

## CONCLUSION ON PESTICIDE PEER REVIEW

### Conclusion on the peer review of the pesticide risk assessment of the active substance calcium carbonate<sup>1</sup>

European Food Safety Authority<sup>2</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Calcium carbonate is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004<sup>3</sup>, as amended by Commission Regulation (EC) No 1095/2007<sup>4</sup>.

Calcium carbonate was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as ‘the Regulation’), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009<sup>5</sup>, in accordance with Commission Implementing Regulation (EU) No 540/2011<sup>6</sup>, as amended by Commission Implementing Regulation (EU) No 541/2011<sup>7</sup>. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010<sup>8</sup>, the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Spain being the designated rapporteur Member State submitted the DAR on calcium carbonate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 10 January 2008. The peer review was initiated on 14 July 2008 by dispatching the DAR to the notifier Flügel GmbH and on 20 October 2010 to the Member States for consultation. Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct a focused peer review in the area of mammalian toxicology, and deliver its conclusions on calcium carbonate.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of calcium carbonate as a repellent for use in forestry and orchards, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

It should be emphasized that the substance notified as calcium carbonate is mined limestone.

<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2009-00273, issued on 1 July 2011.

<sup>2</sup> Correspondence: pesticides.peerreview@efsa.europa.eu

<sup>3</sup> OJ L 379, 24.12.2004, p.13

<sup>4</sup> OJ L 246, 21.9.2007, p.19

<sup>5</sup> OJ L 309, 24.11.2009, p.1

<sup>6</sup> OJ L 153, 11.6.2011, p.1

<sup>7</sup> OJ L 153, 11.6.2011, p.187

<sup>8</sup> OJ L 37, 10.2.2010, p.12

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance calcium carbonate. EFSA Journal 2011;9(7):2298. [28 pp.] doi:10.2903/j.efsa.2011.2298. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

Data gaps were identified in the section for identity, physical and chemical properties and analytical methods.

Based on the representative uses, no data gaps or critical areas of concerns were highlighted in the mammalian toxicology section.

No significant residues in plant or animal matrices are expected based on the representative uses. Therefore a consumer risk assessment was not required.

Calcium carbonate is the main component of naturally occurring sedimentary rocks composed largely of the mineral calcite (limestone). Considering the nature of the substance and the limited usage leading to negligible levels of environmental exposure, a definition of residue in the environment for monitoring is deemed to be unnecessary for calcium carbonate (limestone,  $\text{CaCO}_3$ ).

Due to negligible levels of environmental exposure arising from the representative uses, the risk can be considered low for non-target organisms. No data gaps or critical areas of concern were identified in the ecotoxicology section.

#### **KEY WORDS**

Calcium carbonate, limestone, peer review, risk assessment, pesticide, repellent

## TABLE OF CONTENTS

Summary .....	1
Table of contents .....	3
Background .....	4
The active substance and the formulated product .....	6
Conclusions of the evaluation .....	6
1. Identity, physical/chemical/technical properties and methods of analysis .....	6
2. Mammalian toxicity.....	6
3. Residues.....	7
4. Environmental fate and behaviour.....	7
5. Ecotoxicology.....	7
6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments .....	8
6.1. Soil.....	8
6.2. Ground water .....	8
6.3. Surface water and sediment .....	9
6.4. Air.....	9
List of studies to be generated, still ongoing or available but not peer reviewed.....	10
Particular conditions proposed to be taken into account to manage the risk(s) identified .....	10
Issues that could not be finalised.....	10
Critical areas of concern.....	10
References .....	12
Appendices .....	13
Abbreviations .....	26

## BACKGROUND

Calcium carbonate is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004<sup>9</sup>, as amended by Commission Regulation (EC) No 1095/2007<sup>10</sup>.

Calcium carbonate was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as ‘the Regulation’), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009<sup>11</sup>, in accordance with Commission Implementing Regulation (EU) No 540/2011<sup>12</sup>, as amended by Commission Implementing Regulation (EU) No 541/2011<sup>13</sup>. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010<sup>14</sup>, the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Spain being the designated rapporteur Member State submitted the DAR on calcium carbonate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 10 January 2008 (Spain, 2007). The peer review was initiated on 14 July 2008 by dispatching the DAR to the notifier Flügel GmbH and on 20 October 2010 to the Member States for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The comments and the notifier’s response were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 15 February 2011. On the basis of the comments received and the RMS’ evaluation thereof it was concluded that the EFSA should organise a consultation with Member State experts in the area of mammalian toxicology.

The outcome of the telephone conference, together with EFSA’s further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, and additional information to be submitted by the notifier, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in May – June 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a repellent for use in forestry and orchards, as proposed by the notifier. A list of the relevant end points

---

<sup>9</sup> OJ L 379, 24.12.2004, p.13

<sup>10</sup> OJ L 246, 21.9.2007, p.19

<sup>11</sup> OJ L 309, 24.11.2009, p.1

<sup>12</sup> OJ L 153, 11.6.2011, p.1

<sup>13</sup> OJ L 153, 11.6.2011, p.187

<sup>14</sup> OJ L 37, 10.2.2010, p.12

for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (15 February 2011),
- the Evaluation Table (27 June 2011),
- the report(s) of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the points of clarification (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of May 2011 containing all individually submitted addenda (Spain, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

## THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Calcium carbonate (IUPAC) is considered by the International Organization for Standardization not to require a common name.

The representative formulated product for the evaluation was 'Morsuvin', a paste, water-based, film-forming composition (PA) containing 417 g/kg calcium carbonate, 50 g/kg tall oil pitch, 43 g/kg fish oil and 87.5 g/kg sodium aluminium silicate.

Calcium carbonate has been notified as a repellent against game browsing damage on trees in forestry and orchards (pome and stone fruits). The formulation is applied with a brush and used only as a protective coat on the outside of the trees. Full details of the representative uses can be found in the list of end points in Appendix A.

## CONCLUSIONS OF THE EVALUATION

### 1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance document was followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000).

The minimum purity of calcium carbonate is open as a data gap was identified for five batch data. It should be noted that a study report of a 5-batch analysis is available, however according to Regulation (EC) No 1095/2007 it cannot be taken into account in the peer review. No FAO specification exists.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of calcium carbonate or the representative formulation. It should be noted that the active substance is composed of mined limestone. Data gaps were identified for a shelf-life study and for explosive properties, oxidizing properties, flammability and auto-flammability of the formulation. The main data regarding the identity of calcium carbonate and its physical and chemical properties are given in Appendix A.

Data gaps were identified for analytical methods for the determination of the impurities in the technical material and for the determination of calcium carbonate in the representative formulation. The need for methods of analysis for monitoring this compound in food of plant and animal origin and in the environment has been waived due to the nature of the compound. A method for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

### 2. Mammalian toxicity

Calcium carbonate was discussed at the PRAPeR TC 55 Experts' Teleconference on mammalian toxicology.

Overall, it was noted that the database is quite limited and mainly based on summaries of assessments performed for purposes other than the pesticide use.

The limited data available indicate that calcium carbonate is harmful in contact with skin, and irritating to skin and eyes, however it was not possible to draw a firm conclusion. No relevant data were submitted for short- and long-term toxicity, genotoxicity, carcinogenicity and reproductive toxicity (limited information would indicate that calcium carbonate is not a teratogen, but a firm conclusion could not be derived); however, as the paintbrush application of a paste was not considered to be a source of significant exposure based on the unlikely dermal absorption of calcium carbonate and the negligible inhalation exposure, it was agreed that there is no need to set an Acceptable Operator Exposure Level (AOEL), or an Acceptable Daily Intake (ADI) or an Acute Reference Dose (ARfD), based on the representative uses.

### **3. Residues**

Metabolism and residue studies were not considered relevant for evaluation due to the nature of the active substance and the representative uses. Calcium carbonate will be used only as protective coating on the outside (bark) of trees in forestry and orchards. In some cases this protective layer exists for many years. Moreover, calcium carbonate is an additive in food stuff (E 170). Calcium carbonate will remain on the outer surface of the trees and will not be present in the fruit at harvest. A consumer risk assessment was therefore not required.

### **4. Environmental fate and behaviour**

Calcium carbonate is the main component of naturally occurring sedimentary rocks composed largely of the mineral calcite (limestone).

After application (by brush) the formulation dries and forms a protective coating. The dried formulation is not water soluble. Because of the method of application leading to negligible levels of environmental exposure and the natural presence of calcium carbonate in soils and aquatic sediments, further consideration of its fate and behaviour in the environment was concluded to be unnecessary.

### **5. Ecotoxicology**

Based on the available data, 'Morsuvin' is harmful to aquatic organisms.

Because of the method of application leading to negligible levels of environmental exposure, the risk can be considered low for birds and mammals, aquatic organisms, bees, non-target arthropods, earthworms, soil macro- and micro- organisms, terrestrial non-target plants and biological methods for sewage treatment plants.

## 6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

### 6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Not applicable  Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for calcium carbonate (limestone, CaCO <sub>3</sub> ).	Not applicable	-

### 6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Not applicable  Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for groundwater exposure assessment is deemed to be unnecessary for calcium carbonate (limestone, CaCO <sub>3</sub> ).	Not applicable	Not applicable	-	-	-



### 6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
<p>Not applicable</p> <p>Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for calcium carbonate (limestone, CaCO<sub>3</sub>).</p>	-

### 6.4. Air

Compound (name and/or code)	Toxicology
<p>Not applicable</p> <p>Considering the nature of the substance and the limited exposure from the representative uses a definition of residue in the environment for risk assessment by other disciplines is deemed to be unnecessary for calcium carbonate (limestone, CaCO<sub>3</sub>).</p>	-

## **LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED**

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Five batch data (relevant for all representative uses evaluated; submission date proposed by the notifier: study report of a 5-batch analysis is available, however according to Regulation (EC) No 1095/2007 it cannot be taken into account in the peer review; see section 1)
- Shelf-life study (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Explosive properties, oxidizing properties, flammability and auto-flammability of the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: studies available, however according to Regulation (EC) No 1095/2007 they cannot be taken into account in the peer review; see section 1)
- Analytical method(s) for the determination of the impurities in the technical material (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Analytical method for the determination of calcium carbonate in the representative formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

## **PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED**

- None.

## **ISSUES THAT COULD NOT BE FINALISED**

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

- None.

## **CRITICAL AREAS OF CONCERN**

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a

plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

- None.

**REFERENCES**

- EFSA (European Food Safety Authority), 2011. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance calcium carbonate.
- European Commission, 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3030/99 rev.4, 11 July 2000.
- European Commission, 2008. Review Report for the active substance calcium carbonate finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 October 2008 in view of the inclusion of calcium carbonate in Annex I of Directive 91/414/EEC. SANCO/2606/08 – rev. 1, 01 August 2008.
- Spain, 2007. Draft Assessment Report (DAR) on the active substance calcium carbonate prepared by the rapporteur Member State Spain in the framework of Directive 91/414/EEC, August 2007.
- Spain, 2011. Final Addendum to Draft Assessment Report on calcium carbonate, compiled by EFSA, May 2011.

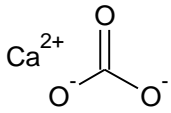
## APPENDICES

### APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

#### Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Calcium carbonate - there is no ISO common name
Function ( <i>e.g.</i> fungicide)	Repellent
Rapporteur Member State	Spain

#### Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	calcium carbonate
Chemical name (CA) ‡	calcium carbonate
CIPAC No ‡	843
CAS No ‡	471-34-1
EC No (EINECS or ELINCS) ‡	EINECS: 207-439-9
FAO Specification (including year of publication) ‡	No FAO specification
Minimum purity of the active substance as manufactured ‡	Open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	CaCO <sub>3</sub>
Molecular mass ‡	100.09
Structural formula ‡	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

**Physical and chemical properties (Annex IIA, point 2)**

Melting point (state purity) ‡	825°C with decomposition
Boiling point (state purity) ‡	Not applicable
Temperature of decomposition (state purity)	825°C
Appearance (state purity) ‡	Solid, white, no odour
Vapour pressure (state temperature, state purity) ‡	Not applicable
Henry's law constant ‡	Not applicable
Solubility in water (state temperature, state purity and pH) ‡	Nearly not soluble in water: 0.014g/L, good solubility in hydrochloric acid
Solubility in organic solvents ‡ (state temperature, state purity)	Not soluble in ethanol
Surface tension ‡ (state concentration and temperature, state purity)	Not applicable
Partition co-efficient ‡ (state temperature, pH and purity)	Not applicable
Dissociation constant (state purity) ‡	Not applicable
UV/VIS absorption (max.) incl. $\epsilon$ ‡ (state purity, pH)	Not applicable
Flammability ‡ (state purity)	Not highly flammable (statement)
Explosive properties ‡ (state purity)	Not explosive (statement)
Oxidising properties ‡ (state purity)	Not oxidizing (statement)

Summary of representative uses evaluated (*Calcium carbonate*)\*

Crop and/or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)	Remarks
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	kg a.s./hL min – max (l)	water L/ha min – max	kg ppp/ha min – max (l)		
(a)			(b)	(c)	Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	kg a.s./hL min – max (l)	water L/ha min – max	kg ppp/ha min – max (l)	(m)	
Deciduous and coniferous trees in forestry	Germany	Morsuvin	F	Game repellent	PA	417 g/kg	coating with brush; individual plants; entire plants	September -March	1-2	6-7 months	10-20% w/v	n. a.	10 kg / 1000 plants	n. a.	
Deciduous and coniferous trees in forestry	Germany	Morsuvin	F	Game repellent	PA	417 g/kg	coating with brush; individual plants; terminal sprouts	September -March	1-2	6-7 months	10-20% w/v	n. a.	3 kg / 1000 plants	n. a.	
Orchards (pome and stone fruit)	Germany	Morsuvin	F	Game repellent	PA	417 g/kg	coating with brush; individual plants; entire plants	September -March	1-2	6-7 months	10-20% w/v	n. a.	10 kg / 1000 plants	n. a.	
Orchards (pome and stone fruit)	Germany	Morsuvin	F	Game repellent	PA	417 g/kg	coating with brush; individual plants; terminal sprouts	September -March	1-2	6-7 months	10-20% w/v	n. a.	3 kg / 1000 plants	n. a.	

<p>* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).</p> <p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(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). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).</b></p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p>
---	--



## Methods of Analysis

### Analytical methods for the active substance (Annex IIA, point 4.1)

Technical a.s. (analytical technique)	Open
Impurities in technical a.s. (analytical technique)	Open
Plant protection product (analytical technique)	Open

### Analytical methods for residues (Annex IIA, point 4.2)

#### Residue definitions for monitoring purposes

Food of plant origin	No residue definition
Food of animal origin	No residue definition
Soil	No residue definition
Water surface	No residue definition
drinking/ground	No residue definition
Air	No residue definition

#### Monitoring/Enforcement methods

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required.
Soil (principle of method and LOQ)	Not required.
Water (principle of method and LOQ)	Not required.
Air (principle of method and LOQ)	Not required.
Body fluids and tissues (principle of method and LOQ)	Not required. Calcium carbonate is not regarded as toxic or very toxic.

### Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

Active substance	RMS/peer review proposal
	Calcium carbonate will not be classified from a physical/chemical viewpoint.

## Impact on Human and Animal Health

### Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	No data available, not needed.
Distribution ‡	No data available, not needed.
Potential for accumulation ‡	No data available, not needed.
Rate and extent of excretion ‡	No data available, not needed.
Metabolism in animals ‡	No data available, not needed.
Toxicologically relevant compounds ‡ (animals and plants)	No data available, not needed.
Toxicologically relevant compounds ‡ (environment)	No data available, not needed.

### Acute toxicity (Annex IIA, point 5.2)

Rat LD <sub>50</sub> oral ‡	Data available of limited validity, no further data needed.	
Rat LD <sub>50</sub> dermal ‡	Data available of limited validity, no further data needed.	
Rat LC <sub>50</sub> inhalation ‡	Data available of limited validity, no further data needed.	
Skin irritation ‡	Data available of limited validity, no further data needed.	
Eye irritation ‡	Data available of limited validity, no further data needed.	
Skin sensitisation ‡	Data available of limited validity, no further data needed.	

### Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	No data available, not needed.	
Relevant oral NOAEL ‡	No data available, not needed.	
Relevant dermal NOAEL ‡	No data available, not needed.	
Relevant inhalation NOAEL ‡	No data available, not needed.	

### Genotoxicity ‡ (Annex IIA, point 5.4)

No data available, not needed.	
--------------------------------	--

### Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	No data available, not needed.	
Relevant NOAEL ‡	No data available, not needed.	
Carcinogenicity ‡	No data available, not needed.	

## Reproductive toxicity (Annex IIA, point 5.6)

### Reproductive toxicity

Reproduction target / critical effect †

No data available, not needed.

Relevant parental NOAEL †

No data available, not needed.

Relevant reproductive NOAEL †

No data available, not needed.

Relevant offspring NOAEL †

No data available, not needed.

### Developmental toxicity

Developmental target / critical effect †

Data available of limited validity, no further data needed.

Relevant maternal NOAEL †

Data available of limited validity, no further data needed.

Relevant developmental NOAEL †

Data available of limited validity, no further data needed.

## Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity †

No data available, not needed.

Repeated neurotoxicity †

No data available, not needed.

Delayed neurotoxicity †

No data available, not needed.

## Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies †

No data available, not needed.

Studies performed on metabolites or impurities †

No data available, not needed.

## Medical data † (Annex IIA, point 5.9)

No adverse health effects have been reported in the literature among workers using calcium carbonate.

Overdose: hypercalcaemia, alkalosis, abdominal distention, nausea, flatulence, eructation and belching with acid reflux, reduced secretion of parathyroid hormone, retention of phosphate, precipitation of Ca<sup>2+</sup> salts in the kidney and renal insufficiency.

Therapeutic doses of calcium carbonate used as an antacide range up to 1 g, and in case of treatment of hypocalcaemic tetany up to 4 g. Hypercalcaemia from as little as 3 to 4 g a day: problematic in uremic patients. Clinical cases of poisoning incidents are described after 20-30 years of regular consumption of about 7-15 g calcium carbonate.

**Summary (Annex IIA, point 5.10)**

	Value	Study	Safety factor
ADI ‡	No data available, not required.	-	-
AOEL ‡	No data available, not required.	-	-
ARfD ‡	No data available, not required.	-	-

**Dermal absorption ‡ (Annex IIIA, point 7.3)**

Formulation (Morsuvin)

Negligible

**Exposure scenarios (Annex IIIA, point 7.2)**

Operator

Paintbrush application of a paste was not considered to be a source of significant exposure.

Workers

Paintbrush application of a paste was not considered to be a source of significant exposure.

Bystanders

Paintbrush application of a paste was not considered to be a source of significant exposure.

**Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)**

Calcium carbonate

RMS/peer review proposal

Data available of limited validity to conclude, no further data needed.

## **Residues**

Not applicable. Calcium carbonate is a very common mineral and a component of the earth's crust. The formulated product will not be used directly onto food or feed plants, therefore no residues in food or feed will occur.

## Fate and behaviour in the environment

### Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1)

Calcium carbonate is present in the environment as inorganic mineral (limestone). Calcium carbonate is nearly not soluble in water, but the solubility of calcium carbonate varies depending on the interaction of several environmental factors. When dissociation occurs, calcium carbonate is transformed to calcium and carbonate ions in the presence of water.

### Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.2)

Anaerobic degradation ‡: No data available. Not required.

Soil photolysis ‡: No data available. Not required.

### Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

No data available. Not required. Owing to the manual application by coating trees with a brush no entry of the active substance into soil and water will be expected. Therefore, calculation of  $PEC_{soil}$  is not considered necessary.

### Soil adsorption/desorption (Annex IIA, point 7.1.2)

No data available. Not required.

### Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

No data available. Not required.

### PEC (soil) (Annex IIIA, point 9.1.3)

No data available. Not required.

### Route and rate of degradation in water (Annex IIA, point 7.2.1)

Not applicable: Calcium carbonate is nearly not soluble in water, but the solubility of calcium carbonate varies depending on the interaction of several environmental factors. When dissociates, calcium carbonate completely dissociates to calcium and carbonate ions in the presence of water.

Carbonate is produced from various natural resources, particularly carbonate based rocks and respiration of aquatic plants during the hours of darkness.

### PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Owing to the manual application by coating trees with brush no entry of the active substance into soil and water will be expected. Therefore, calculation of  $PEC_{SW}$  and  $PEC_{SED}$  is not considered necessary.

**PEC (ground water) (Annex IIIA, point 9.2.1)**

Not calculated. The dissolution products of calcium carbonate are naturally occurring in the environment. Owing to the manual application by coating trees with a brush no entry of the active substance into soil and water will be expected. The contamination of groundwater due to the use of calcium carbonate as a plant protection product based on the applied for application method is expected to be negligible.

**Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)**

No data available. Not required.

**PEC (air)**

No data available. Not required.

**Residues requiring further assessment**

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology), and or for which consideration of groundwater exposure is necessary.

Not necessary. Calcium and carbonate ions are naturally occurring in the environment.

**Monitoring data, if available (Annex IIA, point 7.4)**

Soil (indicate location and type of study)	Not applicable. Calcium and carbonate ions are naturally present in the environment.
Surface water (indicate location and type of study)	Not applicable. Calcium and carbonate ions are naturally present in sediments in surface water.
Ground water (indicate location and type of study)	Not applicable. Calcium and carbonate ions are naturally present in groundwater.
Air (indicate location and type of study)	Not applicable. Calcium is not volatile and CO <sub>2</sub> is naturally occurring in the environment.

**Points pertinent to the classification and proposed labelling with regard to fate and behaviour data**

Biodegradability assessment not applicable for a mineral.  
No classification proposed.

## Ecotoxicology

### Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

No data submitted. Not required.

### Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

No data submitted. Not required.

### Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg a.s./L)
Laboratory tests ‡				
Fish				
Zebrafish	Morsuvin	96 hr (flow-through)	Mortality, EC <sub>50</sub>	> 42
Aquatic invertebrate				
<i>Daphnia magna</i>	Morsuvin	48 h (static)	Mortality, EC <sub>50</sub>	> 42
Algae				
<i>Desmodenus subspicatus</i>	Morsuvin	72 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	> 42 > 42

### Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Not required.

## Bioconcentration

No data submitted. Not required.

### Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

No data submitted. Not required.

### Hazard quotients for honey bees (Annex IIIA, point 10.4)

No data submitted. Not required.

### Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

No data submitted. Not required.



**Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5, Annex IIIA, points, 10.6 and 10.7)**

Earthworms

No data submitted. Not required.

Other soil macro-organisms

No data submitted. Not required.

**Toxicity/exposure ratios for soil organisms**

Earthworms

No data submitted. Not required.

Other soil macro-organisms

No data submitted. Not required.

Calcium and carbonate ions are natural soil components, non toxic to soil micro-organisms. Worst case use of 'Morsuvin' will not significantly change the natural concentrations of calcium or carbonate in soil.

**Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)**

No data submitted. Not required.

**Effects on biological methods for sewage treatment (Annex IIA 8.7)**

No data submitted. Not required.

**Ecotoxicologically relevant compounds** (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	None
water	None
sediment	None
groundwater	None

**Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)**

Calcium carbonate

RMS/peer review proposal

No classification proposed.

'Morsuvin'

RMS/peer review proposal

R 52

## ABBREVIATIONS

1/n	slope of Freundlich isotherm
$\lambda$	wavelength
$\varepsilon$	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
$\mu\text{g}$	microgram
$\mu\text{m}$	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT <sub>50</sub>	period required for 50 percent disappearance (define method of estimation)
DT <sub>90</sub>	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC <sub>50</sub>	effective concentration (biomass)
EC <sub>50</sub>	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER <sub>50</sub>	emergence rate/effective rate, median
ErC <sub>50</sub>	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice

GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
$K_{doc}$	organic carbon linear adsorption coefficient
kg	kilogram
$K_{Foc}$	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC <sub>50</sub>	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD <sub>50</sub>	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

NOEL	no observed effect level
OM	organic matter content
PA	paste
Pa	pascal
pcs	pieces
PD	proportion of different food types
PEC	predicted environmental concentration
PEC <sub>air</sub>	predicted environmental concentration in air
PEC <sub>gw</sub>	predicted environmental concentration in ground water
PEC <sub>sed</sub>	predicted environmental concentration in sediment
PEC <sub>soil</sub>	predicted environmental concentration in soil
PEC <sub>sw</sub>	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK <sub>a</sub>	negative logarithm (to the base 10) of the dissociation constant
P <sub>ow</sub>	partition coefficient between <i>n</i> -octanol and water
PPE	personal protective equipment
ppm	parts per million (10 <sup>-6</sup> )
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r <sup>2</sup>	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
t <sub>1/2</sub>	half-life (define method of estimation)
TER	toxicity exposure ratio
TER <sub>A</sub>	toxicity exposure ratio for acute exposure
TER <sub>LT</sub>	toxicity exposure ratio following chronic exposure
TER <sub>ST</sub>	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WHO	World Health Organisation
wk	week
yr	year