

Brussels, XXX SANTE/11271/2018 [...](2018) XXX draft

ANNEXES 1 to 2

ANNEXES

to the

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

renewing the approval of the active substance tolclofos-methyl 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

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ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ¹	Date of approval	Expiration of approval	Specific provisions
Tolclofos-methyl CAS No 57018-04-9 CIPAC No 479	O-2,6-dichloro-p-tolylO,O-dimethyl phosphorothioate O-2,6-dichloro-4-methylphenyl O,O-dimethyl phosphorothioate	≥ 960 g/kg The following impurity is of toxicological concern and must not exceed the following level in the technical material:	1 August 2019	31 July 2034	Only for use on ornamentals and on potatoes. 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 tolclofos-methyl, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: - the risk to aquatic organisms and mammals;
		Methanol max. 1 g/kg			 the risk to consumers, in particular the potential risk from metabolite DM-TM-CH₂OH in potatoes; the risk to operators, workers and bystanders. Conditions of use shall include risk mitigation measures, where appropriate.

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

ANNEX II

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

- (1) in Part A, entry 126 on tolclofos-methyl is deleted;
- (2) in Part B, the following entry is added:

No.	Common Name, Identification Numbers	IUPAC Name	Purity ²	Date of approval	Expiration of approval	Specific provisions
"XXX	Tolclofos-methyl CAS No 57018-04-9 CIPAC No 479	O-2,6-dichloro-p-tolylO,O-dimethyl phosphorothioate O-2,6-dichloro-4-methylphenyl O,O-dimethyl phosphorothioate	≥ 960 g/kg The following impurity is of toxicological concern and must not exceed the following level in the technical material:	1 August 2019	31 July 2034	Only for use on ornamentals and on potatoes. 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 tolclofos-methyl, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: - the risk to aquatic organisms and mammals;
		N	Methanol max. 1 g/kg			 the risk to consumers, in particular the potential risk from metabolite DM-TM-CH₂OH in potatoes; the risk to operators to operators, workers and bystanders; Conditions of use shall include risk mitigation measures, where appropriate."

² Further details on identity and specification of active substance are provided in the review report.