Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

Confidential Annex

MASSOCIDE AD04

Product type 18

Alpha-cypermethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-YY025228-97

Evaluating Competent Authority: SPAIN

Date: May 2024

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NB: This information is confidential and should not be disclosed to third parties

COMPOSITION

A. QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION OF THE BIOCIDAL PRODUCT

Trade Name / Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Alpha-cypermethrin	Reaction mass of (S)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2 dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2 imethylcyclopropanecarboxylate (1:1)	Active substance	67375-30-8	Not available*	0.4
Silicon Dioxide, Amorphous Synthetic	Silicon dioxide	Absorbent	112926-00-8	231-545-4	0.1
Benzoate denatonium	Benzyldiethyl [(2,6 xylylcarbamoyl) methyl] ammonium benzoate	deterrent	3734-33-6	223-095-2	0.001%
Calcium carbonate	Limestone	Carrier	1317-65-3	215-279-6	99.499
MASS BALANCE					**100.00**

* INDEX number: 607-422-00-X

B. QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION OF THE ACTIVE SUBSTANCES AND CO-FORMULANT CALCIUM CARBONATE

TRADE name	Common name / IUPAC name	Function	CAS number	EC number	Content in SDS (%)	Content in BP (%)
Calcium carbonate	Calcium carbonate (Limestone)	Carrier	1317-65-3	215-279-6	>99%	>98.5%
Quartz (SiO_2)	Quartz	*	14808-60-7	238-878-4	<0.1%	<0.1%

* Natural component of calcium carbonate.

INFORMATION ON THE SUBSTANCES OF CONCERN

Human health:

Silicon Dioxide Amorphous Synthetic (CAS no. 112926-00-8) is acting as co-formulant (absorvent) in MASSOCIDE AD04 biocidal product. This substance is approved as an active substance for PT18 according to the Regulation (EU) No 408/2014, with specific particle size distribution for characterisation of the active substance: 90% below 4.8 µm; 50% below 3 µm and 1% below 1.9 µm. The form of silica was assessed as the active substance synthetic amorphous silicon dioxide with the following characteristics: primary particle size < 25 nm (CAR Synthetic amorphous silicon dioxide, March 2014). MASSOCIDE AD04 biocidal product is presented as a dustable powder and according to the granulometry provided by the applicant, the average particle size (d50) of the Amorphous Silicon Dioxide used in this biocidal product is equal to 16.5 µm, which is above the approval of the active substance. Therefore, it cannot be considered as an active substance for MASSOCIDE AD04.

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IUPAC name or other accepted chemical name	Silicon Dioxide, Amorphous Synthetic
EC number	231-545-4
CAS number	112926-00-8
Concentration (g/kg or g/L)	1 g/kg
Classification and Labelling according to assessment report and CoRAP opinion: Index number:	H373: May cause damage to organs through prolonged or repeated exposure.
Relevant toxicological/ecotoxicological information	No other relevant toxicological information has been identified.
Other grounds for concern	-

Environment:

A substance of concern (SoC) is defined in Art 3(f) of Regulation (EU) No. 528/2012/EC or the Biocidal Product Regulation (BPR) as a classified co-formulant present in the biocidal product at a concentration above the respective specific or generic concentration limit of the Regulation (EC) No 1272/2008, thus leading to the classification of the biocidal product.

The product MASSOCIDE AD 0.4 contains the coformulant Silicon Dioxide. Synthetic amorphous silicon dioxide doesn't have an harmonised classification and labelling according to Reg. (EC) No 1272/2008. In the AR (FR, 2014) a classification for STOT RE 2 (inhalative route, H373) is proposed but no classification is warranted for dangers to the aquatic environment. Therefore synthetic amorphous silicon dioxide present in the product does not contribute to the C&L of the biocidal product based on its danger to the environment, nor does it meet the criteria for being a PBT or vPvB substance.

However, as Silicon Dioxide is an active substance from other product types contained in the product for which a draft final Competent Authority Report is available it should be considered as SoCs according to the Guidance on the BPR, Volume IV Environment – Assessment and Evaluation (Part B+C) as it is present in the biocidal product at a concentration ≥ 0.1%.

Therefore the risk assessment of the product MASSOCIDE AD 0.4 is based on the information provided in the Assessment Report of alpha-cypermethrin as included in the Assessment Reports of PT18 uses (final CAR of July 2014) and on the information provided in the Assessment Report of Synthetic amorphous silicon dioxide PT18 (March 2014) which is identified as a substance of concern.

ASSESSMENT OF THE ED PROPERTIES OF NON-ACTIVE SUBSTANCES (CO-FORMULANTS)

Since 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, endocrine disruption assessment of co-formulants is mandatory according to the article 19. According to our assessment, none of the co-formulants contained in the product MASSOCIDE AD04 are identified as endocrine disruptors. None of the co-formulants are currently being evaluated in the frame of REACH for its potential ED properties.

Pending a standardized procedure is made available at EU level, the following sources were considered to check the potential of endocrine disrupting properties of the co-formulants contained in the biocidal product.

Substance identified as ED under the BPR: https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d

Substance identified as ED under the PPPR: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/index.cfm?event=search.as&a_from=&a_to=&e_from=&e_to=&additionalfilter_class_p1=&additionalfilter_class_p2=&string_tox_1=&string_tox_1=&string_tox_2=&string_tox_2=&string_tox_3=&string_tox_3=&string_tox_4=&string_tox_4=

ECHA Candidate List of substances of very high concern for Authorisation: https://echa.europa.eu/candidate-list-table

ECHA's Endocrine disruptor assessment list: https://echa.europa.eu/ed-assessment

EU Community rolling action plan (CoRAP): https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table.

Lists of the EU on substances suspected of interfering with the hormone systems of humans and wildlife: https://ec.europa.eu/environment/chemicals/endocrine/documents/studies_en.htm

- BKH report
- BKH-RPS report
- WRc-NSF Final Report

U.S. EPA Endocrine Disruptor Screening Program (EDSP21): https://comptox.epa.gov/dashboard/chemical_lists/EDSPUOC

---EPA|ENDOCRINE: EDSP21 Tier 1 Screening Chemicals: List 1: https://comptox.epa.gov/dashboard/chemical_lists/edsp21list1

---EPA|ENDOCRINE: EDSP21 Tier 1 Screening Chemicals: List 2: https://comptox.epa.gov/dashboard/chemical_lists/edsp21list2

---List of 52 Tier 1 chemicals as of September 23, 2015. EPA is recommending additional testing, known as Tier 2 testing: https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-tier-1-screening-determinations-and

TOXCAST: EPA ToxCast Screening Library: https://comptox.epa.gov/dashboard/chemical_lists/toxcast

DANISH CENTRE ON ENDOCRINE DISRUPTERS: http://cend.dk/files/DK_ED-list-final_2018.pdf

Substance name	CAS number	Classification	Identified as ED in				Food/ foodstuff? *	ED alert found in			
			BPR / PPPR	REACH SVHC process/list ed in CL	CoRAP	EU priority list		USEPA EDSP21	USEPA ToxCast	REACH registration dossier	Other international review programme
Calcium carbonate	1317-65-3	-	No	No	No	No	Yes	No	No	No	No
Silicon Dioxide, Amorphous Synthetic	112926-00-8	-	No	No	No	No	Yes	No	No	No	No
Benzoate denatonium	3734-33-6	Acute Tox.4; H302 Acute Tox.4; H332 Eye Dam. 1; H318	No	No	No	No	No	No	No	No	No
Quartz (SiO_2)*	14808-60-7	-	No	No	No	No	No	No	No	No	No

* Natural component of calcium carbonate.

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge and the data provided in Alpha-cypermethrin assessment report, there is no indication of concern regarding the ED properties of the substances used in the MASSOCIDE ADO04 biocidal product.

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorization will be revised.

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

Section No. (IUCLID dossier)	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
3.1 3.2 3.3 3.5 4.2	Brioschie, M.	2016	Title: Determination of the Physic-chemical Properties. Test facility: Chemservice S.r.l. Study code: CH-071-2016 Data protection claimed → Yes
3.4.1	Brioschie, M.	2016	Title: Determination of the Accelerated Storage Stability and Corrosion Characteristics. Test facility: Chemservice S.r.l. Study code: CH-408-2016 Data protection claimed → Yes
3.4.1	Brioschie, M.	2016	Title: Two years Storage Stability and Corrosion Characteristics. Test facility: Chemservice S.r.l. Study code: CH-075-2016 Data protection claimed → Yes
4.1 4.4	Brioschie, M.	2016	Title: determination of the oxidizing properties and explosive properties. Test facility: Chemservice S.r.l. Study code: CH-072-2016 Data protection claimed → Yes
4.17.1	Mazzei, A.; Lunghi, A.	2016	Title: Relative Self-Ignition Temperature for solids on the Sample Massocide AD04 Test facility: Innovhub – Stazioni Sperimentali per l'Industria Study code: 201600851 Data protection claimed → Yes
5	Brioschie, M.	2016	Title: Validation of the Analytical Method for the Determination of the Active Ingredients Content. Test facility: Chemservice S.r.l. Study code: CH-073-2016 Data protection claimed → Yes
6.7	Parker, R.	2020 Amendment (Initial version:2016)	Title: Laboratory bioassay to determine the efficacy of products against multiple target species Test facility: i2LResearch Ltd Study code: 15/381 Data protection claimed → Yes
6.7	Latorre, R.	2020 Amendment (Initial version:2016)	Title: Field trial to determine the efficacy of two products against German cockroaches, *Blattella germanica* Test facility: i2LResearch Ltd Study code: 15/382 Data protection claimed → Yes
6.7	Parker, R.	2021 Amendment (Initial version:2016)	Title: Field trial to determine the efficacy of Massocide AD against black ants Test facility: i2LResearch Ltd Study code: 15/383 Data protection claimed → Yes
6.7	Nácarová,	2021	Title: Simulated-use study to validate the

Section No. (IUCLID dossier)	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
	J.		efficacy of a product with a knockdown and kill claim against ticks Test facility: i2L Research Europe s.r.o. Study code: 21/201 Data protection claimed → Yes
6.7	Parker, R.	2021	Title: Simulated-use study to validate the efficacy of a product against target insect pests Test facility: i2LResearch Study Code: 21/207 Data protection claimed → Yes
6.7	Foltan, P.	2020	Title: Field trial to determine the efficacy of two products against chicken mites, *Dermanyssus gallinae* Test facility: i2l Research Limited Study code: 15-354 Data protection claimed → Yes
6.7	Foltan, P.	2016	Title: Field trial to determine the efficacy of two products against Lesser mealworms, *Alphitobius diaperinus* Test facility: i2l Research Limited Study code 15/385 Data protection claimed → Yes
6.7	COMERCIAL QUIMICA MASSO,SA	2021	Title: MASSOCIDE AD 0.4 % Dust powder container Performance Test facility: COMERCIAL QUIMICA MASSO,SA Data protection claimed → Yes
6.7	COMERCIAL QUIMICA MASSO,SA	2023	Title: MASSOCIDE AD 0.4 % Dust powder container performance Test facility: COMERCIAL QUIMICA MASSO,SA Data protection claimed → Yes