# Justification for the selection of a candidate CoRAP substance

| | |
|---|---|
| **Substance Name (Public Name):** | 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether |
| **Chemical Group:** | |
| **EC Number:** | 200-076-7 |
| **CAS Number:** | 51-03-6 |
| **Submitted by:** | Swedish Chemicals Agency |
| **Published:** | 20/03/2013 |

**Note**

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

# Contents

# 1 IDENTITY OF THE SUBSTANCE

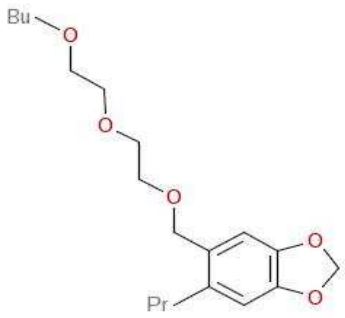
## 1.1 Name and other identifiers of the substance

**Table 1: Substance identity**

| | |
|---|---|
| **Public Name:** | 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether |
| **EC number:** | 200-076-7 |
| **EC name:** | 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether |
| **CAS number (in the EC inventory):** | 51-03-6 |
| **CAS number:** | 51-03-6 |
| **CAS name:** | |
| **IUPAC name:** | 5-{[2-(2-butoxyethoxy)ethoxy]methyl}-6-propyl-1,3-benzodioxole |
| **Index number in Annex VI of the CLP Regulation** | |
| **Molecular formula:** | C19H30O5 |
| **Molecular weight or molecular weight range:** | 338.4385 |
| **Synonyms:** | PBO,<br>5-[2-(2-butoxyethoxymethyl]-6-propyl-1,3-benzodioxole<br><br>Common name (ISO): Piperonyl butoxide |

**Type of substance** ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

**Structural formula:**



# 2 CLASSIFICATION AND LABELLING

## 2.1 Harmonised Classification in Annex VI of the CLP

No harmonised entry available.

## 2.2 Proposal for Harmonised Classification in Annex VI of the CLP

No proposal for harmonised classification

## 2.3 Self classification

In registration data self classified for: **According to CLP**

Registration 1:
Aquatic chronic 1; H410: Very toxic to aquatic life with long lasting effects.

Registration 2:
Aquatic chronic 2; H411: Toxic to aquatic life with long lasting effects.

**According to DSD**

1: N; R50/53: Dangerous for the environment; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

2: N; R51/53: Dangerous for the environment; Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Additionally in the C&L data inventory database self classification is done for:

Acute Toxicity 1; H330: fatal if inhaled.

Acute Toxicity 2; H310: Fatal in contact with skin.

Acute Toxicity 3; H331: toxic if inhaled.

Aquatic Acute 1; H400: Very toxic to aquatic life.

Reproductive toxicity 2; H361: Suspected of damaging fertility or the unborn child.

# 3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

## 3.1 Legal basis for the proposal

☒ Article 44(1) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

## 3.2 Grounds for concern

| | | |
|---|---|---|
| ☐ (Suspected) CMR | ☒ Wide dispersive use | ☐ Cumulative exposure |
| ☐ (Suspected) Sensitiser | ☒ Consumer use | ☐ High RCR |
| ☒ (Suspected) PBT | ☐ Exposure of sensitive populations | ☐ Aggregated tonnage |
| ☒ Suspected endocrine disruptor | ☐ Other (provide further details below) | |

***Information from databases:***

| | |
|---|---|
| **EC Endocrine Substances Database** | Conclusion: Potential evidence of ED effects<br>Human Health: CAT3b Wildlife CAT2 |
| **QSAR toolbox profiler ERBA** | NO ER Binding Alert |
| **Predicted ERBA TIMES** | |
| **FDA Endocrine Screening Database** | |

Uses indicate wide dispersive use for professional workers and consumers. Additional information from ProSP indicates uses in consumer products.

Repeated dose toxicity indicates liver and kidney as target organs. In a 2year rat carcinogenicity test amongst other effects, reduced growth and enlargement of ovaries, thyroid and small testes was noted.

The substance is concluded negative for genotoxicity.

Information in registration dossier for reproductive toxicity is not detailed in the robust study summary and the registrant conclusion for the 2 generation and developmental toxicity tests is of no concern for fertility and teratogenicity.

## 3.3 Information on aggregated tonnage and uses

| | | |
|---|---|---|
| ☐ 1 – 10 tpa | ☒ 10 – 100 tpa | ☐ 100 – 1000 tpa |
| ☐ 1000 – 10,000 tpa | ☐ 10,000 – 100,000 tpa | |
| ☐ 100,000 – 1000,000 tpa | ☐ > 1000,000 tpa | |
| ☐ Confidential | | |

Note: In addition to the above ticked tonnage there is another registration where the tonnage band is confidential.

| | | | |
|---|---|---|---|
| ☒ Industrial use | ☒ Professional use | ☒ Consumer use | ☐ Closed System |

## 3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

| | |
|---|---|
| ☐ Compliance check | ☐ Dangerous substances Directive 67/548/EEC |
| ☐ Testing proposal | ☐ Existing Substances Regulation 793/93/EEC |
| ☐ Annex VI (CLP) | ☐ Plant Protection Products Regulation 91/414/EEC |
| ☐ Annex XV (SVHC) | ☒ Biocidal Products Directive 98/8/EEC |
| ☐ Annex XIV (Authorisation) | ☐ Other (provide further details below) |
| ☐ Annex XVII (Restriction) | |
| The substance is under Review as a Biocidal active substance, it is needed to consider if information and evaluation on ED could already take place under the BPD. | |

## 3.5 Information to be requested to clarify the suspected risk

| | |
|---|---|
| ☒ Information on toxicological properties | ☐ Information on physico-chemical properties |
| ☐ Information on fate and behaviour | ☒ Information on exposure |
| ☒ Information on ecotoxicological properties | ☒ Information on uses |
| ☐ Other (provide further details below) | |
| Evaluation of the available information regarding potential for ED (EC List), together with potential PBT properties and exposure considerations. | |

## 3.6 Potential follow-up and link to risk management

| | | | |
|---|---|---|---|
| ☐ Restriction | ☐ Harmonised C&L | ☐ Authorisation | ☐ Other (provide further details) |
| No immediate action based on available data foreseen. | | | |