

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1446**of 3 September 2021****correcting Implementing Regulations (EU) No 540/2011 and (EU) No 563/2014 as regards the CAS number of the basic substance chitosan hydrochloride****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ⁽¹⁾, and in particular Article 23(5) in conjunction with Article 13(2) and Article 78(2) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 563/2014 ⁽²⁾ approved the basic substance chitosan hydrochloride and included it in the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾.
- (2) After Implementing Regulation (EU) No 563/2014 entered into force, an error was noted concerning the CAS number (Chemical Abstracts Number of the American Chemical Society) used for the basic substance chitosan hydrochloride in the Annexes to Implementing Regulation (EU) No 563/2014.
- (3) The CAS number is a unique chemical substance identifier, which is also used for identification of an active substance used in plant protection; it is used as reference for the purpose of trade and regulatory activities for chemicals globally and not limited to pesticidal substances.
- (4) The column on common name and identification numbers mentions 'Chitosan hydrochloride CAS no: 9012-76-4'. However, the CAS number 9012-76-4 is assigned to the substance chitosan, while chitosan hydrochloride has the CAS number 70694-72-3. Therefore, as confusion about the substance identity may arise in chemicals management and trade, a correction of the CAS number mentioned in Implementing Regulation (EU) No 563/2014 and consequently in Implementing Regulation (EU) No 540/2011 is necessary.
- (5) For reasons of clarity, it is appropriate to replace Annex I to Implementing Regulation (EU) No 563/2014 and the relevant entry in Part C of the Annex to Implementing Regulation (EU) No 540/2011.
- (6) In the interest of clarity and legal certainty for economic operators and enforcement authorities, this Regulation should enter into force as a matter of urgency.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 563/2014 of 23 May 2014 approving the basic substance chitosan hydrochloride in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 156, 24.5.2014, p. 5).

⁽³⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Correction to Implementing Regulation (EU) No 563/2014

Annex I to Implementing Regulation (EU) No 563/2014 is corrected in accordance with Annex I to this Regulation.

Article 2

Correction to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is corrected in accordance with Annex II to this Regulation.

Article 3

Entry into force

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 September 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annex I to Implementing Regulation (EU) No 563/2014 is replaced by the following:

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
Chitosan hydrochloride CAS No: 70694-72-3	Not applicable	European Pharmacopeia Max. content of heavy metals: 40 ppm	1 July 2014	Chitosan hydrochloride shall comply with Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽²⁾ and Commission Regulation (EU) No 142/2011 ⁽³⁾ . Chitosan hydrochloride may be used in accordance with specific conditions included in the conclusions of the review report on chitosan hydrochloride (SANCO/12388/2013) and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014.'

⁽¹⁾ Further details on identity, specification and manner of use of basic substance are provided in the review report.

⁽²⁾ OJ L 300, 14.11.2009, p. 1.

⁽³⁾ OJ L 54, 26.2.2011, p. 1.

ANNEX II

In Part C of the Annex to Implementing Regulation (EU) No 540/2011, entry 2 on chitosan hydrochloride is replaced by the following:

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
2	Chitosan hydrochloride CAS No: 70694-72-3	Not applicable	European Pharmacopeia Max. content of heavy metals: 40 ppm	1 July 2014	Chitosan hydrochloride shall comply with Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011. Chitosan hydrochloride may be used in accordance with specific conditions included in the conclusions of the review report on chitosan hydrochloride (SANCO/12388/2013) and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014.

⁽¹⁾ Further details on identity, specification and manner of use of basic substance are provided in the review report.