EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving (13Z)-Hexadec-13-en-11-yn-1-yl acetate as an active substance for use in biocidal products of product-type 19 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

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(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 9(1), point (a), thereof,

Whereas:

(1) On 13 March 2018, the European Chemicals Agency ('the Agency') received an application, in accordance with Article 7(1) of Regulation (EU) No 528/2012, for the approval of (13Z)-Hexadec-13-en-11-yn-1-yl acetate as an active substance for use in biocidal products of product-type 19, repellents and attractants, as described in Annex V to that Regulation. The application was evaluated by the competent authority of France ('the evaluating competent authority').

(2) On 1 June 2021, the evaluating competent authority submitted the assessment report together with the conclusions of its evaluation to the Agency. The Agency discussed the assessment report and the conclusions of the evaluating competent authority in technical meetings.

(3) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 8(4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of the Agency[2] on 8 March 2022, having regard to the conclusions of the evaluating competent authority.

(4) In that opinion the Agency concludes that biocidal products of product-type 19 containing (13Z)-Hexadec-13-en-11-yn-1-yl acetate may be expected to satisfy the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, provided that certain conditions concerning their use are complied with.

(5) In its opinion the Agency recommends that (13Z)-Hexadec-13-en-11-yn-1-yl acetate be approved subject to the conditions that only biocidal products consisting of a passive non-retrievable dispenser (for example a wax emulsion inserted into a ball) to be applied using a compressed air gun may be authorised, and that biocidal products

[1] OJ L 167, 27.6.2012, p. 1.

[2] Biocidal Products Committee Opinion on the application for approval of the active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate; Product-type: 19; ECHA/BPC/323/2022, adopted on 8 March 2022.

may only be authorised for professional use, as the representative biocidal product and category of user submitted in the application for approval of the active substance ('the conditions proposed by the Agency'). The Agency proposed to impose those conditions as a consequence of the acceptance of the adaptations in the data submitted for the approval of the active substance by the evaluating competent authority, in accordance with Annex IV to Regulation (EU) No 528/2012. The evaluating competent authority accepted the adaptations because (13Z)-Hexadec-13-en-11-yn-1-yl acetate is a pheromone, which is a class of substances generally recognised as being of low concern to human and animal health and the environment, and because of the very low exposure of humans and the environment to the active substance due to use of the representative biocidal product.

(6) However, restrictive conditions for the making available on the market or the use of biocidal products containing an active substance are usually established in the approval of an active substance when risks are identified during the examination of approval of the active substance and no other suitable risk mitigation measures can be identified on a specific use. No risks to human health, animal health or the environment have been identified by the Agency in its opinion which would necessitate the conditions proposed by the Agency. The approval of an active substance is also usually not restricted only to the representative product and user category presented in the application for approval. Moreover, the imposition of the conditions proposed by the Agency would limit innovation in the development of products containing a pheromone, which is a class of substances generally recognised as being of low concern to human and animal health and the environment.

(7) The Commission therefore considers it not necessary to include the conditions proposed by the Agency in this Regulation. However, in order to emphasise the possible need for additional data on the active substance to demonstrate the safety for human health, animal health or the environment of other uses or category of users in the case of an application for authorisation of products other than the representative product, it is appropriate to lay down that the product assessment needs to pay particular attention to the exposures, the risks and the efficacy linked to any of the uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance, and that, for uses leading to higher exposure of the users, bystanders or the environment compared to the Union level risk assessment of the active substance, applications for product authorisation need to contain all data required for active substances in accordance with Annex II to Regulation (EU) No 528/2012, subject to the possibilities of adaptation of the data requirements in accordance with Annex IV to that Regulation.

(8) Taking into account the opinion of the Agency, it is appropriate to approve (13Z)-Hexadec-13-en-11-yn-1-yl acetate as an active substance for use in biocidal products of product-type 19 subject to compliance with certain conditions.

(9) 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

(13Z)-Hexadec-13-en-11-yn-1-yl acetate is approved as an active substance for use in biocidal products of product-type 19 subject to the 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,

For the Commission
The President
Ursula VON DER LEYEN