------------------------------|-------------------------------------------------------------------------|
| Supplementary studies on the active substance                       | No data available, not required                                         |
| Endocrine disrupting properties                                      | No indications of an endocrine disruption potential                     |
| Studies performed on metabolites or impurities                      | No data available, not required                                         |

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

| Study                                                                 | Outcome                                                                 |
|----------------------------------------------------------------------|-------------------------------------------------------------------------|
| No effects on health expected                                        |                                                                         |

Summary³ (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

| Study                                                                 | Value (mg/kg bw (per day)) | Study | Uncertainty factor |
|----------------------------------------------------------------------|----------------------------|-------|--------------------|
| Acceptable Daily Intake (ADI)                                        | No suitable data available. Not needed                                 |       |                    |
| Acute Reference Dose (ARfD)                                          | No suitable data available. Not needed                                 |       |                    |
| Acceptable Operator Exposure Level (AOEL)                            | No suitable data available. Not needed                                 |       |                    |
| Acute Acceptable Operator Exposure Level (AAOEL)                     | No suitable data available. Not needed                                 |       |                    |

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

| Study                                                                 | Concentrate: 25% Spray dilution: 75% (Default values) |
|----------------------------------------------------------------------|-------------------------------------------------------|
| Representative formulation (indicate name, type e.g. EC and concentration of active substance) |                                                      |

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

| Study                                                                 | EFSA Model (application rate 5.1 and 12 kg a.s./ha): |
|----------------------------------------------------------------------|-------------------------------------------------------|
| Operators                                                            | Exposure estimates to sodium hydrogen carbonate as a plant protection product are below the recommended dietary intake of sodium (1.5 g sodium/adult/day equivalent to 78.6 mg sodium hydrogen carbonate /kg bw per day) without PPE |
| Workers                                                              | Exposure estimates to sodium hydrogen carbonate as a plant protection product are below the recommended dietary intake of sodium (1.5 g sodium/adult/day equivalent to 78.6 mg sodium hydrogen carbonate /kg bw/day) without PPE |

³ If available include also reference values for metabolites
Bystanders and residents

| EFSA Model (application rate 5.1 and 12 kg a.s./ha): |
|------------------------------------------------------|
| Exposure estimates to sodium hydrogen carbonate as a plant protection product are below the recommended dietary intake of sodium (1.5 g sodium/adult/day equivalent to 78.6 mg sodium hydrogen carbonate /kg bw/day) without PPE |

Classification with regard to toxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

**Substance:**

| Sodium hydrogen carbonate |
|---------------------------|
| None |

**Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]**:

- None

**Peer review proposal** for harmonised classification according to Regulation (EC) No 1272/2008:

- None

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4 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

5 It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) No 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

No standard studies according to EU/OECD guidance documents and EU data requirements have been submitted to address the residue behaviour of sodium hydrogen carbonate. Due to the nature of the active substance no such studies are required.

### Primary crops

| Crop groups         | Crop(s) | Application(s) | DAT (days) |
|---------------------|---------|----------------|------------|
| Fruit crops         |         |                |            |
| Root crops          |         |                |            |
| Leafy crops         |         |                |            |
| Cereals/grass crops |         |                |            |
| Pulses/Oilseeds     |         |                |            |
| Miscellaneous       |         |                |            |
| Not applicable      |         |                |            |

OECD Guideline 501

Due to the nature of the active substance no plant metabolism studies are required.

### Rotational crops

| Crop groups         | Crop(s) | PB1 (days) | Comments |
|---------------------|---------|------------|----------|
| Root/tuber crops    |         |            |          |
| Leafy crops         |         |            |          |
| Cereal (small grain)|         |            |          |
| Other               |         |            |          |

OECD Guideline 502

Due to the nature of the active substance no metabolism studies in rotational crops are required.

### Processed commodities

| Conditions          |            |            |            |
|---------------------|------------|------------|------------|
| 20 min, 90°C, pH 4  |            |            |            |
| 60 min, 100°C, pH 5 |            |            |            |
| 20 min, 120°C, pH 6 |            |            |            |

OECD Guideline 507

Due to the nature of the active substance no processing studies are required.

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Not applicable

### Plant residue definition for monitoring (RD-Mo)

OECD Guidance, series on pesticides No 31

A residue definition is not required

### Plant residue definition for risk assessment (RD-RA)

A residue definition is not required

### Conversion factor (monitoring to risk assessment)

Not applicable
Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

| OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish) | Animal | Dose (mg/kg bw/d) | Duration (days) | N rate/comment |
|------------------------------------------------------|--------|------------------|----------------|----------------|
| Animals covered                                      | Laying hen | Due to the nature of the active substance no livestock metabolism studies are required. |  | |
|                                                      | Goat/Cow | In addition the representative use is in table- and wine grapes which are no livestock feed item. |  | |
|                                                      | Pig     |                                               |  | |
|                                                      | Fish    |                                               |  | |
|                                                      |         | Not applicable                               |  | |

Time needed to reach a plateau concentration in milk and eggs (days)

Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31

Animal residue definition for risk assessment (RD-RA)

Conversion factor (monitoring to risk assessment)

Metabolism in rat and ruminant similar (Yes/No)

Fat soluble residues (Yes/No) (FAO, 2009)

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) OECD Guideline 502

Field rotational crop study OECD Guideline 504

Not applicable

Not applicable

Not applicable

Not applicable

No
Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)

| Plant products (Category) | Commodity | T (°C) | Stability (Month/Year) |
|---------------------------|-----------|--------|------------------------|
| High water content        |           |        | Due to the nature of the active substance no storage stability studies are necessary. |
| High oil content          |           |        |                        |
| High protein content      |           |        |                        |
| High starch content       |           |        |                        |
| High acid content         |           |        |                        |

| Animal | Animal commodity | T (°C) | Stability (Month/Year) |
|--------|------------------|--------|------------------------|
|        | Muscle           |        | Due to the nature of the active substance no storage stability studies are necessary. |
| -      | Liver            |        |                        |
| -      | Kidney           |        |                        |
| -      | Milk             |        |                        |
| -      | Egg              |        |                        |

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3)

Due to the nature of the active substance no studies on the magnitude of residues are necessary.

Inputs for animal burden calculations

Not relevant

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

Due to the nature of the active substance no livestock feeding studies are necessary.

Conversion Factors (CF) for monitoring to risk assessment

Not relevant

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

Not relevant

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

Including all uses (representative uses and uses related to an MRL application).

| ADI | TMDI according to EFSA PRIMo | NTMDI, according to (to be specified) | IEDI (% ADI), according to EFSA PRIMo |
|-----|------------------------------|---------------------------------------|---------------------------------------|
|     | Not needed                    | Not applicable                         | Not applicable                        |

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NEDI (% ADI), according to (to be specified)
Factors included in the calculations

|                             |      |
|-----------------------------|------|
| NEDI (% ADI)                | Not applicable |
| Factors included in the calculations | Not applicable |

ARlD
IESTI (% ARlD), according to EFSA PRIMo
NESTI (% ARlD), according to (to be specified)
Factors included in IESTI and NESTI

|                             |      |
|-----------------------------|------|
| IESTI (% ARlD)              | Not applicable |
| NESTI (% ARlD)              | Not applicable |
| Factors included in IESTI and NESTI | Not applicable |

Consumer risk assessment limited to the representative uses
Not relevant

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)
Sodium hydrogen carbonate is proposed a candidate for inclusion into Annex IV of Regulation (EC) No 396/2005.
Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

| Mineralisation after 100 days | In soil in the presence of water sodium hydrogen carbonate completely dissociates to sodium and bicarbonate ions. Due to the natural background concentration of the dissociation products of sodium hydrogen carbonate in soil studies are considered unnecessary for this compartment. |
| Non-extractable residues after 100 days | See above. |
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | See above. |

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

| Mineralisation after 100 days | Anaerobic mineralisation is not considered different than aerobic mineralisation, as oxygen does not play a direct role in degradation of sodium hydrogen carbonate. |
| Non-extractable residues after 100 days | See above. |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | See above. |

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | In soil in the presence of water sodium hydrogen carbonate completely dissociates to sodium and bicarbonate ions. Due to the natural background concentration of the dissociation products of sodium hydrogen carbonate in soil studies are considered unnecessary for this compartment. |
| Mineralisation at study end | See above. |
| Non-extractable residues at study end | See above. |

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Parent | Dark aerobic conditions |
| --- | --- |
| Not applicable: Sodium hydrogen carbonate completely dissociates to sodium and bicarbonate ions in the presence of water. |
Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Met 1 | Dark aerobic conditions |
|-------|-------------------------|
| Not applicable: Sodium hydrogen carbonate completely dissociates to sodium and bicarbonate ions in the presence of water. |

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

| Parent | Aerobic conditions |
|--------|--------------------|
| Not applicable: Sodium hydrogen carbonate completely dissociates to sodium and bicarbonate ions in the presence of water. |

| Met 1 | Aerobic conditions |
|-------|--------------------|
| Not applicable: Sodium hydrogen carbonate completely dissociates to sodium and bicarbonate ions in the presence of water. |

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

| Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent) |
| (d) Not applicable |
| Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent) |
| Met I Not applicable | Met II Not applicable |
| Kinetic formation fraction (f. f. k_f / k_dp) of transformation products, arithmetic mean |
| Met I Not applicable | Met II Not applicable |

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

| Soil accumulation and plateau concentration |
| Sodium hydrogen carbonate spontaneously dissociates to sodium and bicarbonate in moist soils or water. Sodium and bicarbonate do not accumulate in soil or water since sodium is taken up by the plants and microorganisms while bicarbonate is associated to cations or is reduced to form water and carbon dioxide. No studies were performed with the product, since it is possible to extrapolate from data obtained with the active substance. |

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Parent | Dark anaerobic conditions |
|--------|---------------------------|
Not applicable: Sodium hydrogen carbonate completely dissociates to sodium and bicarbonate ions in the presence of water.

### Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Met 1 | Dark anaerobic conditions |
|-------|---------------------------|
| Not applicable: Sodium hydrogen carbonate completely dissociates to sodium and bicarbonate ions in the presence of water. |

### Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

| Parent | Soil photolysis |
|--------|-----------------|
| Not applicable: Sodium hydrogen carbonate completely dissociates to sodium and bicarbonate ions in the presence of water. |

### Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Parent |
|--------|
| Not required. Sodium is bound loosely in soil due to cation binding to negatively charged soil components. A rapid equilibrium is observed between soluble and exchangeable forms of sodium. Due to the natural background concentration of the dissociation products of sodium hydrogen carbonate in soil, considering that the degradation products are not of concern, mobility studies are not required. |

### Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Metabolite 1 |
|--------------|
| Not required. Due to the natural background concentration of the dissociation products of sodium hydrogen carbonate in soil, considering that the degradation products are not of concern, mobility studies are not required. As already set out in the PEC soil and PEC groundwater section, the chemical species that might be present in the environment are sodium ions, carbonate, carbonic acid and carbon dioxide (so not sodium hydrogen carbonate crystals). Undissociated sodium hydrogen carbonate could be excluded as being present in any significant amount in soil. As transformation products the other compounds (chemical species) identified above would be classified as degradation products of no concern at step 1 of the guidance document on the relevance of metabolites in groundwater (SANCO/221/2000-rev.10-final). |
Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Column leaching |
|-----------------|
| Not required.   |

Sodium hydrogen carbonate spontaneously dissociates in water to give sodium and bicarbonate ions. Due to its substance specific characteristics sodium and bicarbonate ions can potentially leach through the soil to groundwater resources. However, sodium and bicarbonate ions are natural products and are not toxicologically relevant. Ions reaching groundwater can’t be distinguished from ions from natural sources. Sodium is bound loosely in soil due to cation binding to negatively charged soil components. A rapid equilibrium is observed between soluble and exchangeable forms of sodium. Hence, due to the natural background concentration of the dissociation products of sodium hydrogen carbonate in soil, considering that the degradation products are not of concern, mobility studies are not required. As already set out in the PEC soil and PEC groundwater section, the chemical species that might be present in the environment are sodium ions, carbonate, carbonic acid and carbon dioxide (so not sodium hydrogen carbonate crystals). Undissociated sodium hydrogen carbonate could be excluded as being present in any significant amount in soil. As transformation products the other compounds (chemical species) identified above would be classified as degradation products of no concern at step 1 of the guidance document on the relevance of metabolites in groundwater (SANCO/221/2000-rev.10-final).

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Column leaching |
|-----------------|
| Not required. (See above: ‘Column leaching’.) |

Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

| Lysimeter/ field leaching studies |
|---------------------------------|
| Not required. (See above: ‘Column leaching’.) |
**Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)**

| Hydrolytic degradation of the active substance and metabolites > 10 % | Not necessary. |
|---|---|
| Sodium hydrogen carbonate spontaneously dissociates in water to give sodium and bicarbonate ions. Therefore, these can be considered individually. The sodium ions are stable and do not degrade. Bicarbonate will equilibrate with carbonate and carbonic acid to yield carbon dioxide and water. The carbonate equilibria will regulate concentrations of carbonic acid, bicarbonate or carbonate in aqueous solutions depending upon the system’s pH. With regard to metabolites, the resultant weathering or chemical breakdown of sodium hydrogen carbonate produces substances considered to be of no concern for groundwater. Hence, due to the natural background concentration of the dissociation products of sodium hydrogen carbonate in surface water and that the degradation products are of no concern, studies are considered unnecessary for this compartment. |

**Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)**

| Photolytic degradation of active substance and metabolites above 10 % | Not necessary. |
|---|---|
| (See above: Hydrolytic degradation) |

| Quantum yield of direct phototransformation in water at Σ > 290 nm | Not necessary. |
|---|---|
| (See above: Hydrolytic degradation) |

**‘Ready biodegradability’ (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)**

| Readily biodegradable (yes/no) | Yes |
|---|---|
| Pure sodium hydrogen carbonate, in its undissociated form, is expected to be biodegradable; based on the carbonate equilibria, sodium hydrogen carbonate will not be persistent in the aquatic environment under natural conditions. Hence, sodium hydrogen carbonate may be considered as readily biodegradable. |
Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

| Parent | 
| --- | 
| Not required. Due to the natural background concentration of the dissociation products of sodium hydrogen carbonate in soil and sediments and that the degradation products are not of concern, studies are not required. As transformation products the other compounds (chemical species) identified would be classified as degradation products of no concern, in the guidance document on aquatic risk assessment (EFSA, 2013). |

| Metabolite | 
| --- | 
| Not required. Due to the natural background concentration of the dissociation products of sodium hydrogen carbonate in soil and sediments and that the degradation products are not of concern, studies are not required. As transformation products the other compounds (chemical species) identified would be classified as degradation products of no concern, in the guidance document on aquatic risk assessment (EFSA, 2013). |

| Mineralisation and non extractable residues (for parent dosed experiments) | 
| --- | 
| Not required. Due to the natural background concentration of the dissociation products of sodium hydrogen carbonate in soil and sediments and that the degradation products are not of concern, studies are not required. As transformation products the other compounds (chemical species) identified would be classified as degradation products of no concern, in the guidance document on aquatic risk assessment (EFSA, 2013). |

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

| Parent | Distribution | 
| --- | --- | 
| Not required. Due to the natural background concentration of the dissociation products of sodium hydrogen carbonate in soil and sediment and that the degradation products are not of concern, studies are not required. As transformation products the other compounds (chemical species) identified would be classified as degradation products of no concern, in the guidance document on aquatic risk assessment (EFSA, 2013). |

| Metabolites | 
| --- | 
| Not required. Due to the natural background concentration of the dissociation products of sodium hydrogen carbonate in soil and sediment and that the degradation products are not of concern, studies are not required. As transformation products the other compounds (chemical species) identified would be classified as degradation products of no concern, in the guidance document on aquatic risk assessment (EFSA, 2013). |

| Mineralisation and non extractable residues (from parent dosed experiments) | 
| --- | 
| Water / sediment system | pH water phase | pH sed | Mineralisation x % after n d. (end of the study). | Non-extractable residues in sed. max x % after n d | Non-extractable residues in sed. max x % after n d (end of the study) | 
| --- | --- | --- | --- | --- | --- | 
| Not relevant. |
### Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

| Process                                      | Description                                                                                                                                                                                                 |
|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Direct photolysis in air                     | No data submitted, not required. Sodium hydrogen carbonate is not volatile and does not degrade in air. CO₂ is the main component that would be released to the atmosphere from the dissociation of NaHCO₃ and from the carbonate equilibria mechanism. However, the possible releases of CO₂ are considered to be negligible compared to the natural biological respiration process. Hence, air is not a relevant route of exposure for sodium hydrogen carbonate and studies are not required. |
| Photochemical oxidative degradation in air    | No data submitted, not required. (See above.)                                                                                                                                                                |
| Volatilisation                               | No data submitted, not required. (See above.)                                                                                                                                                                |
| Metabolites                                  | No data submitted, not required. (See above.)                                                                                                                                                                |

### Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure

No definition of residue is proposed for sodium hydrogen carbonate because sodium cation and bicarbonate (carbonic acid and carbonate ion) are naturally occurring in the environment.

### Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

### Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

| Location and Type of Study                  | Description                                                                                                                                                                                                 |
|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Soil (indicate location and type of study)  | Not applicable, sodium hydrogen carbonate is naturally present in the environment.                                                                                                                                 |
| Surface water (indicate location and type of study) | Not applicable, sodium hydrogen carbonate is naturally present in the environment.                                                                                                                                 |
| Ground water (indicate location and type of study) | Not applicable, sodium hydrogen carbonate is naturally present in the environment.                                                                                                                                 |
| Air (indicate location and type of study)    | Not applicable, sodium hydrogen carbonate is naturally present in the environment.                                                                                                                                 |
PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

| Parent Method of calculation |  |
|------------------------------|---|
| PEC<sub>soil</sub> calculations for the plant protection product NatriSan and its active substance sodium hydrogen carbonate have been assessed with the EU models and the FOCUS groundwater interception values. |  |

| Application data for the Southern Zone |  |
|---------------------------------------|---|
| Crop: Wine grapes and table grapes |  |
| Depth of soil layer: 5cm |  |
| Soil bulk density: 1.5g/cm<sup>3</sup> |  |
| % plant interception: 65 % (leaf development) |  |
| Number of applications: 8 |  |
| Interval (d): 3 |  |
| Application rate(s): 5100 g a.s./ha |  |

| Application data for the Central Zone |  |
|---------------------------------------|---|
| Crop: Wine grapes and table grapes |  |
| Depth of soil layer: 5cm |  |
| Soil bulk density: 1.5g/cm<sup>3</sup> |  |
| % plant interception: 65 % (leaf development) |  |
| Number of applications: 6 |  |
| Interval (d): 3 |  |
| Application rate(s): 12000 g a.s./ha |  |

| **PEC<sub>soil</sub> (mg/kg)** | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|--------------------------|-----------------------------------------|-----------------------------|-----------------------------------------|
| Initial (Southern Zone)       |                          | 19.04                                   |                             |                                         |
| Initial (Central Zone)        |                          | 33.60                                   |                             |                                         |
| Short term 24h                 |                          |                                        |                             |                                         |
| Long term 7d                   |                          |                                        |                             |                                         |
| Plateau concentration          | Not required             |                                         |                             |                                         |

No short-term and long-term actual concentrations (PEC<sub>soil, actual</sub>) and time weighted average concentrations (PEC<sub>soil, twa</sub>) were calculated since the active substance sodium hydrogen carbonate completely dissociates to sodium and bicarbonate ions in the presence of water. PEC<sub>soil</sub> values have been calculated for the sodium and bicarbonate ions.

Metabolite I

| Method of calculation |  |
|-----------------------|---|
| Not relevant          |  |

| Application data |  |
|------------------|---|
| Not relevant     |  |
PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)

| Application rate |
|------------------|
| Not relevant     |

Not calculated.

Sodium hydrogen carbonate spontaneously dissociates in water to give sodium and bicarbonate ions. The sodium ions are stable and do not degrade. Bicarbonate will equilibrate with carbonate and carbonic acid to yield carbon dioxide and water. The carbonate equilibria will regulate concentrations of carbonic acid, bicarbonate or carbonate in aqueous solutions depending upon the system’s pH.

The sodium ion is ubiquitously present in the environment and it has been measured extensively in aquatic ecosystems. Sodium and chloride concentrations in water are tightly linked. They both originate from natural weathering of rock, from atmospheric transport of oceanic inputs and from a wide variety of anthropogenic sources. The sodium concentration was reported for a total number of 75 rivers in North and South America, Africa, Asia, Europe and Oceania, with a 10th percentile of 1.5 mg/L, mean of 28 mg/l and 90th percentile of 68 mg/l (UNEP, 1995). No values for background concentrations in groundwater volumes were presented.

No limits available for sodium in drinking water. EPPO recommended sodium level in drinking water less than 200 mg/L but there are no official limits available e.g. from the WHO. According to the Background document for development of WHO Guidelines for Drinking-water quality the taste threshold for sodium bicarbonate is 420 mg/L.

With regard to metabolites, the resultant weathering or chemical breakdown of NaHCO$_3$ produces substances considered to be of no concern for groundwater.

FOCUS models are not suitable to predict groundwater concentrations of elements like Na$^+$ or salts like HCO$_3^-$. Hence, illustrative calculations are not presented.

However, given the high natural background levels of Na$_2$HCO$_3$, Na$^+$ and HCO$_3^-$ no further calculations are presented.

With the current uniform principles amendment of 3 May 2018$^*$ the groundwater limit of 0.1µg/L no longer applies to sodium hydrogen carbonate due to the fact that it is an inorganic compound. As already clearly set out in the PEC soil and PEC groundwater section, the chemical species that might leach to groundwater are sodium ions, carbonate, carbonic acid and carbon dioxide. These chemical species would be classified as degradation products of no concern at step 1 of the guidance document on the relevance of metabolites in groundwater (SANCO/221/2000-rev.10-final).

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$^*$ Commission Regulation (EU) 2018/676 of 3 May 2018 correcting Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and the of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 114.8.5.2018, p. 2)
PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

| Model / Crop | Parent (µg/L) |
|--------------|---------------|
| Chateaudun   |               |
| Hamburg      |               |
| Jokioinen    |               |
| Kremsmunster |               |
| Okehampton   |               |
| Piacenza     |               |
| Porto        |               |
| Sevilla      |               |
| Thiva        |               |

PEC(gw), From lysimeter / field studies

| Parent          | 1st year | 2nd year | 3rd year |
|-----------------|----------|----------|----------|
| Annual average (µg/L) | No studies available |

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parameters used in FOCUSsw step 1 and 2

The PEC_{SW} of sodium hydrogen carbonate, sodium and bicarbonate in surface water after use of the plant protection product NatriSan has been assessed according to the EU recommendations for estimating drift entries in surface water.

Parameters used in FOCUSsw step 3 (if performed)

Not necessary

Application rate (Southern zone)

Crop and growth stage: Wine grapes and table grapes BBCH 12 - 89
Number of applications: 8
Interval (d): 3
Application rate(s): 5100 g a.s./ha
Application window: Not relevant

Application rate (Central zone)

Crop and growth stage: Wine grapes and table grapes BBCH 12 - 89
Number of applications: 6
Interval (d): 3
Application rate(s): 12000 g a.s./ha
Application window: Not relevant
FOCUS STEP 1

| Scenario                  | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | Actual | TWA | PEC<sub>SED</sub> (µg/kg) | Actual | TWA |
|---------------------------|---------------------------|--------------------------|--------|-----|--------------------------|--------|-----|
| Initial (Southern Zone)   | 1088                      |                          |        |     |                          |        |     |
| Initial (Central Zone)    | 1920                      |                          |        |     |                          |        |     |

The illustrative calculations presented demonstrate that the absolute worst PEC<sub>SW</sub> values for Na<sup>+</sup> and HCO<sub>3</sub> are below the natural background levels. Given the ubiquitous presence of Na<sup>+</sup> and HCO<sub>3</sub> in nature further PEC<sub>sed</sub> calculations are not presented.

FOCUS STEP 2

| Scenario | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | Actual | TWA | PEC<sub>SED</sub> (µg/kg) | Actual | TWA |
|----------|---------------------------|--------------------------|--------|-----|--------------------------|--------|-----|
| Northern EU | Not necessary           |                          |        |     |                          |        |     |
| Southern EU | Not necessary           |                          |        |     |                          |        |     |

FOCUS STEP 3

| Scenario          | Water body | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | Actual | TWA | PEC<sub>SED</sub> (µg/kg) | Actual | TWA |
|-------------------|------------|---------------------------|--------------------------|--------|-----|--------------------------|--------|-----|
| Not necessary      |            |                           |                          |        |     |                          |        |     |

**Metabolite**

- Parameters used in FOCUSsw step 1 and 2: Not necessary
- Parameters used in FOCUSsw step 3 (if performed): Not necessary
- Application rate: Not necessary
- Main routes of entry: Not necessary
FOCUS STEP 3
Scenario

| Water body | Day after overall maximum | PEC<sub>SW</sub> (µg/L) | PEC<sub>SED</sub> (µg/kg) |
|------------|---------------------------|------------------------|------------------------|
| Actual     | TWA                       | Actual                 | TWA                    |

Not necessary

**Estimation of concentrations from other routes of exposure (Regulation (EU) No 284/2013, Annex Part A, point 9.4)**

**Method of calculation**

No other routes of exposure were identified to be necessary for calculation of PEC values and consideration during environmental fate risk assessment.

**PEC**

| Maximum concentration | Not applicable |
|-----------------------|-----------------|
## Ecotoxicology

### Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

| Species    | Test substance | Time scale | End point | Toxicity (mg/kg bw per day) |
|------------|----------------|------------|-----------|----------------------------|
| **Birds**  |                |            |           |                            |
| Chicken    | a.s. NaHCO₃    | Acute      | LD₅₀      | > 8075                     |
| Preparation|                | Acute      | LD₅₀      | Not available              |
|            | a.s. NaHCO₃    | Long-term  | LD₅₀      | Not available              |
| Chicken    | a.s. NaHCO₃    | Long-term  | NOEL      | > 8075                     |
| **Mammals**|                |            |           |                            |
| Rat        | a.s. NaHCO₃    | Acute      | LD₅₀      | >2000                      |
| Preparation|                | Acute      | LD₅₀      | Not available              |
|            | a.s. NaHCO₃    | Long-term  | NOAEL     | Not available              |

### Endocrine disrupting properties (Annex Part A, points 8.1.5)

No evidence of any reproducible endocrine effect.

### Additional higher tier studies (Annex Part A, points 10.1.1.2):

None required.

### Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):

No additional data submitted.

### Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

A low risk to birds and mammals could be concluded for all the representative uses due to the natural exposure to sodium and hydrogen carbonate via food/water and its common occurrence in the animal metabolism. It can be concluded that the application of NatriSan is very unlikely to present a significant risk to terrestrial vertebrates.
Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)

| Group                          | Test substance | Time-scale (Test type)       | End point      | Toxicity¹ |
|-------------------------------|----------------|------------------------------|----------------|-----------|
| **Laboratory tests**          |                |                              |                |           |
| **Fish**                      |                |                              |                |           |
| Rainbow trout (Oncorhynchus mykiss) | a.s. KHCO₃      | Acute (96h), flow-through   | Mortality, LC₅₀ | 1400 mg a.s./L<sub>(nom)</sub> |
| Bluegill sunfish (Lepomis macrochirus) | a.s. KHCO₃      | Acute (96h), flow-through   | Mortality, LC₅₀ | 1500 mg a.s./L<sub>(nom)</sub> |
| **Aquatic invertebrates**     |                |                              |                |           |
| Waterflea (Daphnia magna)     | Preparation VitiSan (containing 999.9 g/kg KHCO₃) | Acute (48h), semi-static | Immobility, EC₅₀ | >1000 mg prep./L<sub>(nom)</sub> (equivalent to >999.9 mg KHCO₃/L) |
| Sediment-dwelling organisms  |                |                              |                |           |
| No endpoints available, not required |                |                              |                |           |
| **Algae**                     |                |                              |                |           |
| No endpoint available.        |                |                              |                |           |
| **Higher plant**              |                |                              |                |           |
| No endpoints available, not required |                |                              |                |           |
| Further testing on aquatic organisms |            |                              |                |           |
| No additional testing was required. |            |                              |                |           |
| Potential endocrine disrupting properties (Annex Part A, point 8.2.3) |            |                              |                |           |
| No evidence of any reproducible endocrine effect. |            |                              |                |           |

¹<sub>(nom)</sub> nominal concentration; <sub>(mm)</sub> mean measured concentration; prep.: preparation; a.s.: active substance

**Bioconcentration in fish (Annex Part A, point 8.2.2.3)**

Sodium hydrogen carbonate is highly soluble in water and as a result has a very limited potential for bioconcentration. Sodium hydrogen carbonate can be classified as not bio-accumulative, as it is highly soluble in water and fully dissociates. Specific tests to evaluate bio-concentration potential are therefore considered unnecessary.
Exposure/toxicity ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

FOCUS\textsubscript{sw} step 1 – PEC/RAC ratios for sodium hydrogen carbonate – EU Northern Zone use in vineyards at 6 x 12 kg a.s./ha (covering the use in the Southern Zone at 8 x 5.1 kg/ha)

| Scenario | PEC global max (mg/L) | Fish acute | Aquatic invertebrates |
|----------|------------------------|------------|-----------------------|
|          |                        | Oncorhynchus mykiss | Daphnia magna |
|          |                        | LC\textsubscript{50} | EC\textsubscript{50} |
|          |                        | 1400 mg/L\textsuperscript{a} | > 999.9 mg/L\textsuperscript{a} |
|          |                        | AF: 100 | AF: 100 |
|          |                        | RAC: 14 mg/L | 9.99 mg/L |
| FOCUS Step 1 | 1.92 | 0.14 | 0.19 |

Trigger

*acceptability of risk: PEC/RAC < 1

\textsuperscript{a} Available data for Potassium hydrogen carbonate can be taken into consideration for sodium hydrogen carbonate due to the non-significant differences in toxicological properties from different salts.

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

| Species     | Test substance | Time scale/type of endpoint | End point                                             | toxicity                  |
|-------------|----------------|-----------------------------|-------------------------------------------------------|---------------------------|
| Honeybee    | preparation    | Acute                       | Oral toxicity (48 h LD\textsubscript{50})              | > 537.4 μg as/bee         |
|             | VitiSan* (99.49% KHCO\textsubscript{3}) |                            |                                                       |                           |
| Honeybee    | preparation    | Acute                       | Contact toxicity (48h LD\textsubscript{50})            | > 559.1 μg as/bee         |
|             | VitiSan* (99.49% KHCO\textsubscript{3}) |                            |                                                       |                           |
| a.s., preparation | Chronic | 10 d-LC50                  | Not available                                         |                           |
| a.s., preparation | Bee brood development | NOEC\textsubscript{larvae} | μg/larva/developmental period                         |                           |
| a.s., preparation | Sub-lethal effects (behavioural and reproductive) | NOEC hypopharyngeal glands | Not available                                 |                           |

* Due to the non-significant differences in toxicological properties from different salts (e.g. potassium and sodium salts) the study can also be taken into consideration for sodium hydrogen carbonate.

Potential for accumulative toxicity:

No data available.

Semi-field test (Cage and tunnel test)

No data available.
Field tests
No data available.

**Risk assessment** for vineyard, critical use of 6 x 12 kg a.s./ha

| Species       | Test substance             | Risk quotient | HQ/ETR   | Trigger |
|---------------|-----------------------------|---------------|----------|---------|
| Honeybee      | Preparation VitiSan (99.49% KHCO₃) | HQcontact     | < 21.5   | > 85    |
|               | Preparation VitiSan (99.49% KHCO₃) | ETRacute adult oral | < 0.24* | > 0.2   |
|               | Preparation VitiSan (99.49% KHCO₃) | HQo (according to SANCO/10329/2002) | 22.22    | 50      |

* The ETR of 0.24 in treated crop is slightly above the trigger of 0.2. However since the LD₅₀ value is an unbound “greater than” value, the risk is considered to be low without further refinement. Overall, considering all the available information, the nature and identity and the environmental fate and behaviour of sodium hydrogen carbonate, a low risk to bees could be concluded.

**Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)**

**Laboratory tests with standard sensitive species**

Regarding the toxicity data on the active substance sodium hydrogen carbonate a waiver was requested, please refer to Vol 3(CA) – B.9 point B.9.3.2.

No studies with the product NatriSan have been conducted to address the effects on non-target arthropods other than bees. However given the ubiquitous character of sodium and hydrogen carbonate in the environment and the peer-review accepted waiver for Potassium hydrogen carbonate (EFSA, 2012) which is toxicologically similar to sodium hydrogen carbonate waiving the effect studies on non-target arthropods can be considered acceptable.

**First tier risk assessment**

No studies with the product NatriSan have been conducted to address the effects on non-target arthropods other than bees. However given the ubiquitous character of sodium and hydrogen carbonate in the environment and the peer-review accepted waiver for Potassium hydrogen carbonate (EFSA, 2012) which is toxicologically similar to sodium hydrogen carbonate waiving the effect studies on non-target arthropods can be considered acceptable and no risk assessment is required.

**Extended laboratory tests, aged residue tests**

No data available. Not required.
Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) No 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) No 284/2013 Annex Part A, points 10.4, 10.5)

Earthworms and other non-target soil meso- and macro fauna

No studies were submitted to address effects on earthworms and other non-target soil organisms following exposure of the active substance or the formulated product, please refer to Vol 3(CA) – B.9 point B.9.4.1. Taking the natural background concentration and natural occurrence of sodium and hydrogen carbonate into account RMS concludes that waiving the effect studies on earthworms with NatriSan can be considered acceptable.

Higher tier testing (e.g. modelling or field studies)
No data available.

Nitrogen transformation

No studies were submitted to address the effects on soil nitrogen transformation following exposure of the active substance or the formulated product. However in the basic substance application document of sodium hydrogen carbonate (June 2014) for soil a median sodium concentration of 5 g/kg (range 0.15 – 25 g/kg) was referenced. In Vol 3 CP B8, B.8.2 in table CP8.1.3-6 following an application rate of 6 x 12 kg sodium hydrogen carbonate/ha the maximum PECs in soil were reported for sodium ions as 9.07 mg/kg and for hydrogen carbonate ions as 24.53 mg/kg. Taking the natural background concentration and natural occurrence of sodium and hydrogen carbonate into account adverse effects on soil microorganisms from the application of NatriSan are unlikely, thus the risk posed by the application of NartiSan following the proposed GAP on soil nitrogen transformation can be considered low and no further risk assessment is necessary.

Toxicity/exposure ratios for soil organisms

No studies were submitted to address effects on earthworms and other non-target soil organisms following exposure of the active substance or the formulated product. However in the application document of sodium hydrogen carbonate as basic substance (June 2014) for soil a median sodium concentration of 5 g/kg (range 0.15 – 25 g/kg) was referenced. In Vol 3 CP B8, B.8.2 in table CP8.1.3-6 following an application rate of 6 x 12 kg sodium hydrogen carbonate/ha the maximum PECs in soil were reported for sodium ions as 9.07 mg/kg and for hydrogen carbonate ions as 24.53 mg/kg. Therefore taking the natural background concentration and natural occurrence of sodium and hydrogen carbonate into account the risk posed by the application of NartiSan following the proposed GAP on earthworms and other non-target soil organisms can be considered low and no further risk assessment is required.

Effects on terrestrial non target higher plants (Regulation (EU) No 283/2013, Annex Part A, point 8.6 and Regulation (EU) No 284/2013 Annex Part A, point 10.6)

Screening data

No effect studies were submitted to address the effects on terrestrial non-target plants, but in the public literature study Subbarao et al., 2003 (KCA B.9.6, Doc-No. 892-001) sodium was referenced as functional plant nutrient, being able to replace potassium for certain plant species and to be commonly found in plant tissues. In the basic substance application document of sodium hydrogen carbonate (June 2014) for soil a median sodium concentration of 5 g/kg (range 0.15 – 25 g/kg) was referenced. In Vol 3 CP B8, B.8.2 in table CP8.1.3-6 following an application rate of 6 x 12 kg sodium hydrogen carbonate/ha the maximum PECs in soil were reported for sodium ions as 9.07 mg/kg and for hydrogen carbonate ions as 24.53 mg/kg. Therefore taking the natural background concentration and natural occurrence of sodium and hydrogen carbonate into account adverse effects on soil microorganisms from the application of NatriSan are unlikely, thus the risk posed by the application of NartiSan following the proposed GAP on terrestrial non-target plants can be considered low and no further risk assessment is required.
reported for sodium ions as 9.07 mg/kg and for hydrogen carbonate ions as 24.53 mg/kg. Therefore taking the natural soil background concentration of sodium and hydrogen carbonate and the common occurrence of sodium in plant tissues into account, the risk posed by the application of NartiSan following the proposed GAP on terrestrial non-target plants can be considered low and no further risk assessment is required.

Laboratory dose response tests
No data available. Not required.

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

No effect studies were submitted by the notifier to address the effects on biological methods for sewage treatment. However the study of Hamoda (1995, please refer to KCA B.9.8/01) on the effects of sodium chloride on activated sludge systems found that the salt did not inhibit biomass growth. For sodium, it can therefore be concluded that it will very likely have no negative effect on biological methods for sewage treatment when used as a plant protection product according to the GAP. Hydrogen carbonate is known to have important pH stabilizing properties in the aquatic environment. As a consequence, adverse effects on biological methods for sewage treatment from the application of sodium hydrogen carbonate are considered to be very unlikely waiving the effect studies on biological methods for sewage treatment can be considered acceptable and no further risk assessment is necessary.

| Test type/organism     | End point                      |
|------------------------|--------------------------------|
| Activated sludge       | No data available.            |
| Pseudomonas sp.        | No data available.            |

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s.:
No data available.

Available monitoring data concerning effect of the PPP:
No data available.

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)
Ecotoxicologically relevant compounds

| Compartment  | Definition                        |
|--------------|-----------------------------------|
| soil         | A residue definition is not required² |
| water        | A residue definition is not required² |
| sediment     | A residue definition is not required² |
| groundwater  | A residue definition is not required² |

¹ metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent
² Sodium hydrogen carbonate dissociates in the presence of water to produce the ions Na⁺ and HCO₃⁻, both naturally occurring in all compartments of the environment. It is not possible to distinguish between the residues arising from the use of sodium hydrogen carbonate as a plant protection product and its natural presence in environmental compartments.
### Classification and labelling with regard to ecotoxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

| Substance | Sodium hydrogen carbonate |
|-----------|---------------------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]⁷: | No classification. |

Peer review proposal⁸ for harmonised classification according to Regulation (EC) No 1272/2008:

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⁷ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

⁸ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.