EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10590/2021 Rev. 0
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ANNEXES 1 to 2

ANNEXES

to the

COMMISSION IMPLEMENTING REGULATION (EU) .../...

renewing the approval of the active substance cypermethrin as a candidate for substitution 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 the Annex to Commission Implementing Regulation (EU) No 540/2011

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity[1]	Date of approval	Expiration of approval	Specific provisions
Cypermethrin CAS No 52315-07-8 CIPAC No 332	(RS)-α-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR) -3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or (RS)-α-cyano-3-phenoxybenzyl-(1RS)-cis-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	920 g/kg cis:trans : 40/60 to 60/40 The following impurities are of toxicological concern and must not exceed the following levels in the technical material: hexane : 5g/kg	*1 February 2022*	*31 January 2029*	Authorisations shall be limited to professional users. When authorising plant protection products containing cypermethrin for spray applications outdoors, in order to ensure the protection of non-target organisms, in particular aquatic organisms and non-target arthropods, including bees: • risk mitigation measures achieving reduction of drift shall be required that lead to exposure ≤5.8 mg as.s/ha in off-crop areas and, in addition, for spring applications to concentrations in water bodies ≤ 0.0038 µg a.s./L, • only uses outside flowering of the crop and when no flowering weeds are present may be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on cypermethrin, and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to: - the protection of aquatic organisms, non-target arthropods, including bees; - the consumer risk assessment; - the technical specification of the active substance used in plant protection products. Where considered appropriate, Member States shall set monitoring requirements when granting authorisations in accordance with Article 6(i) of the Regulation (EC) No 1107/2009, in order to complement the monitoring under Directive 2000/60/EC and Directive 2009/128/EC. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the toxicological profile of the metabolites bearing the 3-phenoxybenzoyl moiety;

[1] Further details on the identity and the specification of the active substance are provided in the renewal report.

Common Name, Identification Numbers	IUPAC Name	Purity[1]	Date of approval	Expiration of approval	Specific provisions
					2. the relative toxicity of individual cypermethrin isomers, in particular the enantiomer (1S cis αR); 3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water. 4. Points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605. The applicant shall submit: - the information referred to in point 1 by [*publication office, please insert date corresponding to 1 year from the date of entry into force of this Regulation*]; - the information referred to in point 2 by [*publication office, insert date corresponding to 2 years from the date of entry into force of this Regulation*]; and - the information referred to in point 3 within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. As regards Points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605 an updated assessment of the information already submitted and, where relevant, further information to confirm the absence of endocrine activity shall be submitted by [*publication office, insert date corresponding to two years from the date of entry into force of this Regulation*]

ANNEX II

The Annex to Commission Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 103 on cypermethrin is deleted;

(2) in Part E, the following entry is added:

No.	Common Name, Identification Numbers	IUPAC Name	Purity[1]	Date of approval	Expiration of approval	Specific provisions
'XX	Cypermethrin CAS No 52315-07-8 CIPAC No 332	(RS)-α-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR) -3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or (RS)-α-cyano-3-phenoxybenzyl-(1RS)-cis-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	920 g/kg cis:trans : 40/60 to 60/40 The following impurities are of toxicological concern and must not exceed the following levels in the technical material: hexane : 5g/kg	*1 February 2022*	*31 January 2029*	Authorisations shall be limited to professional users. When authorising plant protection products containing cypermethrin for spray applications outdoors, in order to ensure the protection of non-target organisms, in particular aquatic organisms and non-target arthropods, including bees: • risk mitigation measures achieving reduction of drift shall be required that lead to exposure ≤5.8 mg as.s/ha in off-crop areas and, in addition, for spring applications to concentrations in water bodies ≤ 0.0038 µg a.s./L, • only uses outside flowering of the crop and when no flowering weeds are present may be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on cypermethrin, and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to: - the protection of aquatic organisms, non-target arthropods, including bees; - consumer risk assessment; - the technical specification of the active substance used in plant protection products. Where considered appropriate, Member States shall set monitoring requirements when granting authorisations in accordance with Article 6(i) of the Regulation (EC) No 1107/2009, in order to complement the monitoring under Directive 2000/60/EC and Directive 2009/128/EC.

[1] Further details on the identity and the specification of the active substance are provided in the renewal report.

No.	Common Name, Identification Numbers	IUPAC Name	Purity[1]	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the toxicological profile of the metabolites bearing the 3-phenoxybenzoyl moiety; 2. the relative toxicity of individual cypermethrin isomers, in particular the enantiomer (1S cis αR); 3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water. 4. Points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605 The applicant shall submit: - the information referred to in point 1 by [*publication office, please insert date corresponding to 1 year from the date of entry into force of this Regulation*]; - the information referred to in point 2 by [*publication office, insert date corresponding to 2 years from the date of entry into force of this Regulation*]; and - the information referred to in point 3 within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. As regards Points 3.6.5 and 3.8.2 of Annex II toRegulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605 an updated assessment of the information already submitted and, where relevant, further information to confirm the absence of endocrine activity shall be submitted by [*publication office, insert date corresponding to two years from the date of entry into force of this Regulation*]'