



Basic Substance
Talc E553b
SANTE/11639/2017 rev.4
22 March 2018

Final Review report for the basic substance Talc E553b
Finalised in the Standing Committee on Plants, Animals, food and Feed
at its meeting on 22 March 2018
in view of the approval of Talc E553b as basic substance
in accordance with Regulation (EC) No 1107/2009¹

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of Talc E553b, made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009² concerning the placing of plant protection products on the market, with a view to the possible approval of this substance as basic substance.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 23 July 2015 an application from COMPO Expert France SAS, hereafter referred to as the applicant, for the approval of the substance Talc E553b as basic substance.

The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application which was finalised in the new version of January 2016.

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

EFSA submitted to the Commission the results of its work in the form of a technical report for Talc E553b on 1 June 2016³.

The Commission examined the application, the comments by Member States and EFSA and the EFSA technical report on the substance together with the additional information provided on it by the applicant on 15 September 2016 to address the remaining open points raised in the commenting phase and required further scientific assistance to the EFSA for the evaluation of such additional information.

¹ Review Report established in accordance with Art. 13 of Regulation (EU) No 1107/2009; it does not necessarily represent the views of the European Commission.

² OJ L 309, 24.11.2009, p. 1-50.

³ 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. 2016:EN-1044.

The applicant further amended the initial application on 19 May 2017 to address the collated comments.

EFSA submitted to the Commission the results of its work in the form of a technical report for Talc E553b on 27 July 2017⁴.

The Commission examined the final amended application, the comments by Member States and EFSA and the new EFSA Technical report on the substance together with the additional information and comments provided on it by the applicant, before finalising the current draft review report, which was referred to the Standing Committee on Plants, Animals, Food and Feed for examination. The draft review report was finalised in the meeting of the Standing Committee of 22 March 2018.

Given the importance of the EFSA technical report, the comments, additional information and clarifications submitted (background document C), all these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed in support of **Commission Implementing Regulation (EU) 2018/691**⁵ concerning the approval of Talc E553b as basic substance under Regulation (EC) No 1107/2009.

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

Without prejudice to the provisions of Regulation (EC) No 178/2002⁶, in particular with respect to the responsibility of operators, following the approval of Talc E553b as basic substance, operators are responsible for using it for plant protection purposes in conformity with the legal provisions of Regulation (EC) No 1107/2009 and the conditions established in the sections 4, 5 and Appendices I and II of this review report.

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

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

⁴ Outcome of the consultation with member States and EFSA on the additional information submitted in relation to the basic substance application for Talc E553B for use in plant protection as repellent on fruit trees and grapevines. 2017:EN-1277.

⁵ OJ L 117, 8.5.2018, p. 6–8.

⁶ OJ L 31, 1.2.2002 p. 1-24 - Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

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

The overall conclusion based on the application, including the results of the evaluation carried out with the scientific assistance of EFSA, and the comments and further additional information provided by the applicant to address the open points identified in the Technical report from EFSA, is that there are clear indications that it may be expected that Talc E553b fulfils the criteria of Article 23.

Talc is used for several purposes e.g. in pharmaceuticals, in animal feed, for cosmetics. It is also a food additive ruled as Talc E553b⁷, therefore it fulfils the criteria of a ‘foodstuff’ as defined in Article 2 of Regulation (EC) No 178/2002.

Talc E553b is supported as basic substance to be used in suspension in water in outdoors applications on grapevines and fruit orchards and acts as physical hydrophobic barrier.

Considering the EFSA conclusions on the basic substance application for Talc E553b, the rate of application and the conditions of use which are described in detail in Appendix I and II, it is concluded that the use of Talc E553b would not lead to concerns for human health. Furthermore, no residues or unacceptable effects on the environment are expected given the conditions of use and its degradation pathway.

Talc E553b is not a substance of concern, does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects and is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Finally, it is not placed on the market as a plant protection product.

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

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

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

4. Identity and biological properties

The main properties of Talc E553b are given in Appendix I.

⁷ 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 – OJ L 83, 22.3.2012, p. 1-295.

Specifications must be complied with those laid down for Talc E553b in the Commission Regulation (EU) No 231/2012 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.

In addition, taking into account the presence of respirable crystalline silica in talc it is important the maximum level of this toxicologically relevant impurity to be below 0,1%.

Purity as set in those specifications is reported in Appendix I.

5. Particular conditions to be taken into account in relation to the uses as basic substance of Talc E553b

Talc E553b must be identified by given specifications in Appendix I and must be used in compliance with method of preparation and condition of use as reported in Appendices I and II.

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

- Only uses as basic substance having a fungifuge and insectifuge action in accordance with conditions specified in Appendix I and II;
- Use of wettable powder in compliance with conditions specified and dilution explained in Appendix II.
- Period of treatment should be avoided during flowering time.

Users shall respect the conditions of use and where applicable, any precautionary statements included on the product's safety data sheet or any other relevant information made available at purchase phase in accordance with Regulation 1907/2006⁸. In particular, users should preventively use adequate personal respiratory protective equipment in case of dust formation and take precautions to avoid any unacceptable effects on the environment.

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

The identification of Talc E553b as food ingredient means that Regulation (EC) No 178/2002 on food safety applies and consequently this includes the respect to maximum permissible levels of chemical and biological contaminants legally set for this type of food additive.

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Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396 30.12.2006, p. 1).

6. List of studies to be generated

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

7. Updating of this review report

The information in this report may require to be updated from time to time to take account of technical and scientific developments, as well as of the results of the examination of any information referred to the Commission in the framework of Article 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection, as appropriate, with any amendment of the approval conditions for Talc E553b in Part C of Annex of the Regulation (EC) No 540/2011⁹.

8. Recommended disclosure of this review report

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

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

⁹ OJ L 153, 11.6.2011, p. 1–186.

APPENDIX I
Identity and biological properties
Talc E553b

Common name (ISO)	Not available.
Chemical name (IUPAC)	Magnesium hydrogen metasilicate silicate mineral
Chemical Name (CA)	Magnesium hydrogen metasilicate silicate mineral
	Talc E553b
Common names	Talc, Talcum
Definition	Naturally occurring form of hydrous magnesium silicate containing varying proportions of such associated minerals as alpha-quartz, calcite, chlorite, dolomite, magnesite, and phlogopite. The product should be free of asbestos.
CAS No	14807-96-6
CIPAC, EINECS	Not available, 238-877-9
FAO SPECIFICATION	Not available
Purity	<p>Specifications as food grade must comply with those laid down for Talc E553b in the Commission Regulation (EU) No 231/2012¹⁰.</p> <p>Loss on drying : Not more than 0,5 % (105 °C, 1 hour)</p> <p>Acid soluble matter: Not more than 6 %</p> <p>Water soluble matter : Not more than 0,2 %</p> <p>Acid-soluble iron : Not detectable</p>

¹⁰ 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 – (OJ L 83, 22.3.2012, p. 1).

Relevant impurities	<p>As above-mentioned, Food grade in conformity with Commission Regulation (EU) No 231/2012.</p> <p>Arsenic : Not more than 10 mg/kg</p> <p>Lead: Not more than 2 mg/kg</p> <p>Asbestos free.</p> <p>< 0.1% of Respirable Crystalline Silica</p>
Molecular mass and structural formula	<p>Molecular formula: $Mg_3Si_4O_{10}(OH)_2$</p> <p>Molar mass: 379.26 g/mol</p>
Mode of Use	<p>Spray applications. Used outdoors on grapevines and fruit trees. Details in appendix II.</p>
Preparation to be used	<p>Wettable powder. Mixture of dried powder (minimum 85% with natural water). To prepare the water dispersion just before the application and maintained stirred.</p> <p>Solution for application using the following protocol:</p> <ul style="list-style-type: none"> • Fill half of the sprayer tank with water; • Switch on the brewing system; • Gradually add talc dispersed (mixture of dried powder : minimum 85% with natural water) through the tank filter; • Gradually fill the additional volume of water. <p>The quantity and volume of water applied are described in Appendix II according to the uses.</p>
Function of plant protection	<p>Insectifuge, fungifuge.</p>

APPENDIX II

List of uses supported by available data

TALC E553B

Crop and/or situation (a)	Example product name as available	F G I (b)	Target (c)	Product**		Application				Application rate per treatment			Total rate (da ys) (m)	Remarks	
				Type (d-f)	Conc of a.i. g/kg	Method kind (f-h)	Growth stage and season *	Number min max	Interval between applic	kg a.i./hl min max (kg/hl)	Water l/ha min max	kg a.i./ha max			
Fruit trees Ex: Apple fruit <i>Malus domestica</i> , Pear tree <i>Pyrus sp</i> , Olive tree <i>Olea europea</i> , <i>etc.</i>	Invelop* ®	F	Physical barrier Insectifuge: Insects and mites like <i>Cacopsylla pyri</i> , <i>Cacopsylla fulguralis</i> , <i>Drosophila suzukii</i> , <i>Panonychus ulmi</i> , <i>Bactrocera oleae</i> ,	Wettable Powder (WP)*	850	Foliar application spraying	From BBCH 41	2-5	3 to 4 weeks	1 st application: 2.13 to 3.54 Succeeding applications : 1.7 to 2.83	600 to 1000	1 st application: 21.25 Succeeding applications: 17	38.25 to 89.25	Not relevant	Water solution prepared just before application and maintained stirred

Fruit trees			Physical barrier Fungifuge :			Foliar application spraying	From		2		600				
Ex: Apple fruit <i>Malus domestica</i> , Pear tree <i>Pyrus sp</i> ,			Foliar fungi like mildews: <i>Venturia inaequalis</i> , <i>Erysiphe necator</i>				BBCH 41	3-5	to 3 weeks	1.28 to 2.13	to 1000	12.75	38.25 to 63.75		
Grapevine <i>Vitis vinifera</i>						Foliar application spraying	From BBCH 20	2-5	3 to 4 weeks	4.25 to 8.5	150 to 300	12.75	25.5 to 63.75		

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

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