TECHNICAL REPORT

APPROVED: 1 June 2016

# Outcome of the consultation with Member States and EFSA on the basic substance application for talc E553B for use in plant protection as repellent on fruit trees and grapevines

European Food Safety Authority (EFSA)

## Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context, EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for talc E553B are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of talc E553B as a basic substance for use in plant protection as repellent (fungifuge and insectifuge) on fruit trees and grapevines. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.



**Keywords:** talc E553B, basic substance, application, consultation, plant protection, pesticide, fungifuge, insectifuge, repellent

**Requestor:** European Commission

**Question number:** EFSA-Q-2016-00190

**Correspondence:** pesticides.peerreview@efsa.europa.eu

**Suggested citation:** EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for talc E553B for use in plant protection as repellent on fruit trees and grapevines. EFSA supporting publication 2016:EN-1044. 39 pp.

## Summary

Talc E553B is an active substance for which, in accordance with Article 23(3) of Regulation (EC) No 1107/2009, the European Commission received an application from Compo Expert France SAS for approval as a 'basic substance'. Regulation (EC) No 1107/2009 introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest in applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission on 4 March 2016, EFSA was asked to organise a consultation on the basic substance application for talc E553B, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table within three months of acceptance of the specific request.

A consultation on the basic substance application for talc E553B, organised by EFSA, was conducted with Member States via a written procedure in October-December 2015. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by EFSA on the basic substance application for talc E553B and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Talc E553B is a powdered natural hydrous magnesium silicate containing varying proportion of such associated materials as alpha quartz, calcite, chlorite, dolomite, magnesite and phlogopite. The product proposed in the submission, Invelop, is a mixture of Talc E553B with maximum 15 % of natural water.

Invelop is intended to be used as spraying application on grapevines and fruit trees as an insectifuge and fungifuge. The submission provided does not contain sufficient data to show efficacy with regard to the representative uses.

With regards to the impact on human and animal health, since the specification for talc E553B complies with the one referring to food additive use, no concern is raised if exposure to talc is by oral route according to the conditions referred in the Commission Regulation (EC) No 889/2008. However, if talc E553B is inhaled, it could potentially accumulate in the lungs and be of concern for operators and bystanders. A field study of short duration (1-2 hours) where only 1-2 hectares were treated, showed that operators' exposure appear to remain below the level of detection for inhalable dust. However, in order to perform an exposure risk assessment for a full working day (6h) the setting of an acceptable operator exposure level (AOEL) is needed. The proposed AOEL is based on a 1971 study (Bethge-Iwanska, 1971) where either technical talc or pharmaceutical talc was administered to rats by inhalation for a period of 7 days to 9 months at air concentrations of 346-383 mg/m$^3$ without causing death. EFSA does not support this proposal since both types of exposure produced pathological changes in the respiratory tract of the animals (catarrhal and atrophic inflammation, atrophy and focal emphysema, thickening of pulmonary arteries walls and narrowing of their lumen). Therefore, the concentrations used in the study cannot be considered as no-observed adverse effect concentrations (NOAEC) on which an AOEL could be derived. Estimates of operators' exposure by inhalation could not be considered as insignificant (44% of the proposed AOEL according to the EFSA calculator (EFSA, 2014)), therefore, it has not been demonstrated that no adverse effect by inhalation is to be expected from the application of talc E553B on fruit trees and grapevines.

Since talc E553B is assumed to comply with the specification as food additive and since following application, talc is partly removed by rain and by washing, no residues of concern are expected to be present in plant commodities at harvest and a quantitative consumer risk assessment is not needed.

Whether the representative uses might result in groundwater exposure above the parametric limit of 0.1 µg/L, that is the water quality limit pertinent for decision making in accordance with the Uniform Principles remains open, based on the information available in the application.

In the area of ecotoxicology a low risk was concluded for birds and wild mammals, aquatic organisms, non-target arthropods other than bees, soil macro-fauna and soil microorganisms for all the representative uses. For bees a low risk could be concluded only when mitigation measures are taken into account (e.g. applications outside the flowering period of the crop/weeds in the field). A low risk to organisms involved in the sewage treatment could be concluded due to the low exposure.

# Table of contents

# 1. Introduction

## 1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1107/2009[1] (hereinafter referred to as 'the Regulation') introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as 'basic' and used for plant protection purposes.

Talc E553B is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Compo Expert France SAS for approval as a 'basic substance' for use in plant protection as repellent (fungifuge and insectifuge) on fruit trees and grapevines.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for talc E553B, which was conducted via a written procedure in October-December 2015. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for talc E553B and to present EFSA's scientific views on the individual comments received in the format of a reporting table.

The application and, where relevant, any update thereof submitted by the applicant for approval of talc E553B as a 'basic substance' in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (Compo Expert France SAS, 2015 and 2016).

## 1.2. Interpretation of the Terms of Reference

On 6 March 2013 the European Commission requested EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 4 March 2016, EFSA was asked to organise a consultation on the basic substance application for talc E553B, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The agreed deadline for providing the finalised report is 4 June 2016.

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

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

## 2. Assessment

The comments received on the basic substance application for talc E553B and the conclusions drawn by EFSA are presented in the format of a reporting table.

The comments received are summarised in columns 2 and 3 of the reporting table. The applicant's considerations of the comments, where available, are provided in column 4, while EFSA's scientific views and conclusions are outlined in column 5 of the table.

The finalised reporting table is provided in Appendix A of this report. In addition, an overview table on the identity and biological properties of the substance and the list of intended uses in plant protection (GAP table) are provided in Appendix B and C, respectively.

## Documentation provided to EFSA

1. Compo Expert France SAS, 2015. Basic substance application on talc E553B submitted in the context of Article 23 of Regulation (EC) No 1107/2009. July 2015. Documentation made available to EFSA by the European Commission.

2. Compo Expert France SAS, 2016. Basic substance application update on talc E553B submitted in the context of Article 23 of Regulation (EC) No 1107/2009. January 2016. Documentation made available to EFSA by the applicant.

## References

EFSA (European Food Safety Authority), 2009. Risk Assessment for Birds and Mammals. EFSA Journal 2009; 7(12):1438, doi:10.2903/j.efsa.2009.1438

EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874

## Abbreviations

| | |
|---|---|
| AOEL | acceptable operator exposure level |
| AOEM | agricultural operator exposure model |
| a.s. | active substance |
| DAR | draft assessment report |
| GAP | good agricultural practice |
| EFSA | European Food Safety Authority |
| EU | European Union |
| $LD_{50}$ | lethal dose, median; dosis letalis media |
| MRL | maximum residue level |
| MS | Member State |
| NOAEC | no-observed adverse effect concentration |
| NTA | non-target arthropods |
| OECD | Organisation for Economic Co-operation and Development |
| PEC | predicted environmental concentration |
| $PEC_{soil}$ | predicted environmental concentration in soil |
| TER | toxicity exposure ratio |

# Appendix A – Collation of comments from Member States and EFSA on the basic substance application for talc E553B and the conclusions drawn by EFSA on the specific points raised

## 1. Purpose of the application

| General | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 1(1) | | DE: The basic substance Talc E 553B is handled similar to products with a trade name (Invelop). It is on the market in order to prevent sunburn of plants, but also 'prevents black spot and apple scab'. Please see http://www.imerystalc.com/content/bu/Agriculture/Products/Invelop/. | A product label should be provided. | This mention 'prevents black spot and apple scab' was eliminated from the web site.<br>Please see attached the future label of Invelop® based on food additive talc E 553b with new allegations. | Addressed:<br>A label proposal of Invelop® based on food additive talc E 553B was submitted. |

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

### 2.1. Identity and Physical and chemical properties of the substance and product to be used

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 2(1) | Predominant uses of the substance outside plant protection | NL: Minor comment: It is unclear whether the purity criteria of all summarized uses of Talc are met by talc E 553b. | Please only summarize uses possible of Talc E553b | OK. The document has been changed. | Addressed:<br>The 'Predominant uses of the substance outside plant protection' was modified in the updated submission. |
| 2(2) | 2.1.5 Description and specification of purity, p.6 | EFSA: The specification for talc E553b complies with the specification for talc in the Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council | | Agree. | Addressed:<br>The specification for talc E553b complies with the specification for talc in the Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council |

### 2.2. Current Former and in case proposed trade names

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|

No comments.

## 2.3. Manufacturer of the substance/products

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|

No comments.

## 2.4. Type of preparation

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|

No comments.

## 2.5. Description of the recipe for the product to be used

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|

No comments.

## 3. Uses of the substance and its product

### 3.1. Field of use

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 3(1) | | DE: No specific data were provided which allow a detailed description of the cited GAPs. | | 3.1 The sentence has been corrected as followed : "Invelop® is intended to be used outdoors by spraying for plant protection on grapevines and fruit trees." In the document there is data provided for both: vineyards and fruit trees. | Addressed:<br>No experience on efficacy with regard to the intended uses exists in the submission.<br>Trials conducted with Invelop are encouraging and promising for its use in the context of the 'alternative control' against pests and diseases even if some results, are still not sufficiently efficient to ensure a complete crop and orchard protection. |

### 3.2. Effects on harmful organisms or on plants

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 3(2) | | DE: The literature cited and submitted does not provide the prediction of sufficient efficacy in the intended uses. The cited literature leaves the mode of action unclear. Overall, only limited effect in | In the dossier it should be made clear that no experience on efficacy with regard to the intended uses exists. | As demonstrated in the studies submitted under point 3.3, 16 result trials have been provided as a summary. Even though the efficacy of basic substance can sometimes be lower when compared to a conventional | Addressed:<br>No experience on efficacy with regard to the intended uses exists in the submission.<br>Trials conducted with Invelop are encouraging and promising |

### 3.2. Effects on harmful organisms or on plants

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| | | the uses described should be expected. | | product this should not question the interest in using this kind of product.<br>However the quoted trial conclusions on *Psylla piri* are encouraging: "at early stages Invelop® has statistically superior efficiency to the chemical method and an equivalent efficiency to clays of reference." (La Pugère, 2011) | for its use in the context of the 'alternative control' against pests and diseases even if some results, are still not sufficiently efficient to ensure a complete crop and orchard protection. |

### 3.3. Summary of intended uses

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 3(3) | | DE: No specific data were provided which allow the exclusion of potential phytotoxic effects. | Please provide reasons for the opinion that no phytotoxicity should be expected. | Over the 16 trials quoted in the document there was no phytotoxicity observed. 7 out of the 16 trials specifically mention the fact that the phytotoxicity criteria was taken into consideration and that none was found in the modalities containing Invelop® alone.<br>Also, in the Qualisol report | In the 16 trials quoted in the submission there was no phytotoxicity observed. 7 out of the 16 trials specifically mention the fact that the phytotoxicity criteria was taken into consideration and that none was found in the applications containing Invelop® alone. |

### 3.3. Summary of intended uses

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| | | | | from 2014, "in the conventional modality using MERPAN it was found some phytotoxicity on leaves as well as the roughness of fruit. The different alternatives solutions [Invelop®] have not caused phytotoxicity nor russetting on fruit." | |

## 4. Classification and labelling of the substance

### Classification and labelling of the substance

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|

No comments.

## 5. Impact on Human and Animal Health

### 5.1. Toxicokinetics and metabolism in humans

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

### 5.2. Acute toxicity

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

### 5.3. Short-term toxicity

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

### 5.4. Genotoxicity

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

### 5.5. Long-term toxicity

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

### 5.6. Reproductive toxicity

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

### 5.7. Neurotoxicity

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 4<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

### 5.8. Toxicity studies on metabolites

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

### 5.9. Medical Data: adverse effects reported in humans

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

### 5.10. Additional Information related to therapeutic properties or health claims

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

### 5.11. Additional information related to use as food

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

### 5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

| 5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 5(1) | 5.13. Impact on human and animal health arising from exposure to the active substance or impurities contained in it, p. 25 | EFSA: it is agreed that talc E553b, (provided that it complies with the specification as food additive) would not be of concern by the oral route. However, if inhaled, it could potentially accumulate in the lungs and be of concern (such as pneumoconiosis). According to the study submitted, exposure of operators appears to remain below the level of detection for inhalable dust. However study was of short duration (1-2 hours) and only 1-2 hectares were treated. It is unknown whether the use during a full working day treating realistic cultivated areas (8-50 ha per day considering vineyards, fruit tree and vegetables), exposure would still remain within acceptable levels. | Further exposure estimates through inhalation should be provided considering standards working days (6h) and realistic field areas (8-10 ha per day for grapes and fruit trees, 20-50 ha per day for vegetables). | Invelop® is intended to be used on fruit trees and vineyards only.<br><br>Operator exposure was estimated for a whole working day (6 hours) and an average breathing rate of 1.25 $m^3$/h as recommended in HEEG Opinion.<br>The estimated exposure through inhalation with AOEM model is = 12.675 mg/day for 10ha/day for grapes and fruit trees (without RPE).<br>The risk by inhalation route was estimated considering an AOEL of 3.83 mg/$m^3$<br><br>The exposure is 44% of the AOEL, indicating that there are no potential health risks to operators.<br><br>The dossier was updated accordingly | EFSA understands from column 4 that the setting of the AOEL is based on a 1971 study (Bethge-Iwanska, 1971) where either technical talc or pharmaceutical talc were administered by inhalation to rats for a period of 7 days to 9 months at air concentrations of 346-383 mg/$m^3$ without causing death. From the summary presented in English (p. 12), both type of exposure produced pathological changes in the respiratory tract (catarrhal and atrophic inflammation, atrophy and focal emphysema, thickening of pulmonary arteries walls and narrowing of their lumen) and therefore these concentrations cannot be considered as NOAEC on which an AOEL could be derived. As the estimated exposure by inhalation cannot be considered as insignificant (44% of the proposed AOEL), it has not been demonstrated that no adverse effect is to be |

| 5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | | | | | expected from the application of talc E553B on fruit trees and vineyards by inhalation. |

## 6. Residues

| Residues | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 6(1) | | NL: Minor comment: it could be specified in this chapter 6 that talc E 553b is totally removed by washing, and therefore, no residues are present, as it is described in 2.1.7.3. | EFSA: It is already mentioned in section 6, that "*Invelop® is removed partly by rain* ***partly by washing***". It seems therefore not appropriate to add as proposed by NL that "*Talc E533 is* ***totally*** *removed by washing*", unless information is provided to confirm this fact. | Agree with EFSA's comment. | Addressed |

## 7. Fate and Behaviour in the environment

### 7.1 Fate and Behaviour in the environment

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| No comments. | | | | | |

### 7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 7(1) | 7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water) Conclusion 7, page 27. | EFSA: Should talc E 553B be approved under Regulation (EC) 1107/2009, it would become a pesticide under the definition in Directive 2006/118/EC consequent to reference to Directive 2006/118/EC in the uniform principles of 1107/2009 (Regulation (EU) 546/2011) regarding decision making for groundwater. An assessment of whether $Mg_3Si_4O_{10}(OH)_2$ would be present in groundwater above 0.1µg/L consequent to the use applied for is therefore required and is not available. In this context the statement 'As a result, it | A quantitative groundwater exposure assessment for $Mg_3Si_4O_{10}(OH)_2$ needs to be provided so risk managers have information on groundwater concentrations that might occur consequent to the uses applied for. EFSA's understanding is that this is required in the absence of a relevant evaluation carried out in accordance with other community legislation showing that the substance doesn't have an unacceptable effect on the environment, having been identified.<br><br>EFSA's understanding is that the | Talc E 553b is a mineral inorganic substance. In the frame of pesticides exposure estimation no tool exists to perform a quantitative assessment. Nevertheless the concentration of talc in groundwater is not supposed to exceed the maximal water solubility. Talc is practically insoluble in water, only a few amount of magnesium and silicium can be found in water solution.<br>There is no threshold value defined for magnesium and silicium in Council Directive 98/83/EC on the quality of drinking water. | If talc E 553B is approved under Regulation (EC) 1107/2009 it will be considered a pesticides under the definition in Directive 2006/118/EC consequent to reference to Directive 2006/118/EC in the uniform principles of 1107/2009 (Regulation (EU) 546/2011) regarding decision making for groundwater. Therefore according to Directive 2006/118/EC the parametric drinking water limit of 0.1 µg/L would apply to talc E 553b. The definition of pesticides in Council Directive 98/83/EC on the quality of drinking water is |

| 7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water) | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | | implies that impact on groundwater …..is also negligible' is not useful. | cited Commission Regulation (EC) No 889/2008 provides rules for organic production, labelling and control but does not contain any 'relevant evaluation carried out in accordance with other community legislation showing that the substance doesn't have an unacceptable effect on the environment'. If such a 'relevant evaluation carried out in accordance with other community legislation showing that the substance doesn't have an unacceptable effect on the environment' exists then this should be added to this application. | The risk to aquatic compartment (groundwater and surface water) is deemed acceptable.<br><br>The dossier was modified accordingly. | only relevant for drinking water quality. Groundwater quality standards and the Uniform Principles follow the definition in Directive 2006/118/EC.<br>0.1 µg/L is a very low water solubility. As a measured water solubility for talc E 553B showing this property was < 0.1 µg/L was not included in the application the information available is insufficient to scientifically conclude against the relevant parametric drinking water limit required by the regulation. Though JECFA (1997) states that talc is insoluble in water this does not preclude absolutely presence in groundwater consequent to use > 0.1 µg/L. |

## 8. Effects on non-target species

### 8.1. Effects on terrestrial vertebrates

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 8(1) | 8.1.1. Birds | DE: Talc may be of natural soil origin, but the concentrations of the substance in the intended uses are very high (up to 125 kg/ha). It is not clear whether these concentrations still do not have an effect on wild birds. | Please show with additional information and/or a sound risk assessment, that concentrations up to 125 kg/ha do not have an adverse effect on wild birds. | A qualitative assessment is developed, based on the inert nature of the talc, its low toxicity in vertebrates (mammals), and its very low bioavailability. Moreover, birds may be permanently exposed to silicates through the grit in their gizzards. It is concluded that the risk from the use of Talc E 553b is very low.<br>The dossier was updated accordingly. | Data were submitted to support the claim that the product poses a low risk to birds (ANA, 2010; Figuerola et al., 2005 and Gionfriddo & Best, 1996).<br>It was considered that since:<br>- the results of the ANA inventories on the flora and fauna carried out in the surroundings of the Trimouns mines (Exposures were deemed to cover the proposed use patterns) showed that 45 birds species were present.<br>- birds are naturally exposed to silicates as part of the grit.<br>toxicity studies and a risk assessment were not deemed necessary.<br><br>Overall it is considered that it is not possible to quantify the magnitude of the risk to birds for the representative uses. However, due to the inert nature of Talc E553B it is |

| 8.1. Effects on terrestrial vertebrates | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | | | | | deemed reasonable to consider that when applied according to the proposed use patterns Talc E553B would pose a low risk to birds. |

**8.1. Effects on terrestrial vertebrates**

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 8(2) | 8.1.2. Mammals | DE: Does the statement that there is a lack of toxicity to mammals also apply for the high concentrations of talc in the intended uses? | Please show with additional information and/or a sound risk assessment, that concentrations up to 125 kg/ha do not have an adverse effect on wild mammals. | A risk assessment is proposed based on the data from OECD SIDS on silicates. It is concluded that at the recommended rates, the risk to mammals from Talc E 553b is acceptable.<br>The dossier was updated accordingly. | A risk assessment based on the EFSA Guidance (EFSA, 2009) was provided by the applicant.<br>Acute and long term endpoints for silicates (OECD SIDS, 2005) were considered representative for Talc E553B.<br><br>Orchard: a high acute and long term risk was identified for small herbivorous mammals and a high long-term risk was identified for frugivorous mammals.<br><br>It is noted that the TER calculations reported in the Basic Substance Application report for the use on grapevines were wrong (input parameters like application rate, etc. not compliant with the uses in GAP). EFSA performed new calculations: a high long term risk was identified for the small herbivorous mammals scenario BBCH 10-19 and BBCH 20-30 (TERs = 3.4 and 4.1 |

**8.1. Effects on terrestrial vertebrates**

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| | | | | | respectively).<br><br>The applicant claims that "small herbivorous mammals are no longer considered as relevant for the risk assessment because of their population dynamics and their reproduction high capability allowing for rapid recolonization". This justification is not substantiated by any relevant data and cannot be supported.<br><br>It is noted that the acute toxicity endpoint was a greater than value and the long-term endpoint corresponded to the highest tested dose.<br><br>Overall, taking into account the above, considered inert nature of Talc E553B and that no concern was raised in the mammalian toxicology section regarding the oral exposure to talc, it was considered that a low acute and long term risk to |

**8.1. Effects on terrestrial vertebrates**

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| | | | | | wild mammals due to the dietary exposure to talc E553B can be concluded. |
| 8(3) | 8.<br>ANA, 2010 | EFSA: Reference was made to the ANA naturalist inventories in French Pyrenees. It was | It should be specified how this study is considered relevant to cover the intended uses and high | The deposit rate from the site was calculated and compared with the application rate of Talc | See 8(1). |

**8.1. Effects on terrestrial vertebrates**

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| | | stated that *These inventories clearly demonstrate that the mine activities and the periodically mineral dust dispersed by the wind do not disturb the fauna and flora*. And *The naturalist inventories of the fauna and flora clearly show that the presence of Talc deposit has no adverse impact.*<br>It is considered that, even if the study might be considered informative in weighting the evidences of the impact of the mineral dusts in non-agricultural areas, it is considered that it is of little relevance for the approbation proposal. | application rates of the talc E 553B. If not relevant, it should be omitted from the report.<br>Furthermore the following statement should be deleted as it is considered not justified: *The naturalist inventories of the fauna and flora clearly show that the presence of Talc deposit has no adverse impact*. | E 553B. The mean annual measured deposit rates from the mine are higher than the maximum application rate. Therefore, the effects of the application of Talc E 553B at the recommended rate can be predicted from the effects of the mine on the surrounding environment.<br>The dossier was updated accordingly. | |

**8.2. Effects on aquatic organisms**

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 8(4) | 8.2 | EFSA Even if no toxicity is expected it is noted that the study | The following statement might be amended as follow (please | The sentence was modified as suggested and the Dossier was | The experimental details and results were poorly reported in |

**8.2. Effects on aquatic organisms**

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| | [redacted] 1998 Essais des eaux – Détermination de la toxicité aiguë d'une substance vis-à-vis de Brachydanio rerio (statique) | report consists of only a short summary and it does not show any data besides the statement that no mortality occurred at doses up 100 g/l results. Therefore it does not allow any further consideration. Moreover it is noted that the exposure period was 24h. This should be specified in the report. | delete the strikethrough):<br>*according to NF T 90-303 ~~proved the perfect safety of talc on fish:~~ no effect was shown at the ~~very high~~ concentration up to 100g/l (**24h** LD50 > 100g/l).* | updated with additional information on the test conditions, as described in guideline NF T 90-303. | the study summary. Few information on the study conditions were included in the summary, however these did not come from the study report (as it only shows the results) but from the reference testing guideline (this is not clearly specified in the study summary and it is considered misleading). Therefore, it was not possible to examine the study and conclude on the validity/reliability of the endpoint provided.<br>No quantitative risk assessment was submitted.<br>It is noted that the substance is inert and not soluble in water.<br>Overall, it is considered justified to conclude a low risk for aquatic organisms to Talc E553B when applied according to the representative uses. |

**8.3. Effects on bees and other arthropods species**

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 8(5) | 8.3.1. Effect on bees | DE: No data were submitted for the assessment of the product with regard to risk for bees. | Please indicate in the dossier. | No data was submitted with the dossier. However,<br>published study showed that talc used at very high rates to remove varroa mites from infested bees has no deleterious effects on bees (Macedo, 2002).<br>The dossier was updated. | The paper is considered to be irrelevant for the present application and it does not prove that talc has no deleterious effects on bees. The paper is a comparison of the efficacy of different powders used in varroa sampling carried out on portions of 300 bees.<br>The method itself is also described as 'not bee-friendly since many can die during the process' (see Dietemann et al, 2013). Standard methods for varroa research, Journal of Apicultural Research, 52:1, 1-54)<br><br>No relevant data were therefore available to carry out a quantitative risk assessment. It is concluded that the risk to bees can be considered low only when mitigation measures are implemented (e.g, application outside the flowering period of the crop and weeds/sowing of the flowering weeds before the |

**8.3. Effects on bees and other arthropods species**

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| | | | | | applications) |
| 8(6) | | DE: No experimental reports were submitted from which information about effects on beneficial organisms can be derived. | Please indicate in the dossier. | In the test performed by La Pugère in 2012, the insect pressure was low which did not allow to conclude on the efficacy of Invelop®. However the notation on beneficial insects is relevant and no statistical effects on beneficial organism was observed.<br>Document : Psylle du Poirier – Efficacité de stratégies à base d'argiles, talc et insecticides contre le psylle du Poirier en positionnement post floral – La Pugère, 2012.<br><br>The dossier was updated accordingly. | The applicant in the Basic Substance Application report states 'The number of beneficial arthropods is significantly higher in the treated plots than in the control ones'. The difference was not statistically significant. It is noted that results at T6+ 5 gg were not reported in the Basic Substance Application report: the number of anthocorids was slightly lower than in the control (again not statistically different). Overall it can be concluded that no negative impact on beneficial insects of Talc E553B could be assessed in the study.<br>It is considered that the data provided are informative to conclude a low risk to NTAs to Talc E553B for the representative uses. |
| 8(7) | 8.3.2. Effect on arthropods | DE: If talc should only be used outside of the periods of bees' activity other non-target arthropods could be affected by the intended uses of talc. | Please show with additional information and/or a sound risk assessment, that concentrations up to 125 kg/ha do not have an adverse effect on non-target | See above 8(6) | See comment 8(5) and 8(6) |

**8.3. Effects on bees and other arthropods species**

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| | | | arthropods. | | |
| 8(8) | 8.3.1 | NL: the text says no effects on bees were observed however no information was submitted that underpins this statement. Based on the recommendation | | See above 8(5) | See comment 8(5) |
| 8(9) | 8.3.2 | NL: based on the reservations included for bees the same applies to NTA. As there are no data on toxicity for bees submitted this cannot be a reasoning for not submitting data on arthropods | | See above 8(6) and 8(7) | See comment 8(6) |
| 8(10) | 3.4.<br>8.3.1 | EFSA: Please specify what it is meant with: "*we recommend the application of talc outside of the periods of bees' activity.*" (e.g. flowering of the crop; flowering of the crop and weeds in the field; etc..) | | The statement has been changed as follows:<br>"we recommend the application of Invelop® outside of the periods of bees' activity specially during the flowering of the crop" | See comment 8(5) |
| 8(11) | 8.3 | EFSA: it is acknowledged that talc E 553b is an inert and no toxic effects should be expected. However it is stated that "*as Invelop® is composed of lamellar mineral particles it may disturb the insects in* | As no studies on the effects on arthropods are available, any other relevant data or, at least, a more detailed statement/ justification addressing the concern should be submitted. | See above 8(6). As no effect of Invelop® application on beneficial arthropods has been reported in efficacy trial, it is considered that the risk to beneficial arthropods is acceptable. | See comment 8(6) |

| 8.3. Effects on bees and other arthropods species | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | | *their movements*". Therefore possible effect on the activity of beneficial arthropods (i.e. deambulation of predatory mites and insects) cannot be excluded. | | | |

| 8.4. Effects on earthworms and other soil macroorganisms | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 8(12) | Ibid. | DE: The concentrations of talc in the intended uses are partly very high. Do these concentrations correspond with the described use of talc as a soil conditioner? | Please describe the concentrations of talc when used as a soil conditioner and conduct a risk assessment for earthworms and other soil macro-organisms if the concentration of talc in the intended uses is higher. | The argument of talc being a soil amendment has been modified in the Dossier. Dolomite is the stone meal which is authorized as soil conditioner but it represents only a minor fraction of talc. Therefore a classic risk assessment is proposed in the updated dossier. Intended agricultural uses lead to a maximum $PEC_{soil}$ of 162 mg/kg the first year and 724 mg/kg by accumulation over years if no degradation nor foliar interception are considered. | An endpoint for earthworms was derived from De Souza et al, 2013. The study was not appropriately summarised in the report. The paper clearly shows that no effects were seen on earthworms number, dry weight and fresh weight in steatite powder enriched substrates respect to the control (not enriched substrate). It is acknowledged that steatite has high talc content. However it is noted that the endpoint was derived from the silicon dioxide content |

| 8.4. Effects on earthworms and other soil macroorganisms | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| | | | | Published data from composting conditioning with talc showed that high concentration of talc in the substrate did not have any effect on the number and growth of earthworms. Endpoints have been derived from this data and a risk assessment conducted for acute and chronic risk. The risk to earthworms is acceptable. The dossier was updated with these new data. | reported in the study (apparently the $SiO_2$ content was assumed to be comparable to the talc content). The study is considered informative, however the endpoint extrapolation is considered questionable.<br>The applicant used the proposed endpoint to provide TER calculations. Based on these calculations, a low risk has been demonstrated with a rather high margin of safety.<br><br>Overall, due to the inert nature of talc E553B and based on the available data, a low risk for soil macroorganisms can be concluded. |

| 8.5. Effects on soil microorganisms | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 8(13) | Ibid. | DE: The concentrations of talc in the intended uses are partly | Please describe the concentrations of talc when used as a soil | The use of talc as a carrier in microbial formulations for | The information submitted was not sufficient to carry out a |

### 8.5. Effects on soil microorganisms

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| | | very high. Do these concentrations correspond with the described use of talc as a soil conditioner? | conditioner and conduct a risk assessment for earthworms and other soil micro-organisms if the concentration of talc in the intended uses is higher. | biofertilizers based on plant growth promoting rhizobacteria demonstrate that soil bacteria (and particularly the beneficial species) may grow with no harm in talc-based substrate. Therefore, the amount of talc in soil resulting from the use of Talc E 553b at the recommended rate should not disturb the bacterial activity in soil. The dossier has been updated with data on the use of talc in microbial formulations. | quantitative risk assessment. The additional data provided are considered informative.<br>Overall it seems justified to consider the risk to soil microorganisms as low. |

### 8.6. Effects on other non-target organisms (flora and fauna)

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|

No comments.

| 8.7. Effects on biological methods of sewage treatment | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |

No comments.

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

| Overall conclusions with respect of eligibility of the substance to be approved as basic substance | | | | | |
|---|---|---|---|---|---|
| **No.** | **Column 1**<br>**Reference to Application Template** | **Column 2**<br>**Comments from Member States / EFSA** | **Column 3**<br>**Proposal by Member States/EFSA on how the application should be updated to address the comment** | **Column 4**<br>**Follow up response from applicant** | **Column 5**<br>**EFSA's scientific views on the specific points raised in the commenting phase conducted on the application** |
| 9(1) | 9 a) Talc is not a substance of concern | DE: In our opinion environmental risk assessment could not be finalised for several organism groups due to a lack of data. Therefore, no decision on the criteria whether or not talc is a "substance of concern" can be taken. | Please refer to the comments in section 8. The applicant should provide needed information. | The dossier was updated with requested information. Talc E 553b is confirmed to be not a substance of concern. | Noted.<br>Please refer to the relevant sections above. |

## 10. Other comments

**Other comments**

| No. | Column 1<br>Reference to Application Template | Column 2<br>Comments from Member States / EFSA | Column 3<br>Proposal by Member States/EFSA on how the application should be updated to address the comment | Column 4<br>Follow up response from applicant | Column 5<br>EFSA's scientific views on the specific points raised in the commenting phase conducted on the application |
|---|---|---|---|---|---|
| 10(1) | | DE: General comment on the efficacy evaluation in the dossier: the idea of the approval of basic substances is that no product authorisation takes place after the final decision on the a.s. | Therefore, it should be made clear that neither sufficient efficacy nor side effects are well approved and may occur. | Don't agree.<br>The article 23 of the EC regulation 1107/2009 on basic substances doesn't specify any requirements for the demonstration of efficiency, but mentions that basic substance "which main purpose is not to be used for plant protection but is nevertheless useful in plant protection". The usefulness of Invelop® was demonstrated by 16 trials in reputable stations which show an agronomic interest of talc E 553b in plant protection, with talc E 553b acting as physical barrier against insects and fungi. No signs of phytotoxicity were observed in these trials.<br>Published data and risk assessments show that no harmful side effect to non-target organism is expected | Addressed:<br>Trials conducted with Invelop are encouraging and promising for its use in the context of the 'alternative control' against pests and diseases even if some results, are still not efficient enough to ensure a complete crop and orchard protection. |

## Appendix B – Identity and biological properties

| | |
|---|---|
| **Common name (ISO)** | There is no ISO common name for this substance |
| **Chemical name (IUPAC)** | Magnesium hydrogen metasilicate<br>silicate mineral |
| **Chemical name (CA)** | Magnesium hydrogen metasilicate<br>silicate mineral |
| **Common names** | Talc, talcum |
| **CAS No** | 14807-96-6 |
| **CIPAC No and EEC No** | Not available |
| **FAO specification** | Not available |
| **Minimum purity** | COMMISSION REGULATION (EU) No 231/2012<br>of 9 March 2012 |
| **Relevant impurities** | Free of asbestos<br>As: max 10 mg/kg<br>Pb: max 2 mg/kg |
| **Molecular mass and structural formula** | Molecular formula: $Mg_3Si_4O_{10}(OH)_2$<br>Molar mass: 379.26 g/mol |
| **Mode of Use** | Spray applications |
| **Preparation to be used** | Invelop (Wettable Powder, WP).<br>(min. 85% in natural water) |
| **Function of plant protection** | insectifuge, fungifuge |

## Appendix C – List of uses

Active ingredient, talc E 553b represents 85% of the final product Invelop®

| Crop and/or situation (a) | Member State for use | Example product name as availa | FGI (b) | Target (c) | Product** | | Application | | | | Application rate per | | | Total rate | PHI (days) (m) | Remarks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Conc of a.i. g/kg | Method kind (f-h) | Growth stage and season* (j) | Number min max | Interval between applications (min) | kg a.i./hl min max | Water l/ha min max | kg a.i./ha min max | kg a.i./ha min max (kg/h | | |
| Fruit trees Ex: Apple fruit *Malus domestica,* Pear tree *Pyrus sp,* Olive tree *Olea europea,* ... | FR France All Member State | Invelop® | F | Physical barrier Insectifuge: Insects and acariens like *Cacopsylla pyri, Cacopsylla fulguralis, Drosophila suzukii, Panonychus ulmi, Bactrocera oleae,* | Wettable Powder (WP)** | 850 | Foliar application spraying | From before first warm period to end of summer | 2-5 | 3 to 4 weeks | 0.85 to 3.54 | 600 to 1000 | 8.5 to 21.25 | 42.5 to 106,25 | Not relevant | Water solution prepared just before application and maintained stirred |
| Fruit trees Ex: Apple fruit *Malus domestica,* Pear tree *Pyrus sp,* | | | | Physical barrier Fongifuge : Foliar fungi like mildews: *Venturia inaequalis, Erysiphe necator* | | | | From bud break (BBCH10) to first warm period | 3-5 | 1 to 3 weeks | 0.85 to 2.13 | 600 to 1000 | 8.5 to 12,75 | 25.5 to 63.75 | | |
| Grapevine *Vitis vinifera* | | | | | | | | | 2-5 | 2 to 4 weeks | 4.25 to 8.5 | 150 to 300 | 12.75 | | | |

* The product should be applied early in the morning or late in the evening for a maximum of efficiency. It should not be used on wet plants or in case of rainy weather. It should be applied again after a heavy rain. Although no effects have been observed on bees, we recommend the application of Invelop® apart from the periods of

bees' activity specially during the flowering of the crop. This is for a maximum efficacy related to the critical stages observed during the experimental trials and in order not to disturb pollinator insects.

** The product is a mineral dispersed in water (dispersion). Water dispersion prepared just before application and maintained stirred.

(a): For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b): Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c): *e.g.* pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor

(d): *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..

(e): GCPF Codes – GIFAP Technical Monograph N° 2, 1989

(f): All abbreviations used must be explained

(g): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated

(i): g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)

(j): Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k): Indicate the minimum and maximum number of application possible under practical conditions of use

(l): The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha

(m): PHI - minimum pre-harvest interval