Biocidal Products Committee (BPC)

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

8 March 2022

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate for product type 19

In accordance with Article 8(4) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 19 of the following active substance:

Common name:	**(13Z)-Hexadec-13-en-11-yn-1-yl acetate**
Chemical name:	**(13Z)-Hexadec-13-en-11-yn-1-yl acetate**
EC No.:	**Not allocated**
CAS No.:	**78617-58-0**

New active substance submitted under Article 8(4) of the BPR

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of the BPC opinion

Following the submission of an application by M2i on 13 March 2018 the evaluating Competent Authority France submitted an assessment report and the conclusions of its evaluation to the ECHA on 1 June 2021. To review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-42) and its Working Groups (WG-IV-2021). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the application for approval of the active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate in product type 19 was adopted on 8 March 2022.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that (13Z)-Hexadec-13-en-11-yn-1-yl acetate in product type 19 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

The new active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate is a pheromone used as an attractant (product type (PT) 19), as an alternative method to control the insect *Thaumetopoea pityocampa*, by mating disruption.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Analytical methods for the determination of active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate and its impurities are available and considered as validated. However, no analytical method for the determination of the stabilizer in the technical active substance and in the product is available. The analytical method is requested as post approval data in section 2.5 of this opinion.

No analytical methods were provided for the relevant matrices: food of plant origin, foodstuffs of animal origin, soil, water, air, animal and human body fluids and tissus because the environmental exposure is shown to be very low when the product is used as a biocide and the active substance is not classified toxic or very toxic.

No harmonised classification is available for (13Z)-Hexadec-13-en-11-yn-1-yl acetate.

The proposed classification and labelling for (13Z)-Hexadec-13-en-11-yn-1-yl acetate according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed Classification according to the CLP Regulation	
Hazard Class and Category Codes	Aquatic acute 1, H400 Aquatic chronic 1, H410
Labelling	
Pictogram codes	GHS09
Signal Word	Warning
Hazard Statement Codes	H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 10 for acute toxicity to aquatic life M = 10 for chronic toxicity to aquatic life
Justification for the proposal	
The worst case acute endpoint is derived from the algal study: E_rC50 = 4.50E-02 mg./L. As this endpoint is between 0.01 < E_rC50 ≤ 0.1 mg/L, the pheromone is classified Acute 1 (H400) with a M factor of 10. As only acute data are available for the classification of the active substance, the chronic classification is calculated with the E_rC50 and the M-factor derived for acute aquatic hazard classification is also applied to the long-term aquatic hazard classification. Therefore, the pheromone is classified Chronic 1 (H410) with a M factor of 10.	

b) Intended use, target species and effectiveness

The product containing 4.33% (w/w) of the active substance is applied by professionals as an attractant for the control of the pine processionary moth (*Thaumetopoea pityocampa)* by mating disruption: the product application introduces in the air a large amount of synthetic pheromone specific to the *Thaumetopoea pityocampa* during the flight period. This cloud of pheromone reduces the chances of encounter between males and females, thus limiting the mating and, therefore, the number of spits. The method is called the sexual confusion method.

The pine processionary caterpillars are controlled to avoid the contact of humans and pets with their bristles which provoke harmful reactions (inflammatory skin reactions and serious allergic reactions of the respiratory mucosa).

The active substance (13Z)-Hexadec-13-en-11-yn-1 acetate is encapsulated into natural waxes/oils leading to a gel which is itself introduced into a biodegradable polymer shell to form the final balls corresponding to the formulated product Pine T Pro Ball. The product is applied seasonally to the top of the pine trees (generally about 5 -10 meters from the ground) by professionals (trained employees with the required agreement for biocontrol product application) via a compressed air gun (similar to a paintball gun). Under the impact, the balls burst on the trunk of the trees to form a film which dries in few hours, from which the active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate diffuses continuously and passively (the ball is considered as a 2A Passive non-retrievable dispenser as defined in the "Guidance document on semiochemical active substances and plant protection products, 2016"[1]).

Field tests were conducted with the product to show the efficacy of the mating disruption treatment with the sexual confusion method against pine processionary moth (*Thaumetopoea pityocampa)*. It is recommended to apply the balls to the trees if no rainfall is expected for at least 12 hours after application, as the formulation has to dry to become a hydrophobic film.

Reduction of pine processionary caterpillars and nests in pine areas is demonstrated in forest and urban areas, at the following application rates:

- in forests at the dose of 400 balls /ha;
- in urban areas (groves, narrow band of trees, isolated trees): 1 ball per 1 m of height and per tree.

Innate efficacy is therefore demonstrated for the active substance approval.

The development of resistancy to the active substance is unlikely based on the mode of action of the active substance as a specific signalling chemical to the insect organism mating behaviour.

c) Overall conclusion of the evaluation including need for risk management measures

The active substance is a pheromone, a natural substance generally assumed to dissipate rapidly in the environment, primarily by volatilization and degradation. This is partly

[1] Guidance document on semiochemical active substances and plant protection products. SANTE/12815/2014 rev. 5.2 – May 2016. This guidance has been used in the absence of specific guidance for biocides. However, it is scientifically equally applicable to assess the hazard even though the biocidal use may be different.

because persistence is counterproductive to a communication signal received by the olfactory system of the insects.

As other pheromones, (13Z)-Hexadec-13-en-11-yn-1-yl acetate has a non-toxic mode of action based on mating disruption of Lepidoptera which rely on olfactory cues to find the location of specific females to mate. The signals exchanged between males and females are very species-specific for an effective mating when adult processionnary search for mates at the top of pine trees. Consequently, the mode of action of (13Z)-Hexadec-13-en-11-yn-1-yl acetate is very species-specific and there are no indications for adverse effects on the endocrine systems of vertebrates.

Moreover, considering that the active substance is micro-encapsulated and then formulated to be introduced into biodegradable balls for application with a compressed air gun on pine trees, the exposure during and after application of the product can be considered as very low.

Consequently, as mentioned in the summary sections below, waiving of some core data has been applied for this specific substance due to its physico-chemical properties, its highly species-specific non-toxic mode of action and its very limited exposure considering humans and environment.

Human health

Considering the results of available studies performed at GLP laboratory, the active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate does not present any acute oral or dermal toxicity and does not have any irritating or sensitizing properties. Regarding the results obtained on genotoxic potential (tested in bacteria and mammalian cells), the active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate is not considered genotoxic.

According to the guidance for waiving of data requirements for Pheromones for inclusion in Annex I/IA of Directive 98/8/EC (based on the OECD Series on Pesticides (Number 12): Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control ENV/JM/MONO (2001)12), and since there is not a significant exposure potential and no tolerance/ Maximum Residue Levels are to be set, the repeated toxicity, carcinogenicity and reproductive toxicity studies with the active substance have been waived. The same applies for testing related to both endocrine disruption adversity and activity.

The active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate is not classified for human health hazards according to the CLP Regulation (EC) No 1272/2008.

Considering the intended use and the mode of application, exposure to humans is considered very low.

In the frame of this specific context, the existing data (*i.e,* acute toxicity, irritation, sensitisation and mutagenicity) have been considered sufficient to support the human health assessment.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure[2] and description of scenario**	**Exposed group**	**Conclusion**
Loading	Primary exposure: Balls loaded into the paintball gun	Professionals	Acceptable with RMMs
Post-application	Primary exposure: Collection of the balls fallen on the ground during application	Professionals	Acceptable with RMMs
Post-application	Secondary exposure of the general public: when visiting treated pine areas	General public	Acceptable with RMMs

The assessment of the risk for human health during the use of the product has been carried out for the active substance only (no substance of concern).

Considering the method of application of the product (outdoors, in the upper part of the pine canopy, using a compressed air gun), and when applying the following risk management measures the professional exposure is considered very low and the risk is acceptable:

- wear gloves during all phases of use (loading, application and collection of balls on the ground).

The risk for the general public is considered acceptable with the following risk mitigation measures:

- during the application, a safety perimeter (approximately 10 m) must be set to avoid the presence of the general public;
- after application in forests, inspect carefully the area and pick up all the fallen balls;
- after application in urban zone, make sure that no balls or debris are left on the ground;
- information to the general public should be given in the treated areas, before and after the application of the product.

The risk for the general public is then considered acceptable.

Dietary exposure is considered as not relevant since no contamination of food or feed is expected based on the localised application on the tree trunks.

Environment

The active substance, as other pheromones, is a non-stable substance that dissipates rapidly in the environment mainly by volatilization and fast air degradation.

(13Z)-Hexadec-13-en-11-yn-1-yl acetate has a highly species-specific mode of action on the target organism.

According to the guidance for waiving of data requirements for Pheromones for inclusion in Annex I/IA of Directive 98/8/EC (based on the OECD Series on Pesticides (Number 12): Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control ENV/JM/MONO (2001)12), and since there is not a significant exposure potential, most of the ecotoxicological core data have been waived.

[2] See document: Terminology primary and secondary exposure (available from https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/80f71044-fce2-43b3-a73c-e156effc9fcb/Terminology%20primary%20and%20secondary%20exposure.pdf)

Based on an acute toxicity on algae and a weight of evidence approach, it was demonstrated that the active substance has an aquatic ecotoxicity profile similar to the SCLPs (Straight Chain Lepidopteran Pheromones), therefore the active substance is classified for environment.

The active substance is not considered as an ED for non-target organisms, mainly based on its very specific and non-toxic mode of action relying on olfactory clue.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Emission in air and redeposition to soil	As the active substance is used in a passive diffuser, the main route of emission to the environment is by gaseous phase to the atmosphere. It has been considered that the active substance can also adsorb on air particles and may subsequently deposit on the ground (soil or surface water).	Acceptable

Acceptable risks are reached for the environment for the treatment of pine (urban or forest area) with a paintball application by professional user considering the very limited exposure linked to the specific use of the active substance.

To avoid leaching of the active substance, it is recommended to apply the product only if no rainfall is expected for at least 12 hours after application.

Overall conclusion

The use by professionals of the active substance (13Z)-Hexadec-13-en-11-yn-1-yl as an attractant for control of the insect *Thaumetopoea pityocampa*, by mating disruption does not result in unacceptable risks for the human health and the environment.

It has to be noted that the conclusion of this risk assessment applies only to the specific intended use and the mode of application of the active substance as presented above.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	No classification required	The active substance does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P and not vP	The active substance does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B and not vB	
	Toxic (T)	Not T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No	The active substance does not fulfil criterion (d) of Article 5(1) and/or criterion (e) of Article 10(1)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification required. The active substance does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	The active substance does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	The active substance does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

(13Z)-Hexadec-13-en-11-yn-1-yl acetate does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

(13Z)-Hexadec-13-en-11-yn-1-yl acetate does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012 and is therefore not considered as a candidate for substitution.

The exclusion and substitution criteria were assessed in line with the "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[3] and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment[4]" agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

The active substance does not meet the POP criteria as it does not have a potential for long-range transboundary atmospheric transport.

2.3. BPC opinion on the application for approval of the active substance (13Z)-Hexadec-13-en-11-yn-1-yl acetate in product type 19

In view of the conclusions of the evaluation, it is proposed that (13Z)-Hexadec-13-en-11-yn-1-yl acetate shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 970 g/kg dry weight.

2. The authorisations of biocidal products are subject to the following condition(s):

i. Only biocidal products consisting of a passive non-retrievable dispenser[5] (for example a wax emulsion inserted into a ball) using a compressed air gun shall be authorised. Biocidal products shall only be authorised for professional use.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012 as (13Z)-Hexadec-13-en-11-yn-1-yl acetate is proposed to be classified H410: Very toxic to aquatic life with long lasting effects.

2.4. Elements to be taken into account when authorising products

The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising

[3] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

[4] See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).

[5] According to the definition set in the guidance document on semiochemical active substances and plant protection products (SANTE/12815/2014 rev. 5.2 - May 2016) a passive non-retrievable product type 2A) corresponds to a dispenser (such as biodegradable dispensers) from which the pheromone diffuses continuously into the air where the active substance becomes diluted.

products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

a. Gloves have to be worn during all phases of use (loading, application and collection of balls on the ground).

b. During the application of the product, a safety perimeter (approximately 10 m) must be set to avoid the presence of the general public in the treated area.

c. After application of the product in forests, the operator shall inspect carefully the treated area and pick up all the fallen balls.

d. After application of the product in urban zone, the operator shall inspect carefully the treated area and check that no balls or debris are left on the ground.

e. Information to the general public should be given in the treated areas, before and after the application of the product.

f. For efficacy and to avoid exposure of the environment, the product should be used only if no rainfall is expected for at least 12 hours after application.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of (13Z)-Hexadec-13-en-11-yn-1-yl acetate in PT 19.

However, the following data should be provided to the evaluating Competent Authority France as soon as possible but no later than the date of approval of the active substance:

- an analytical method for the determination of the stabilizer in the technical active substance and in the product should be provided.

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