# Commission Implementing Regulation (EU) 2017/1382 of 25 July 2017 renewing the approval of difethialone as an active substance for use in biocidal products of product-type 14 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1382

of 25 July 2017

renewing the approval of difethialone as an active substance for use in biocidal products of product-type 14

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[(1)], and in particular Article 14(4)(a) thereof,

Whereas:

(1) The active substance difethialone is approved for use in biocidal products of product-type 14 as a rodenticide under Regulation (EU) No 528/2012.

(2) In accordance with Article 13(1) of Regulation (EU) No 528/2012, an application was submitted to the European Chemicals Agency ('the Agency') for the renewal of the approval of that active substance. This application was evaluated by the competent authority of Norway as the evaluating competent authority.

(3) On 21 March 2016, the evaluating competent authority submitted its recommendation on the renewal of the approval of difethialone to the Agency.

(4) On 16 June 2016, the opinion of the Agency was formulated by its Biocidal Products Committee[(2)], having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, difethialone meets the criteria in Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(3)] to be classified as toxic for reproduction category 1B. The substance also meets the criteria in Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(4)] for being very persistent, bioaccumulative and toxic. Difethialone therefore meets the exclusion criteria set in points (c) and (e) of Article 5(1) of Regulation (EU) No 528/2012.

(6) In addition, the use of products containing difethialone raises concerns in relation to instances of primary and secondary poisoning, even where restrictive risk management measures are applied and therefore difethialone also satisfies the criterion to be a candidate for substitution in accordance with Article 10(1)(e) of Regulation (EU) No 528/2012.

(7) Pursuant to Article 12 of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed when at least one of the conditions for derogation set out in Article 5(2) of that Regulation continues to be satisfied.

(8) In accordance with Article 10(3) of Regulation (EU) No 528/2012, the Agency organised a public consultation in order to collect relevant information on difethialone, including information on available substitutes.

(9) The Commission also carried out a specific public consultation in order to gather information as to whether the conditions for derogation set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied. The Commission made the contributions to that consultation publicly available.

(10) The contributions to the two above-mentioned public consultations, as well as the information regarding the availability of alternatives to anticoagulant rodenticides included in Annex 1 to the Commission report on risk mitigation measures for anticoagulant rodenticides[(5)], were discussed with Member States in the Standing Committee on Biocidal Products.

(11) Rodents can carry pathogens that are responsible for many zoonoses, which can pose serious dangers for human or animal health. Non-chemical controls or prevention methods for rodent control, such as mechanical, electrical or glue traps, may not be sufficiently efficient and may raise further questions as to whether they are humane or whether they cause unnecessary suffering to rodents. Alternative active substances approved for use as rodenticides may not be suitable for all user categories or efficient for all rodent species. As effective rodent control cannot rely on those non-chemical controls or prevention methods only, difethialone is considered essential to ensure appropriate rodent control in support of those alternatives. As a consequence the use of difethialone would be to prevent or control a serious danger to human and animal health in which rodents are involved. Therefore, the condition set out in Article 5(2)(b) of Regulation (EU) No 528/2012 is satisfied.

(12) Rodent control currently relies largely on the use of anticoagulant rodenticides, the non-approval of which could lead to insufficient rodent control. This may not only cause significant negative impacts on human or animal health or the environment, but also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences. On the other hand, the risks to human health, animal health or the environment arising from use of products containing difethialone can be mitigated if they are used according to certain specifications and conditions. Therefore, the non-approval of difethialone as an active substance would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance. The condition set out in Article 5(2)(c) of Regulation (EU) No 528/2012 is thus also satisfied.

(13) It is therefore appropriate to renew the approval of difethialone for use in biocidal products of product-type 14, subject to compliance with certain specifications and conditions.

(14) Difethialone is a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012 and therefore the period of renewal set out in Article 10(4) of that Regulation should apply.

(15) As the examination of the applications for the renewal of the approval of difethialone and difenacoum for use in biocidal products of product-type 14 is now finalised, Commission Implementing Decision 2014/397/EU[(6)] is repealed by Implementing Regulation (EU) 2017/1379[(7)].

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

*Article 1*

The approval of difethialone as an active substance for use in biocidal products of product-type 14 is renewed, subject to the specifications and conditions set out in the Annex.

*Article 2*

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, 25 July 2017.

*For the Commission*

*The President*

Jean-Claude JUNCKER

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/1382. (See end of Document for details)*

ANNEX

| Common Name | IUPAC NameIdentification Numbers | Minimum degree of purity of the active substance[a] | Expiry date of approval | Product type | Specific conditions |
|---|---|---|---|---|---|
| Difethialone | IUPAC Name: 3-[3-(4′-bromo[1,1′biphenyl]-4-yl)-1,2,3,4-tetrahydronaphthalen-1-yl]-4-hydroxy-2H-1-benzothiopyran-2-one<br>EC No: Not available<br>CAS No: 104653-34-1 | 976 g/kg<br>The specification of purity is based on the combined concentration of both diastereoisomers (cis and trans). | 30 June 2024 | 14 | Difethialone is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012.<br>The authorisations of biocidal products are subject to the following general conditions:<br>1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an |

**a** The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

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|---|---|---|---|---|---|
| | | | | | application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can |

**a** The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.