



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food Chain
Chemicals, contaminants, pesticides

COMMISSION STAFF WORKING DOCUMENT¹

Basic Substance

Chitosan hydrochloride
SANCO/12388/2013– rev. 2
20 March 2014

Final

Review report for the basic substance *Chitosan Hydrochloride*
Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting
on 20 March 2014
in view of the approval of *Chitosan Hydrochloride* 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 *Chitosan Hydrochloride* 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 19 December 2011 an application from Chipro, hereafter referred to as the applicant, for the approval of the substance *Chitosan Hydrochloride* 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 August 2012.

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 EFSA, who delivered its views on the specific points raised in the commenting phase.

¹ Does not necessarily represent the views of the Commission.

² OJ L 309, 24.11.2009, p. 1-50.

APPENDIX I

Identity and biological properties

CHITOSAN HYDROCHLORIDE

Common name (ISO)	Not relevant
Chemical name (IUPAC)	Not relevant
Chemical Name. (CA)	Not relevant
Common names	Chitosan Linear polysaccharide composed of randomly distributed 1-4 linked D glucosamine and N-acetyl-D-glucosamine produced by de-acetylation of chitin. The use of hydrochloric acid to create the form hydrochloride is to increase solubility in water.
CAS No	9012-76-4
CIPAC No and EEC No	Not relevant
FAO SPECIFICATION	Not relevant
Minimum purity	European Pharmacopeia Chitosan being a product of animal origin must be in compliance with the requirements of Regulation (EC) No 1069/2009 and Commission Regulation (EU) No 142/2011.
Molecular formula	Not relevant
Relevant impurities	Max content of heavy metals: 40 ppm
Molecular mass and structural formula	Not relevant
Mode of Use	Chitosan hydrochloride as specified above to be used in water solution for application on various crops or for seed treatment.
Preparation to be used	Chitosan hydrochloride to be diluted in compliance with rate of application reported in Appendix II.
Function of plant protection	Elicitor, having a fungicide and bactericide effect via the stimulation of natural defence mechanisms.

APPENDIX II

CHITOSAN HYDROCHLORIDE

Crop and/ or situation (a)	Member State or Country	Example product of Chitosan hydrochloride, as available on the market	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application of chitosan hydrochloride				Application rate of chitosan hydrochloride			PHI (days) (m)	Remarks*
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growt h stage & seaso n (j)	No. of application min/max (k)	Interval between applications (min)	a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l)		
Fruits berries and small fruit	All	Chitoplant	F G	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	From 1 Leaf develo pment (main shoot) to 7 Devel opme nt of fruit	4-8	Two weeks	50 - 200	200 - 400	100-800	0	
Vegetables	All	ChitoPlant	F G	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	From 1 Leaf develo pment (main shoot) to 7 Devel opme nt of fruit	4-8	Two weeks	50 - 100	200 - 400	100-400	0	

List of uses supported by available data

Crop and/ or situation (a)	Member State or Country	Example product of Chitosan hydrochloride, as available on the market	F o r I (b)	Pests or group of pests controlled (c)	Formulation		Application of chitosan hydrochloride				Application rate of chitosan hydrochloride			PHI (days) (m)	Remarks*
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Cereals	All	ChitoPlant	F G	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	From 1 Leaf develo pment (main shoot) to 7 Devel opme nt of fruit	4 - 8	2 week	50 - 100	200 - 400	100-400	0	
Spices	All	ChitoPlant	F G	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	Low- Medium volume spraying	From 1 Leaf develo pment (main shoot) to 7 Devel opme nt of fruit	4 - 8	2 week	50 - 100	200 - 400	100-400	0	

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					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growt h stage & seaso n (j)	No. of application min/max (k)	Interval between applications (min)	a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l)		
<i>Crops for animal feed</i>	All	<i>ChitoPlant</i>	F G	<i>Plant elicitor, plant resistance against pathogenic fungi and bacteria</i>	<i>SP Soluble powder</i>	<i>100% chitosan hydrochloride</i>	Low- Medium volume spraying	From 1 Leaf develo pment (main shoot) to 7 Devel opme nt of fruit	4 - 8	2 week	50 - 100	200 - 400	100-400	0	
<i>Cereals Seed treatment</i>	All	<i>ChitoPlant</i>	F G	<i>Plant elicitor, plant resistance against pathogenic fungi and bacteria</i>	<i>SP Soluble powder</i>	<i>100% chitosan hydrochloride</i>	low volume spraying.	Before sowin g	1	Not applicable	50 - 100	Not applicable	Not applicable	0	
<i>Potatoes Seed treatment</i>	All	<i>ChitoPlant</i>	F G	<i>Plant elicitor, plant resistance against pathogenic fungi and bacteria</i>	<i>SP Soluble powder</i>	<i>100% chitosan hydrochloride</i>	low volume spraying/ dipping	Before sowin g	1	Not applicable	50 - 100	Not applicable	Not applicable	0	

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Crop and/ or situation (a)	Member State or Country	Example product of Chitosan hydrochloride, as available on the market	F o r I (b)	Pests or group of pests controlled (c)	Formulation		Application of chitosan hydrochloride				Application rate of chitosan hydrochloride			PHI (days) (m)	Remarks*
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growt h stage & seaso n (j)	No. of application min/max (k)	Interval between applications (min)	a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l)		
Sugar beet Seed treatment	All	ChitoPlant	F G	Plant elicitor, plant resistance against pathogenic fungi and bacteria	SP Soluble powder	100% chitosan hydrochloride	low volume spraying/ dipping	Before sowin g	1	Not applicable	50 - 200	Not applicable	Not applicable	0	

<p>* For uses where the column „Remarks. As above or other conditions to take into account</p> <p>(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)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..</p> <p>(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated</p>	<p>(i) g/kg or g/L. Normally the rate should be given for the substance (according to ISO)</p> <p>(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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