



COMMISSION STAFF WORKING DOCUMENT¹

Basic Substance

Salix cortex

SANCO/12173/2014– rev. 4

29 May 2015

Final

Review report for the basic substance *Salix* spp cortex finalised in the Standing Committee on Plants, Animals Food and Feed at its meeting on 29 May 2015
in view of the approval of *Salix* spp cortex as basic substance in accordance with Regulation (EC) No 1107/2009

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of *Salix* spp cortex, 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 26 April 2013 an application from ITAB (Institut Technique de l'Agriculture Biologique), hereafter referred to as the applicant, for the approval of the substance *Salix alba* bark 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 February 2014.

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 *Salix alba* bark on 3 June 2014³.

¹ Does not necessarily represent the views of the 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 *Salix alba* bark and the conclusions drawn by EFSA on the specific points raised. 2014:EN-609. 34pp.

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 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 on 29 May 2015.

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) 2015/1107**⁴ concerning the approval of *Salix* spp cortex 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 178/2002⁵, in particular with respect to the responsibility of operators, following the approval of *Salix* spp cortex 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 the 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.

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 *Salix alba* bark fulfils the criteria of Article 23.

Salix alba is a species of willow native to Europe and western and central Asia.

⁴ OJ L 181, 9.7.2015, p. 72–74.

⁵ 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.

The use of *Salix* cortex is recognised both as well-established and as traditional use in several EU countries and has been in medicinal use for a period of at least 30 years as requested by Directive 2001/83/EC⁶ regarding traditional herbal medicinal products. A conclusion⁷ from EMA on the assessment of *Salix* cortex (willow bark) as herbal medicine is available. It was therefore considered appropriate to extend the scope of the application from *Salix alba* bark to *Salix* spp cortex.

When used for plant protection, *Salix* spp cortex is produced from an infusion in water of dried aerial part of *Salix*.

The rate of application and the conditions of use which are described in detail in Appendices I and II, would not lead to concerns for human health. Furthermore, no residues are expected and the conditions of use would not significantly increase the background level due to natural occurrence of the plant.

Hence, considering the use in plant protection and the level of exposure deriving from such use, it can be concluded that the information provided is sufficient to consider *Salix* spp cortex as basic substance.

Salix spp cortex is not considered to be a substance of concern according to Regulation (EC) No 1107/2009 as its constituents which might raise concern will not present more than 0.1 % w/w in the dilution applied on the field. *Salix* spp cortex does not have an inherent capacity to cause endocrine disrupting (according to the interim criteria in Regulation 1107/2009), 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 *Salix* spp cortex are given in Appendix I.

Specifications laid down in the European Pharmacopeia must be complied with.

⁶ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

⁷ Assessment report on Salicilis cortex (willow bark) and herbal preparation(s) thereof with well-established use and traditional use; EMEA/HMPC/295337/2007.

5. Particular conditions to be taken into account in relation to the uses as basic substance of *Salix* spp cortex.

Salix spp cortex 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 being fungicide having an eliciting action on the crop's self-defence mechanisms are approved;
- Use of bark and extraction carried out with water via infusion in compliance with conditions specified and dilution explained in Appendices I and II.

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

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 the Plants, Animals, Food and Feed, in connection, as appropriate, with any amendment of the approval conditions for *Salix* spp cortex in Part C of Annex of the Regulation (EC) No 540/2011⁸.

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 not be placed on the market as a plant protection product and 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 the 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.

⁸ OJ L 153, 11.6.2011, p. 1-186.

APPENDIX I
Identity and biological properties
SALIX SPP CORTEX

Common name (ISO)	Not relevant
Chemical name (IUPAC)	Not relevant
Chemical Name. (CA)	Not relevant
Botanical classification	<i>Salix</i> L.
Part used	bark
CAS No	Not relevant
CIPAC No and EEC No	Not relevant
FAO SPECIFICATION	Not relevant
Purity	European Pharmacopeia
Molecular formula	Not relevant
Molecular mass and structural formula	Not relevant
Mode of Use	bark of <i>Salix</i> is used to prepare a water infusion.
Preparation to be used	<p>30 L of natural or rain water is brought to simmering in a stainless steel tank with cover, at 80°C infuse 200 g of <i>Salix</i> spp cortex for 2 hours.</p> <p>After cooling down, and filtration with a stainless steel sieve, adjust pH to 6.2 and proceed the dilution by 3 with water.</p> <p>Therefore, the theoretical concentration of <i>Salix</i> spp cortex present in the infusion is 6.67 g/L, which is then diluted by 3, hence 2.22 g/L in the final preparation applied on plants.</p> <p>The preparation so made has to be applied within maximum 24 hours, to avoid potential microbiological contamination which may occur during the storage.</p> <p>The solvent for extraction and preparation is water (spring water or rainwater) and the pH is 6.2.</p>
Function of plant protection	Fungicide.

APPENDIX II
List of uses supported by available data
SALIX SPP CORTEX

Crop and/or situation (a)	Example product name as available on the market	F G I (b)	Target (c)	Product		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*)
				Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season** (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	g a.i./ha min max (g/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
Fruit trees Peach-tree <i>Prunus persica</i>	Homogenate of <i>Salix</i> spp	F	Foliar fungi like <i>Taphrina deformans</i>	Dispersible concentrate (DC)	2.22	Foliar application spraying	From 1 st Shoots (BCH10) to cluster tightening (BBCH57) Spring	2 to 6	7 days	222.22	500 to 1000	1111.11 to 2222.22	2.22 to 13.33	None	Plant Homogenate extracted with hot water (infusion), filtered and diluted by 3, to be used up to a maximum of 24 h after preparation The product cannot be applied in case of hot temperature. It is used in case of rainy period;
Apple fruit <i>Malus pumila</i> , <i>Malus domestica</i>		F	Foliar fungi like scab disease <i>Venturia inaequalis</i> Powdery mildews: <i>Podosphaera leucotricha</i>				From green leaf tip (BBCH 53) to flowers fading (BBCH 67) Spring								
Grapevine <i>Vitis vinifera</i>		F	Downy mildews: <i>Plasmopara viticola</i> , Powdery mildews: <i>Erysiphe necator</i>				From 1 st shoots (BCH10) to cluster tightening (BBCH57) Spring to summer				100 to 300	222.2 to 666.67	0.44 to 4		

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- * For uses where the column „Remarks. As above or other conditions to take into account
- (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 sucking 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