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SANTE/11298/2021 Rev. 0
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ANNEXES 1 to 2

ANNEXES

to the

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

renewing the approval of the active substance bifenazate 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
Bifenazate 149877-41-8 736	isopropyl 2-(4-methoxybiphenyl-3-yl)hydrazinoformate	980 g/kg Toluene is of toxicological concern and must not exceed 0.7 g/kg in the technical material.	1 July 2022	30 June July 2037	<p>Only uses on non-edible crops in permanent greenhouses shall be authorised.</p> <p>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 bifenazate, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> - the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment; - the risk to bees and bumble bees released for pollination in permanent greenhouses. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit by [<i>publication office, insert date corresponding to two years from the date of entry into force of this Regulation</i>] to the Commission, the Member States and the Authority confirmatory information 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, in particular an updated assessment of the information submitted previously and, where relevant, further information to confirm the absence of endocrine activity.</p>

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

ANNEX II

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

(1) in Part A, entry 109 on bifenazate is deleted;

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

No.	Common Name, Identification Numbers	IUPAC Name	Purity ¹	Date of approval	Expiration of approval	Specific provisions
“XX	Bifenazate 149877-41-8 736	isopropyl 2-(4-methoxybiphenyl-3-yl)hydrazinoforate	980 g/kg Toluene is of toxicological concern and must not exceed 0.7 g/kg in the technical material.	1 July 2022	30 June 2037	<p>Only uses on non-edible crops in permanent greenhouses shall be authorised.</p> <p>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 bifenazate, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> - the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment; - the risk to bees and bumble bees released for pollination in permanent greenhouses. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit by [<i>publication office, please insert date corresponding to two years from the date of entry into force of this Regulation</i>] to the Commission, the Member States and the Authority confirmatory information 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, in particular an updated assessment of the information submitted previously and, where relevant, further information to confirm the absence of endocrine activity.”</p>

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

