

Justification for the selection of a substance for CoRAP inclusion

- Update -

Substance Name (Public Name): propargite

Chemical Group:

EC Number: 219-006-1

CAS Number: 2312-35-8

Submitted by: Bureau REACH, RIVM, the Netherlands

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Cover Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

| | |
|---|--|
| EC name: | propargite |
| IUPAC name: | 2-(4-tert-butylphenoxy)cyclohexyl prop-2-ynyl sulphite |
| Index number in Annex VI of the CLP Regulation | 607-151-00-7 |
| Molecular formula: | C ₁₉ H ₂₆ O ₄ S |
| Molecular weight or molecular weight range: | 350.5 |
| Synonyms/Trade names: | Omite and Comite |

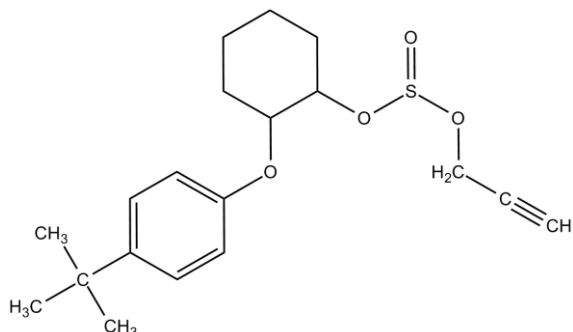
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

none

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Table 2: Harmonised classification

| Index No | International Chemical Identification | EC No | CAS No | Classification | | Spec. Conc. Limits, M-factors | Notes |
|--------------|--|-----------|-----------|---|--|-------------------------------|-------|
| | | | | Hazard Class and Category Code(s) | Hazard statement code(s) | | |
| 607-151-00-7 | 2-(4-tert-butylphenoxy)cyclohexyl prop-2-ynyl sulphite | 219-006-1 | 2312-35-8 | Skin Irrit 2 Eye Dam. 1 Acute Tox. 3 Carc. 2 Aquatic Acute 1 Aquatic Chronic 1 | H315 H318 H331 H351 H400 H410 | M=10 | |

2.2 Self classification

- In the registration: None. The harmonized classification is followed.
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Acute Tox. 4; H302

Acute Tox. 3; H311

Acute Tox. 2; H330

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

Not relevant

3 INFORMATION ON AGGREGATED TONNAGE AND USES

| | | | |
|--|---|--|--|
| From ECHA dissemination site | | | |
| <input type="checkbox"/> 1 – 10 tpa | <input type="checkbox"/> 10 – 100 tpa | <input type="checkbox"/> 100 – 1000 tpa | |
| <input checked="" type="checkbox"/> 1000 – 10,000 tpa | <input type="checkbox"/> 10,000 – 100,000 tpa | <input type="checkbox"/> 100,000 – 1,000,000 tpa | |
| <input type="checkbox"/> 1,000,000 – 10,000,000 tpa | <input type="checkbox"/> 10,000,000 – 100,000,000 tpa | <input type="checkbox"/> > 100,000,000 tpa | |
| <input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa) | | <input type="checkbox"/> Confidential | |
| | | | |
| <input checked="" type="checkbox"/> Industrial use | <input type="checkbox"/> Professional use | <input type="checkbox"/> Consumer use | <input type="checkbox"/> Closed System |
| <p>According to the ECHA website, propargite is manufactured and/or imported in the European Economic Area in 1000 - 10 000 tonnes per year. This substance is used in formulation or re-packing and in manufacturing. No information is available for consumer uses, article service life, widespread uses by professional workers and uses at industrial sites. The substance is used in the plant protection products. However, this substance is not authorised in the EU. Release to the environment of this substance can occur from industrial use: manufacturing of the substance. In 2011, the production in the Italian manufacture was 1782 ton, with the export amount of 1344 ton. No information is available for the export amount after 2012 in the CSR. Propargite is subject to the Prior Informed Consent Regulation (PIC, Regulation (EU) 649/2012). The export was via Italy and the Netherlands. It is noted in the ECHA website that the export was carried out between 2013 and 2018. The exact amount, however, was not stated in the ECHA website.</p> | | | |

4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

| | |
|---|--|
| <input type="checkbox"/> Compliance check, Final decision | <input type="checkbox"/> Dangerous substances Directive 67/548/EEC |
| <input type="checkbox"/> Testing proposal | <input type="checkbox"/> Existing Substances Regulation 793/93/EEC |
| <input checked="" type="checkbox"/> Annex VI (CLP) | <input checked="" type="checkbox"/> Plant Protection Products Regulation 91/414/EEC No 1107/2009 (repealing Regulation 91/414/EEC) |
| <input type="checkbox"/> Annex XV (SVHC) | <input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012) |
| <input type="checkbox"/> Annex XIV (Authorisation) | <input type="checkbox"/> Other (provide further details below) |
| <input type="checkbox"/> Annex XVII (Restriction) | |
| The index number for CLP is 607-151-00-7. | |
| Propargite is an insecticide used to control mites on a variety of field, fruit, and vegetable crops, as well as ornamentals. | |
| The substance has not been approved as active substance under Regulation (EC) no 1107/2009 and is hence banned for pesticide use in EU (cfr. Commission Regulation (EU) no 73/2013) | |

5 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

5.2 Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
- Fulfils criteria as Sensitiser/ Suspected sensitiser
- Fulfils criteria as potential endocrine disruptor
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

| Hazard based concerns | | |
|---|--|---|
| CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R | Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R | <input checked="" type="checkbox"/> Potential endocrine disruptor |
| <input type="checkbox"/> Sensitiser | <input type="checkbox"/> Suspected Sensitiser ¹ | |
| <input type="checkbox"/> PBT/vPvB | <input checked="" type="checkbox"/> Suspected PBT/vPvB ¹ | <input type="checkbox"/> Other (please specify below) |
| Exposure/risk based concerns | | |
| <input type="checkbox"/> Wide dispersive use | <input type="checkbox"/> Consumer use | <input type="checkbox"/> Exposure of sensitive populations |
| <input type="checkbox"/> Exposure of environment | <input type="checkbox"/> Exposure of workers | <input type="checkbox"/> Cumulative exposure |
| <input type="checkbox"/> High RCR | <input type="checkbox"/> High (aggregated) tonnage | <input type="checkbox"/> Other (please specify below) |

It is noted that propargite is included in the List of Chemicals for Initial Tier 1 Screening in the US EPA endocrine disrupting screening program (EDSP) in 2009. (see website: <https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-edsp-tier-1-assessments>).

Propargite is a data-rich substance, with the production in Italy. Except a few studies absent, the dossier is reasonably complete containing physical and chemical information, toxicological information and ecotoxicological information required at tonnage of 1000 tpa (Annex X). A few studies are not available,

¹ CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)

Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

which, however, does not influence the evaluation.

Physical-Chemical Properties

Propargite is an oily, viscous liquid with a strong, sweet odour and a brownish yellow colour at room temperature. Decomposed at 210°C (727.4 torr) without any evidence of boiling, the substance solidified on cooling but exhibited no distinct freezing point above -70°C. Measured partition coefficient between octanol and water (log Kow) is 5.7. Vapour pressure is determined to be < 4.04 x 10E-5 Pa at 20°C. Measured water solubility is 0.215 mg/L at 20 °C.

PBT assessment

Propargite is not readily biodegradable in the modified Sturm Test (OECD 301B). In the simulation tests, the overall DT50 was determined to be 18.3-22.5 days. Given the chemical structure, we have some doubts on the outcome of the simulation study. It is concluded that Propargite may be P and further evaluation of the simulation studies is needed.

Propargite has a log Kow of 5.7. The tested BCF value is 1840, which is below the threshold of 2000. However, the BCF study has some limitations because the test concentration was not stable and the BCF value was not corrected by growth and lipid content. The substance is considered borderline B. Propargite is considered as T according to the CLP. In summary, Propargite is considered to be a potential PBT substance.

ED properties

Propargite showed adverse effects in the long-term toxicity tests in fish and Daphnia. These are no data on the end points (e.g. sex ratio) indicating mode of action of the substance. Due to lack of information, it is not possible to conclude whether or not the substance has endocrine disrupting properties. After the initial evaluation, the US EPA released the EDSP data tested in 11 assays that target EATS pathways. The results of these assays have been included in the updated CSR but not updated here. Only the conclusions were updated here. The EPA concluded that there is no convincing evidence for potential interaction with the estrogen and androgen pathways in mammals and wildlife. However, thyroid-related effects were observed in the male and female pubertal assays in the absence of overt toxicity, as well as in the amphibian metamorphosis assay (AMA). These results suggest that propargite has potential to interact with the thyroid pathway in mammals and amphibians. Based on the EU ED identification criteria, it could be concluded that propargite is an endocrine disruptor, providing a potential concern for workers.

Given the remaining concern for PBT properties (focusing on P) and ED makes the substance a candidate for CoRAP.

5.4 Preliminary indication of information that may need to be requested to clarify the concern

| | |
|---|---|
| <input type="checkbox"/> Information on toxicological properties | <input type="checkbox"/> Information on physico-chemical properties |
| <input checked="" type="checkbox"/> Information on fate and behaviour | <input type="checkbox"/> Information on exposure |
| <input type="checkbox"/> Information on ecotoxicological properties | <input type="checkbox"/> Information on uses |
| <input type="checkbox"/> Information ED potential | <input type="checkbox"/> Other (provide further details below) |

5.5 Potential follow-up and link to risk management

| | | | |
|--|---|---|--|
| <input type="checkbox"/> Harmonised C&L | <input checked="" type="checkbox"/> Restriction | <input checked="" type="checkbox"/> Authorisation | <input type="checkbox"/> Other (provide further details) |
| Harmonised C&L is available for propargite. If the substance is identified as PBT, it may be listed as a SVHC. | | | |