

**COMMISSION IMPLEMENTING REGULATION (EU) 2018/1915****of 6 December 2018****approving the active substance *Metschnikowia fructicola* strain NRRL Y-27328 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****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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 <sup>(1)</sup>, and in particular Article 13(2) thereof,

Whereas:

- (1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 Koppert B.V. submitted to France on 30 September 2014 an application for the approval of the active substance *Metschnikowia fructicola* strain NRRL Y-27328.
- (2) In accordance with Article 9(3) of that Regulation, France, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 3 June 2015 of the admissibility of the application.
- (3) On 17 October 2016, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of that Regulation, it requested on 20 March 2017 that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report on 12 September 2017.
- (5) On 24 November 2017 the Authority communicated to the applicant, the Member States and the Commission its conclusion <sup>(2)</sup> on whether the active substance *Metschnikowia fructicola* strain NRRL Y-27328 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.
- (6) On 20 July 2018, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for *Metschnikowia fructicola* strain NRRL Y-27328 and a draft Regulation providing that *Metschnikowia fructicola* strain NRRL Y-27328 is approved.
- (7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (8) It is therefore appropriate to approve *Metschnikowia fructicola* strain NRRL Y-27328.
- (9) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance *Metschnikowia fructicola* NRRL Y-27328 EFSA Journal 2017;15(12):5084, 19 pp. doi:10.2903/j.efsa.2017.5084.

- (10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(1)</sup> should be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Approval of active substance**

The active substance *Metschnikowia fructicola* strain NRRL Y-27328, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

*Article 2*

**Amendments to Implementing Regulation (EU) No 540/2011**

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

*Article 3*

**Entry into force**

This Regulation shall enter into force on the twentieth day following that 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, 6 December 2018.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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<sup>(1)</sup> 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).

## ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
<p><i>Metschnikowia fructicola</i> strain NRRL Y-27328</p> <p>Accession number in the Agriculture Research Service Culture Collection at the National center for agricultural utilisation research in Peoria, Illinois USA</p>	Not applicable	<p>Minimum concentration:</p> <p><math>1 \times 10^{10}</math> CFU/g</p>	27 December 2018	27 December 2028	<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 review report on <i>Metschnikowia fructicola</i> strain NRRL Y-27328, 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"> <li>— the protection of operators and workers, taking into account that <i>Metschnikowia fructicola</i> strain NRRL Y-27328 is to be considered as a potential sensitizer.</li> </ul> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be ensured by the producer.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

<sup>(1)</sup> Further details on identity and specification of active substance are provided in the review report.

## ANNEX II

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
'129	<i>Metschnikowia fructicola</i> strain NRRL Y-27328 Accession number in the Agriculture Research Service Culture Collection at the National center for agricultural utilisation research in Peoria, Illinois USA	Not applicable	Minimum concentration: $1 \times 10^{10}$ CFU/g	27 December 2018	27 December 2028	<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 review report on <i>Metschnikowia fructicola</i> strain NRRL Y-27328, 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"> <li>— the protection of operators and workers, taking into account that <i>Metschnikowia fructicola</i> strain NRRL Y-27328 is to be considered as a potential sensitizer.</li> </ul> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be ensured by the producer.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.'</p>

<sup>(1)</sup> Further details on identity and specification of active substance are provided in the review report.