European Food Safety Authority

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TECHNICAL REPORT

Outcome of the consultation with Member States and EFSA on the basic substance application for talc and the conclusions drawn by EFSA on the specific points raised[1]

European Food Safety Authority[2]

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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 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 as a basic substance. The current report summarises the outcome of the consultation process organised by the European Commission and presents EFSA's scientific views on the individual comments received.

KEY WORDS

Talc, basic substance, application, consultation, plant protection, pesticide

[1] On request from the European Commission, Question No EFSA-Q-2013-00305, approved on 8 May 2013.

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SUMMARY

Talc 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 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 of 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.

A consultation on the basic substance application for talc, organised by the European Commission, was conducted with Member States and EFSA via a written procedure in June – July 2012. Subsequently the applicant was invited to address the comments received in the format of a Reporting Table.

In March 2013 the European Commission requested the EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In particular, EFSA was asked to consider the comments received on the basic substance application for talc and the response of the applicant thereon, and to finalise the Reporting Table with its scientific views on the specific points raised in the commenting phase.

The current report therefore summarises the outcome of the consultation process organised by the European Commission and presents EFSA's scientific views on the individual comments received in the format of a Reporting Table.

The initial application for basic substance (May 2012) was submitted for talc, which was updated as 'Talc de Luzenac' (September 2012). The composition of the talc depends on the geographical position of the mine, however a 'specification' for talc can be proposed based on this submission. The talc described in the submission ('Talc de Luzenac', corresponding to 'Invelop/Invelop F' product) is not claimed to be of pharmaceutical or food grade. It is not possible to conclude on the similarity to the talc used as E553 and the specification for talc presented in the submission differs from the specification of talc E553b as a food additive.

The criteria indicated in the Article 23 (1)(a) – (d) of Regulation (EC) No 1107/2009 cannot be considered fulfilled for talc. There are no relevant EU evaluations available to show that the substance has no harmful effects on human or animal health, nor an unacceptable effect on the environment. As a consequence, Article 4 of Regulation (EC) No 1107/2009 fully applies. The crystalline silica content of the milled product was not determined, therefore it cannot be decided if it contains crystalline silica dust < 0.1 % or not.

The toxicological compliance of the talc, for which some assessments were provided, with the 'Talc de Luzenac' is not demonstrated, as well as the potential relevance of impurities contained. In addition to these gaps, a specific literature search should be made available before a conclusion on the toxicological profile of the compound can be drawn.

As the talc described in this submission 'Talc de Luzenac' is not of pharmaceutical or food grade (and therefore not equivalent to talc E553), and considering that the available data were not sufficient to conclude on its toxicological profile, a consumer risk assessment could not be completed.

The available environmental risk assessment of talc is very brief and does not include or address all the environmental compartments. Predicted environmental concentrations (PEC) in soil and water have been estimated. Groundwater and air exposure assessments have not been performed.

The available information on the potential effects on non-target organisms was not sufficient for appropriate risk assessments. Therefore the magnitude of the risk to non-target organisms could not be

assessed. However, the exposure, and hence the risk to sewage treatment plants was considered to be limited for the intended uses. It is noted that risk mitigation measures were suggested for bees.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1107/2009[3] (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 is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Compo France SAS for approval as a "basic substance".

The European Commission organised a consultation with Member States and EFSA on the basic substance application for talc, which was conducted via a written procedure in June – July 2012. The comments received were collated by the European Commission in the format of a Reporting Table. Subsequently, the applicant was invited to address the comments in column 3 of the Reporting Table. The comments received and the response of the applicant thereon, together with the application submitted by the applicant, were considered by EFSA in column 4 of the Reporting Table.

The current report aims to summarise the outcome of the consultation process organised by the European Commission 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 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 FRANCE SAS 2012a and 2012b).

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

On 6 March 2013 EFSA was requested to provide its scientific views on the specific points raised during the consultation process conducted on the basic substance application for talc. To this end, a Technical Report containing the finalised Reporting Table is prepared by EFSA. 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.

[3] 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 No L 309, 24.11.2009, p. 1-50.

EVALUATION

The comments received on the application for talc and the conclusions drawn by the EFSA are presented in the format of a Reporting Table.

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

The finalised Reporting Table is provided in the Appendix of this report.

DOCUMENTATION PROVIDED TO EFSA

1. COMPO FRANCE SAS, 2012a. Talc. Basic substance application submitted in the context of Article 23 of Regulation (EC) No 1107/2009. May 2012. Submitted by COMPO FRANCE SAS. Documentation made available to EFSA by the European Commission.

2. COMPO FRANCE SAS, 2012b. Talc De Luzenac. Basic substance application update submitted in the context of Article 23 of Regulation (EC) No 1107/2009. September 2012. Submitted by COMPO FRANCE SAS. Documentation made available to EFSA by the European Commission.

REFERENCES

Beck, B.D. *et al.*, 1987. The pulmonary toxicity of talc and granite dust as estimated from an in vivo hamster bioassay. Toxicology and Applied Pharmacology, 87(2), 222–234.

European Commission, Health and Consumers Directorate General (DG SANCO), 2011. State of play new applications for use of food additives in food. Standing Committee on the food chain and animal health (SCoFCAH), Section " Toxicological Safety of the Food Chain", 14 March 2011.

Wild P. *et al.*, 2002. A cohort mortality and nested case-control study of French and Austrian talc workers. Occup Environ Med, 59: 98–105.

APPENDIX

COLLATION OF COMMENTS FROM MEMBER STATES AND EFSA ON THE BASIC SUBSTANCE APPLICATION FOR TALC AND THE CONCLUSIONS DRAWN BY EFSA ON THE SPECIFIC POINTS RAISED

1. Purpose of the application

General				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)	5.12 Additional information related to use as food, p.14	EFSA: clarification is needed if the talc described in this submission is similar to that used as E553	The term Talc has different meaning: ➢ A mineral with the following chemical formula: hydrous magnesium silicate; the talc particle are flat and plate-like. ➢ A naturally occurring rock ore; the talc mineral content may vary between 35% and 98% depending of the ore origin. The other associated minerals (chlorite, dolomite, magnesite, calcite) depends also of the ore origin. Talc de Luzenac (from the Trimouns mine) is associated with chlorite, an hydrous magnesium and aluminium silicate, a platy mineral very similar to talc and in a smaller proportion to dolomite. Calcite, quartz and rutile can be found as trace minerals. The ore grades are sorted mechanically on the mine. ➢ A commercial product that can be used industrially; produced from the talc ore	It was clarified that the talc described in the submission ('Talc de Luzenac', corresponding to 'Invelop/Invelop F' product) is not tested and not guaranteed as pharmaceutical or food grade. As purity tests are not performed, it is not possible to conclude on the similarity to the talc used as E553. See also comments 2.2(2), 2.2(3), 2.2(4) and 2.2(5).

General				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			with or without a beneficiation process. In the Luzenac French operation, the talc grades are processed from the Trimouns mine, then milled and packed. …/… Concerning the industrial applications, the mineralogical composition of the talc grades are chosen in order to comply with the purity criteria requested by the application. For example, for pharmaceutical grades, talc content should be at least 80%. For food application (E 553b), the carbonates content should be less than 2%. The Talc de Luzenac corresponding to Invelop/Invelop F product is not tested and not guaranteed as pharmaceutical or food grades (purity tests are not performed). Nevertheless Talc de Luzenac is allowed in food contact applications.	
2)	5.12 Additional information related to use as food, p.15	EFSA: it seems that the specification of talc E 553b as food additive slightly differs from the one presented in the submission and in the European Pharmacopeia.	Correct, see above.	The specification for talc presented in the submission differs from the specification of talc E 553b as a food additive[4]. See also comment (1) above

[4] 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, 22.03.2012, pp. 1 - 295

General				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3)	5.12 Additional information related to use as food	EFSA: 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 is not identical to the specification of the material proposed as a basic substance, as a consequence it cannot be concluded if it is a food or not.	The Talc de Luzenac corresponding to Invelop/Invelop F product is not guaranteed as a food additive grade.	The specification for talc indicated 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[5] is not identical to the specification of the material proposed as a basic substance. 'Talc de Luzenac' corresponding to 'Invelop/Invelop F' product is not guaranteed as a food additive grade. See also comments (1) and (2) above.
4)	9. Overall conclusion with respect of eligibility of the substance as basic substance, p.17	EFSA agrees that the criteria indicated in the Article 23 1(a) – (d) of Regulation (EC) No 1107/2009 are fulfilled for talc and can be considered as a basic substance.		The criteria indicated in the Article 23 (1)(a) – (d) of Regulation (EC) No 1107/2009 cannot be considered fulfilled for talc. There are no relevant EU evaluations available to show that the substance has no harmful effects on human or animal health, nor an unacceptable effect on the environment. As a consequence, Article 4 of the Regulation fully applies.

[5] OJ L 83, 22.03.2012, pp. 1 - 295

General				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5)	General	EFSA: no reference to an EU evaluation was provided showing that the substance has no harmful effects on human or animal health nor an unacceptable effect on the environment. With regard to the identity, physical properties and methods of analysis it cannot be concluded from the summary document that the dossier fulfils the requirements of Article 4 of Regulation (EC) No 1107/2009.	See reply to point 5.1	No relevant EU evaluations were presented to show that the substance has no harmful effects on human or animal health, nor an unacceptable effect on the environment. As a consequence, Article 4 of the Regulation (EC) No 1107/2009 fully applies. See also comment (4) above.
6)		FR: Submitted as a physical and thermic barrier: out of scope of Reg. 1107/2009		According to Article 2 of Regulation (EC) No 1107/2009: Scope The Regulation shall apply to products intended, among others, for the following use: (a) '*protecting plants or plant products against all harmful organisms or preventing the action of such organisms…*' 'Talc de Luzenac' is intended to form a physical barrier to control foliar fungi diseases such as *Venturia inaequalis, Plasmopara viticola* and *Botrytis cinerea* (fungifuge action), and insects such as *Cacopsylla pyri, Bactrocera oleae, Hyalesthes obsoletus, Scaphoideus titanus, Rhagoletis completa, Cacopsylla*

General				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				pruni (insectifuge action).

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

2.1. Predominant Use				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

2.2. Identity and Physical and chemical properties of the substance and product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)	2.2.1 Common name of the substance and product and their synonyms/plant nomenclature	FR: It should be indicated in this paragraph the name of the product (plant protection product) "Invelop" and/or "Imerys" and an indication if the plant protection product and the active substance is the same or not.	The name proposed for the active substance is Talc de Luzenac (correction regarding the first proposal). Invelop/Invelop F are the current brand names of these Imerys Talc de Luzenac products. (see new version of the application document points 2.2.1 & 2.3)	It is the understanding of EFSA that an active substance cannot have a common name indicating its origin. It is stated that 'Talc de Luzenac' is a specific talc grade developed for agriculture, however its composition will not change by the described 'manufacturing mode'. The composition of the talc will not change by milling and wetting, it depends on the geographical position of the mine. Our understanding is that based on this proposal, a 'specification' is proposed for the basic substance talc.
2)	2.2.3 Identity p.5 and 2.2.5 Specification of the	EFSA: are these data meaning that the talc content complies with the ISO standard type	This table about ISO Standard 3262 is not relevant. See general comments.	Addressed: it is not intended to comply with ISO Standard 3262.

2.2. Identity and Physical and chemical properties of the substance and product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	purity of the a.s., p.6	A?		
3)	2.2.5. Description and specification of purity of the active substance and product	FR: Please indicate the number and the date of production of the batches used for the determination of the interval values of the major components. Moreover, it is stated "these products contain less than 1% crystalline silica". Nevertheless, as crystalline silica is considered carcinogenic to humans (Group 1) by IARC, a specification of < 0.1% is more appropriate.	7 batches Crystalline silica usually associated with talc mineral is quartz only. The Talc de Luzenac used for Invelop/Invelop F contains less than 1 % total quartz. It is Crystalline silica **dust** which is classified as Group 1 by IARC. Moreover REACH does not consider IARC classification.	The production dates of the batches were indicated in the new version of the application (September 2012). The crystalline silica content of the milled product is not determined, as a consequence, it cannot be decided if it contains crystalline silica dust < 0.1% or not.
4)	2.2.7 Methods of analysis, p. 6	EFSA: clarification is needed whether the talc proposed in this submission is claimed to meet the European Pharmacopeia 2005 (Talc monograph 04/2005:0438)?	Invelop/Invelop F is not a pharmaceutical grade. Please see above.	It was clarified that the talc proposed in this application is not claimed to meet the European Pharmacopeia 2005 (Talc monograph 04/2005:0438). See also comment (1) in section 'General'.
5)	2.2.7.1 Methods of analysis for determination of the	DE: It should be stated more clearly whether TALC complies with all requirements of the European Pharmaocopoeia 2005 (Talc	Invelop/Invelop F are not compliant with the European Pharmacopoeia talc monograph.	It was clarified that the talc proposed in this application is not claimed to meet the European Pharmacopeia

2.2. Identity and Physical and chemical properties of the substance and product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	active substance as manufactured	monograph 04/2005:0438) especially regarding the absence of asbestos resp. cristalline silicates.	The absence of asbestos in Imerys talc de Luzenac crudes is tested periodically internally and externally.	2005 (Talc monograph 04/2005:0438). See also comments (1) in section 'General' and comment 2.2(4).
6)	2.2.7.1 Methods of analysis for determination of the active substance as manufactured	DE: It seems to be that regarding analysis for microorganisms and pesticides the respective data were copied from the dossier for equisetum extract. However, they seem to be not relevant for TALC. It should be clearly stated whether this data were actually analysed in TALC or the respective paragraphs should be deleted.	The microbiology results for 2 samples Talc de Luzenac used for Invelop/Invelop F products are indicated in the new version of the Application document. Talc de Luzenac used for Invelop/Invelop F is produced from a selected ore coming from Trimouns mine, simply milled. No chemical additives are used during the process. Talc de Luzenac used for Invelop/Invelop F never comes in contact with chemical additives. Moreover, herbicides, fungicides and pesticides are not used in the Luzenac production factory. Ok to delete	Addressed: two batches of 'Talc de Luzenac' were analysed for microorganisms as presented in the submission, however this information is not relevant for this substance and can be deleted.
7)	2.2.7.1 Method of analysis for the determination of the active substance as manufactured	FR: The information provided about the pharmacopeia, the heavy metal, microbiology, pesticide residues and mycotoxins should be indicated in the paragraph 2.2.6 (Identity of inactive isomers, impurities and additives). Characterization from the talc monograph of	OK to be changed	See comments 2.2(4), 2.2(5) and 2.2(6). See comments (1) and (2) in section

2.2. Identity and Physical and chemical properties of the substance and product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		the European Pharmacopoeia is reported in this chapter. It could be stated if the active substance talc satisfies to these information, particularly if it contains asbestos or not. If the interval values for the impurities provided from analysis of batches, it should be indicated the number and the date of production of batches used. If this information comes from the literature it should be indicated. Furthermore, it should be indicated the presence or not of a relevant impurity in the technical active substance. Finally, in the paragraph 2.2.7.1, it should indicated if validation data are available for the determination of the active substance, the major component or the maker in the technical active substance This analytical method should be developed on TALC deposited by the Notifier and not on any talc.	The Talc de Luzenac used for Invelop/Invelop F is not compliant with talc monograph. The Talc de Luzenac used for Invelop/Invelop F does not contain asbestos (under detection limit of the method used). Please see above 7 batches samples No relevant impurity or substance of concern is present in the Talc de Luzenac used for Invelop/Invelop F. Please see above It is possible to determine the presence of ores by SEM-EDX (Scanning Electron Microscopy – Energy Dispersive Spectrometry) and if they are coming from Talc de Luzenac. It is not possible to quantify the Talc de Luzenac on/in vegetal matter as the elements of Talc de Luzenac are identical to the ones in the vegetal matter.	'General'; see also comments 2.2(4) and 2.2(5). See comment 2.2(3). See comment 2.2(3). The crystalline silica content of the milled product is not determined, as a consequence, it cannot be decided if it contains crystalline silica dust < 0.1 % or not. The content of crystalline silica dust above 0.1 % would be relevant impurity. No description of the analytical method used was submitted, only the principle of the method.
8)	2.2.7.1 Analytical methods for the	FR: If there are no relevant impurities, an indication that no relevant impurity exists in	No relevant impurity	There are no relevant impurities, however the content of crystalline

2.2. Identity and Physical and chemical properties of the substance and product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	determination of relevant impurities	the technical active substance should be added, otherwise, an analytical method fully validated for the relevant impurities should be detailed. For better clarity, the reference to the MSDS of the formulation Invelop and to product data sheet of Imerys should be removed.	Ok	silica dust was not quantified, and no data are presented on the annual check of the heavy metal content (Pb, Cd, Hg). See also comment 2.2(3).
9)	2.2.7.2 Analytical methods for determination of relevant impurities	DE: It seems to be not appropriate to cite the MSDS and the product data sheet here since there are no analytical methods mentioned in the documents.	Ok	See comment 2.2(8).
10)	2.2.7.3 Analytical methods for the determination residues	FR: An explication on the non applicability of the analytical method for the determination of residues should be added.	Talc de Luzenac is chemically, thermically and biologically inert and then totally removed by the washing operation.	Addressed: the explanation provided by the applicant can be accepted.

2.3. Current, former and in case proposed trade names				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

2.4. Manufacturer of the substance/products				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)	2.4 Manufacturer of the substance/ product	FR: In addition of the address of the manufacturer, it should be indicated in this paragraph the location of the natural quarry.	Trimouns mine is located in French Pyrenees.	Addressed: the location of the natural quarry is mentioned.

No comments.

2.5. Type of preparation				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

2.6. Description of the recipe for the product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

2.7. Function on plant protection				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 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 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

3.2. Effects on harmful organisms or on plants				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)		DE: No information has been provided by the applicant with regard to efficacy and phytotoxicity. The applicant should list own or public available data (e.g. scientific publications) to inform about the experiences of practice with the basic substance as plant protection agent.	9 trials were conducted between 2009 and 2011 and they are added to the new version of the Application document. 33 trials are in progress (see Application document revised). A synthesis will be done when the results will be available.	9 trials were presented in the revised version of the application (September 2012). It is indicated by the applicant that a summary of the trials in progress will be presented when the results will be available.
2)	3.2. Effects on harmful organisms or on plants	FR: The mode of action may/should be supported by published references.	Currently no published references exist regarding the mode of action.	According to the application document currently no published references exist regarding the mode of action.
3)	3.2. Effects on harmful organisms or on plants	FR: Information about the potential effect on crop to be protected may/should have been provided (effect on photosynthesis or on evapotranspiration).	No negative effects were observed on photosynthesis or evapotranspiration during the trials conducted on the different plants.	According to the application document no negative effects were observed on photosynthesis or evaporation/transpiration during the trials conducted on the different plants.

3.2. Effects on harmful organisms or on plants				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				However, no supportive data were provided.

3.3. Summary of intended uses				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)	Growth stage and season	FR : Precise "except during flowering (bees activity" (see 8.3)	Ok	In section 8.3 of the application (Effects on bees and other arthropods species), with regard to the application of talc the following is stated: '*We recommend the application of talc apart from the periods of bees' activity*.' For better clarity, it should be precisely indicated: '*except during flowering (bees activity)*'. This should also be reflected in the table for the summary of intended uses (section 3.3).

4. Classification and labelling of the substance

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 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. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)	General	EFSA: for the assessment of talc health effects no relevant EU evaluations are available: the DG SANCO 2011 document on talc as food additive and the EU Report do not allow for an independent assessment (however it is mentioned that there is no need to set any reference values). The NTP long term inhalation study would need further consideration, in view of the inhalation exposure of operator, worker and bystander. In addition, information is missing on the toxicological impact of possible impurities/trace elements present in the specification, in view of the extremely high application rates. Limited toxicological data are available to define the hazard of talc.	A huge number of studies (epidemiological and animal experiments) have been conducted on talc products. They have been intensively discussed and talc has been evaluated by several regulatory authorities. (details are given in the revised Application dossier at the beginning of Point 5).	The compliance of the talc, discussed in the assessments presented in the revised application, with the material proposed as a basic substance ('Talc de Luzenac') needs to be demonstrated before a conclusion on the toxicological profile of the compound can be drawn.
2)		EFSA: the identity of the compound talc has to be defined to further check its toxicological relevance in the frame of the definition of what a basic substance is.	See Point 2.2 corrected in the Application document.	Depending on confirmation in the physical-chemical section, a consideration of the toxicological relevance of possible impurities present in the specification should be provided, also in view of the high application rates. See EFSA conclusion in comment 2.2(8).

5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3)		DE: Outcome of a preliminary check of the documents provided is that negative effects on human and animal health according to Article 23 Regulation (EC) No 1107/2009 can not be excluded free of doubt. A comprehensive evaluation of health effects on basis of the literature presented is not possible and there are some inconsistent conclusions. The following evidence show that talcum may have negative health effects:		Due to the huge amount of publications available generally on talc health effects, a more detailed literature search with comprehensive evaluation of health effects would be necessary to be able to conclude on the relevance of toxicological effects.
4)		DE: In epidemiological studies an enhanced mortality of workers due to non malignant respiratory diseases, which were related to a high cumulative exposure to talcum (Wild, 2002) occur.	In this study, a non-significant excess mortality was found for all non-malignant respiratory diseases in the French cohort (i.e. Talc de Luzenac) due to a significant excess for pneumoconiosis. No death from mesothelioma was found.	See EFSA conclusion in comment 5.1(3) above.
5)		DE: There are some negative effects on health cited in Grad, 2005: „Acute inhalation exposure can cause coughing, dyspnea, sneezing, vomiting, and cyanosis. Talc, which is water insoluble, dries up the mucous membranes of the tracheobronchial trees. This results in impairment of ciliary function. Inhaling large quantities of talc can result in obstruction of the small airways in addition to drying the mucous membranes, leading to respiratory distress syndrome, or death."	This short article summarizes conclusions from the literature but without publications references. These conclusions are the same than the one we can found in all the literature surveys listed above. Literature surveys take into account any valid articles published whatever the origin of the products, whatever the concerned industries whatever the type of study. Lot of epidemiological studies were performed on the effects of Luzenac talc products on the heath of Luzenac plant	See EFSA conclusion in comment 5.1(3) above.

5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		"Talc produces fibriotic pneumonitis." "Talcosilicosis is caused by talc mined with high silica content mineral. Findings in this form are identical with those of silicosis." "Talcosis, caused by inhalation of pure talc, may include acute or chronic bronchitis as well as interstitial inflammation; radiographically, it appears as interstitial reticulations or small, irregular nodules, typical of small airway obstruction."	millers and Trimouns miners. These studies conducted by well known independent institutes were taken into account in all the reviews performed on talc. Some of these studies are summarized in the revised Application document.	
6)		DE: In a comparative tests with hamster it was shown, that the lung damage is higher with dust of talcum than with dust of granite (Beck et al., 1987).		See EFSA conclusion in comment 5.1(3) above.
7)		DE: In several publications it is discussed, that talcum may result in an increased rate of tumor (i.e. ovarian tumors). But overall the evidence of carcinogenicity is insufficient at the moment. Additional studies would be necessary.	Please see above.	See EFSA conclusion in comment 5.1(3) above.
8)	5. Impact on human and animal health : General comment	FR: More details have to be included in the paragraph 5 regarding the methodologies, the results and the conclusions of all of the studies. Other relevant data has to be included in this document, in particular data from the Health Assessment Document of US-EPA and the IARC evaluation.	Please see above.	See EFSA conclusion in comment 5.1(3) above.

5.2. Toxicokinetics and metabolism in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.3. Acute toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9)			No acute oral data is available on toxicity. Only chronic toxicity data are available. Rats were fed 100 mg talc per day for 101 days; no significant depression of lifespan was observed (Wagner et al. 1977). Only chronic toxicity data is available A group of rats were administered 30-383 mg/m^3 "technical" and "pharmaceutical" grade talc for 6 hours, six days a week for up to nine months and none were reported to have died as a consequence of exposure (Bethge-Iwanska, 1971) In another study, no negative effects were observed when hamsters were exposed by inhalation to 8 mg/m^3 of respirable "baby talc" for 150 minutes/day for 5 days for up to 300 days (IARC 1987). No deaths were reported in a study of Wistar rats that received intratracheal instillation of 50 mg talc dust suspended in	The studies mentioned in Column 3 are not summarised in the revised application and therefore could not be considered for a proper assessment.

5.3. Acute toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			0.5 mL of 0.9 sodium chloride (Jakubowska &Szaflarska-Stojko, 1992). No acute dermal toxicity data are available. The results of primary cutaneous irritation tests showed that talc is not irritating to rabbits (Institut Francais De Recherches Et D'Essais Biologiques, 19 Talc instilled in the conjunctival bag of the rabbit showed no signs of irritation after 12 days (Lauressergues 1978). In a second study, slight irritation (mean score of 11.67) of the rabbit eye was observed upon instillation of talc (Institut Francais de Recherches et Essais Biologiques, 1983 Individual scores were not available for evaluation, however, an average Draize score of less than 15 is considered "practically non-irritating". Any effects encountered were likely due to mechanical irritation. The results of primary cutaneous irritation tests showed that talc is not irritating to rabbits (Institut Francais De Recherches Et D'Essais Biologiques, 1983).Tests on human skin show that talc is not irritating to humans (Frosch, P.J., and Kligman, A.M., 1977).	

5.4. Short –term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.5. Genotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.6. Long-Term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.7. Reproductive toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.8. Neurotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.9. Toxicity studies on metabolites				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.10. Medical Data adverse effects reported in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 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 therapeutic properties or health claims				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
10)			For information, the use of therapeutic talc (PR 7841 from Trimouns mine) for pleurodesis in patients with begnin or malignant pleural effusisons involving the direct application of talc to the human pleural is well known.	Noted.

5.12. Additional information related to use as food				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.13. Acceptable daily intake, acute reference dose, acceptable operator exposure level				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

5.14. Impact on human and animal health arising from exposure to the substance or impurities contained in it				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

6. Residues

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)	6. Residues	EFSA: The specification of the talc proposed as basic substance should be clarified before to conclude that the uses of talc as PPP have no harmful effects on human or animal health. Due to the very important annual dose rate (up to 5x 175 kg/ha = 875 kg/ha/year on fruit trees), possible minor impurities might be present in significant levels and of toxicological relevance in the crop commodities at harvest.	See above considering that the maximum annual dose is 175 kg/ha (please see corrections in the application document).	As the talc described in this submission ('Talc de Luzenac') is not of pharmaceutical or food grade (and therefore not equivalent to talc E553), and not fully identified for impurities (see sections 1 and 2.2), no conclusion can be drawn concerning the residues and the possible impact on human or animal health.

7. Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)	7. Fate and behaviour in the environment	EFSA: An EU evaluation relevant for environmental fate and behaviour assessment is not referred to so is probably not available. Therefore a derogation from Article 4 of the Regulation is not possible. Therefore information on 'its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater air and soil taking into account locations distant from its use following long-range transport need to have been addressed in the application.' The available environmental risk assessment of talc is very brief and does not include / address all the environmental compartments.	Talc is a natural product, inert and not soluble in the water. Due to the characteristics of the product, no study has been conducted.	Even with the clarification that the representative use being considered will have a maximum annual application of 175 kg/ha (2x50 kg/ha + 3 x25 kg/ha), there will be significant environmental exposure in the agricultural environment, where talc is not naturally encountered. Estimates of soil exposure levels and surface water exposure levels (as a result of spray drift) at the time of application are needed for a risk characterisation to exclude harmful effects on soil-dwelling and aquatic organisms. A predicted environmental concentration (PEC) in soil of 233 mg/kg is estimated assuming a mixing depth of 5cm and soil bulk density of 1.5g/cm^3. PEC in surface water of 13.98 mg/L and sediment of 64.5 mg/kg are calculated, assuming 23.96 % spray drift at 3 m to a 30cm deep static water body, and a sediment bulk density of 1.3g/cm^3 with a mixing depth of 5cm. With the information provided by the applicant, groundwater and air exposure assessments are not

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				possible.

8. Effects on non target species

8.1. Effects on terrestrial vertebrates				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)	Basic substance application model 8.1.1.1 and 8.1.1.2	EFSA: An EU evaluation relevant for ecotoxicology is not referred to, so is probably not available. Therefore derogation from Article 4 of the regulation is not possible and risk assessments for non target organisms are necessary. On the bases of the facts that talc has a natural origin or it is used as health product, neither the toxicological profile nor the risk to terrestrial vertebrates can be predicted (especially if the extremely high doses are considered). Moreover, only limited toxicological data are available to define the hazard of talc (see chapter 5, above). Although some data on mammals seem to be available, so some kind of risk assessment at least for wild mammals is possible.	Rats were fed 100 mg talc per day for 101 days: no significant depression of lifespan was observed (Wagner and al, 1977). No negative effects were observed when hamsters were exposed by inhalation to 8 mg/m3 of respirable "baby talc" for 150 minutes/day for up to 300 days (IARC 1987).	Some information on the hazard of talc to mammals is available, however no quantitative risk assessment was available. The studies mentioned in Column 3 could not be considered for a risk assessment (see comment 5.3(9)), therefore the magnitude of the risk to birds and mammals cannot be assessed.

8.2. Effects on aquatic organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2)	Basic substance application model 8.2	EFSA: Please clarify whether the data available for fish (LC_{50}, but also referred as LD_{50}) is >100 g/L or (=)100 mg/L. Is it only	These data are coming from 2 different studies. It is more relevant to take into account the one conducted by the Municipal	See EFSA conclusion in comment 8.2(3), below.

8.2. Effects on aquatic organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		a typo or two separate data are available.	Laboratory of Bordeaux (LC50 > 100g/l). This latest study is based on Talcs from Trimouns.	
3)	Basic substance application model 8.2	EFSA: Please provide more information on the study/studies available on aquatic organisms (detailed study summaries are expected). Could for example the concentration in the water column be maintained in the semi-static conditions?	Luzenac Talc 10M0, similar to Invelop/Invelop F, had negligible effects on the Daphnia magna, including an absence of effects in exposures of 100 mg and 1000 mg Luzenac 10MO/L. These low level effects indicated no need for definitive toxicity testing. Study report provided.	No study or appropriate study summary was available for fish, except a very short summary in French without details on the methodology and results. There was however an indication that water concentration was not maintained. An acute study on daphnids is available for 'Luzenac 10 MO Powder', which allows a quantitative risk assessment for that product. However, overall, based on the data available, the risk assessment for aquatic organisms is considered incomplete.
4)	Basic substance application model 8.2	EFSA: Since at least a data on fish is available, at least a simple risk assessment based on spray drift is possible. Could physical kind of effects (e.g. gill overloading for fish) be excluded for aquatic organisms (such as fish, aquatic invertebrates, algae) considering the expected high concentration in natural waters after the spray application?	See our reply Point 6	See EFSA conclusion in comment 8.2(3), above. Note: A PEC in surface water of 14 mg/L and 65 mg/kg in sediment have been calculated by EFSA (see column 4 entry in section 7).

8.3. Effects on bees and other arthropods species				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5)	Basic substance application model 8.3	EFSA: From the few sentences included in this chapter it seems that a study /studies is/are available for bees. If so, please provide detailed information on the study/studies available (detailed study summaries are expected).	No specific studies were conducted on bees. No negative effects were observed during the trials on the different crops.	No study is available for bees or for other non-target arthropods, therefore the magnitude of the risk cannot be assessed. However, it is noted that risk mitigation measures are suggested for bees. See also comment 8.3(6), below.
6)	Basic substance application model 8.3	EFSA: It is noted that risk mitigation (do not use talc when bees actively foraging) is recommended.		It is noted that risk mitigation measures are suggested for bees. See also comment 3.3(1).
7)	Basic substance application model 8.3	EFSA: Even if the proposed risk mitigation (see above) is applied, high exposure, therefore high risk for non-target arthropods (other than honey bees) cannot be excluded. Therefore a risk assessment should be provided. Effect data on bees available (as suggested by the text in 8.3) might be used for this assessment.	See above.	See EFSA conclusion in comment 8.3(5), above.
8)		DE: No information has been provided by the applicant with regard to effects on bees and other arthropods. It has not been reasoned that the substance is harmless for bees and other arthropods.	See above.	See EFSA conclusion in comment 8.3(5), above.

8.4. Effects on earthworms and other soil macro-organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9)	Basic substance application model 8.4	EFSA: A study from the open literature was made available that indicates no considerable effects of Al_2O_3, which is not talc, but present in the 'technical substance'. Considering the very high doses, a kind of risk assessment for talk is necessary. For this, PECsoil might be calculated.	Literature reference given by error. See general comments in cover letter.	No information is available for soil macroorganisms, therefore the magnitude of the risk cannot be assessed. Note: A PEC in soil of 233 mg/kg has been calculated by EFSA (see column 4 entry in section 7), indicating that there will be significant exposure.

8.5. Effects on soil micro-organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
10)	Basic substance application model 8.5	EFSA: Only an abstract from the open literature was made available on the effects of nano Al_2O_3 and SiO_2 (and other chemicals) on yeast. This publication might be submitted and analysed whether the results can be extrapolated to talc. An analysis regarding the potential effects (or lack of effects) of talc to soil micro-organisms is also necessary.	Literature reference given by error. See general comments in cover letter.	No specific study is available for soil microorganisms, therefore the magnitude of the risk cannot be assessed. Note: A PEC in soil of 233 mg/kg has been calculated by EFSA (see column 4 entry in section 7), indicating that there will be significant exposure.

8.6. Effects on other non target organisms (flora and fauna)				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
11)	Basic substance application model 8.6	EFSA: No information was provided. General conclusions from the awaited assessments to be submitted for chapters 8.1-8.5 (see above) might be used.		No information or assessment was made available on other non-target flora and fauna.

8.7. Effects on biological methods of sewage treatment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
12)	Basic substance application model 8.7	EFSA: No information was provided. The exposure of sewage treatment plants to talc might be considered to be limited for the representative uses.	Considering that Trimouns Talc grades are used in water depollution treatment stations, the presence of Invelop/Invelop F in the sewage treatment plant will be beneficial.	No appropriate information is available. However, the exposure of sewage treatment plants to talc might be considered to be limited for the intended uses.

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

Other comments				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)	Toxicology	FR: An occupational exposure limit value (VLEP) exists. If indoor uses are intended, a reference to this VLEP has to be made.	No indoor uses are intended.	No indoor uses are intended. See also EFSA conclusion in comment 5.1(3).

10. Other comments

Other comments				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

ABBREVIATIONS

µg	microgram
µm	micrometer (micron)
a.s.	active substance
DG SANCO	European Commission Directorate General Health and Consumers
EPA	Environmental Protection Agency (USA)
EU	European Union
g	gram
IARC	International Agency for Research on Cancer
ISO	International Organisation for Standardisation
kg	kilogram
L	litre
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
mg	milligram
mL	millilitre
mm	millimetre
MSDS	material safety data sheet
NTP	National Toxicology Programme (USA)
PEC	predicted environmental concentration
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PPP	plant protection product
REACH	Registration, Evaluation, Authorisation of CHemicals
SEM-EDX	Scanning Electron Microscopy – Energy Dispersive Spectrometry
VLEP	valeur limite d'exposition professionnelle (occupational exposure limit)