# Justification for the selection of a substance for CoRAP inclusion

| | |
|---|---|
| **Substance Name (Public Name):** | 1-[4-(1,1-dimethylethyl)phenyl]-3-(4-methoxyphenyl)propane-1,3-dione |
| **Chemical Group:** | |
| **EC Number:** | 274-581-6 |
| **CAS Number:** | 70356-09-1 |
| **Submitted by:** | Germany |
| **Date:** | 17/03/2015 |

**Note**

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

## Contents

# 1 IDENTITY OF THE SUBSTANCE

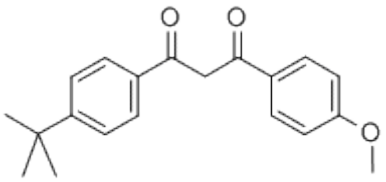
## 1.1 Other identifiers of the substance

**Table 1: Substance identity**

| | |
|---|---|
| **EC name:** | 1-[4-(1,1-dimethylethyl)phenyl]-3-(4-methoxyphenyl)propane-1,3-dione |
| **IUPAC name:** | 1-(4-tert-butylphenyl)-3-(4-methoxyphenyl)propane-1,3-dione |
| **Index number in Annex VI of the CLP Regulation** | |
| **Molecular formula:** | $C_{20}H_{22}O_3$ |
| **Molecular weight or molecular weight range:** | 310.39 g/mol |
| **Synonyms/Trade names:** | Avobenzon<br>BMDM |

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

**Structural formula:**



# 2 CLASSIFICATION AND LABELLING

## 2.1 Harmonised Classification in Annex VI of the CLP

Not listed.

## 2.2 Self classification

- In the registration:

  Aquatic Chronic 4;H413: May cause long lasting harmful effects to aquatic life

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

  Aquatic Chronic 2;H411: Toxic to aquatic life with long lasting effects

  Aquatic Acute 1;H400: Very toxic to aquatic life with long lasting effects.

  Aquatic Chronic 1; H400: Very toxic to aquatic life

  Aquatic Chronic 1; H412: Harmful to aquatic life with long lasting effects.

  Acute Tox. 4;H302: Harmful if swallowed.

  Skin Irrit. 2 ;H315: Causes skin irritation

  STOT SE 3;H335: May cause respiratory irritation.

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

No proposal publically available.

# 3 INFORMATION ON AGGREGATED TONNAGE AND USES

| From ECHA dissemination site | | | |
|---|---|---|---|
| ☐ 1 – 10 tpa | ☐ 10 – 100 tpa | ☐ 100 – 1000 tpa | |
| ☒ 1000 – 10,000 tpa | ☐ 10,000 – 100,000 tpa | ☐ 100,000 – 1,000,000 tpa | |
| ☐ 1,000,000 – 10,000,000 tpa | ☐ 10,000,000 – 100,000,000 tpa | ☐ > 100,000,000 tpa | |
| ☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa) | | ☐ Confidential | |
| | | | |
| ☒ Industrial use | ☒ Professional use | ☒ Consumer use | ☐ Closed System |
| The substance is used as a UVA filter and as such finds application in personal care products. | | | |

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

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|---|---|
| ☐ Compliance check, Final decision | ☐ 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 ; Biocidal Product Regulation (Regulation (EU) 528/2012) |
| ☐ Annex XIV (Authorisation) | ☐ Other (provide further details below) |
| ☐ Annex XVII (Restriction) | |
| | |

# 5 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

## 5.1 Legal basis for the proposal

☒ Article 44(2) a) and c) (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 disrupter

☒ 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<br>☐C ☐M ☐R | Suspected CMR[1]<br>☐C ☐M ☐R | ☐ Potential endocrine disruptor |
| ☐ Sensitiser | ☐ Suspected Sensitiser[1] | |
| ☐ PBT/vPvB | ☒ Suspected PBT/vPvB[1] | ☐ Other (please specify below) |
| **Exposure/risk based concerns** | | |
| ☒ Wide dispersive use | ☒ Consumer use | ☐ Exposure of sensitive populations |
| ☒ Exposure of environment | ☐ Exposure of workers | ☐ Cumulative exposure |
| ☐ High RCR | ☒ High (aggregated) tonnage | ☐ Other (please specify below) |

The substance is fulfilling the screening criteria for persistence and bioaccumulation as defined in Annex XIII, i.e.

**P/vP criterion**

BMDM is not readily biodegradable. The available data do not allow assessing degradation in environmental compartments. Therefore, the substance is considered to be potentially persistent.

**B/vB criterion**

The substance has a log Pow > 4.5. The available data on bioconcentration in fish require further evaluation. BMDM is therefore considered to be potentially bioaccumulative.

**T criterion**

Short-term studies on aquatic ecotoxicology are available for BMDM. No long-term studies on aquatic ecotoxicology are available. Based on the available data, a definitive conclusion on toxicity cannot be drawn.

The substance has a high tonnage (>1000t) and is used as UV-filter in personal care products. Thus an environmental exposure is likely.

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

| | |
|---|---|
| ☐ Information on toxicological properties | ☐ Information on physico-chemical properties |
| ☒ Information on fate and behavior | ☐ Information on exposure |
| ☒ Information on ecotoxicological properties | ☐ Information on uses |
| ☐ Information ED potential | ☐ Other (provide further details below) |

**P/vP criterion**
The substance is not readily biodegradable. The available data do not allow assessing degradation in environmental compartments. Therefore, the substance is considered to be potentially persistent. Further information is required to allow a definitive conclusion on persistence.

**B/vB criterion**
Further evaluation and, if necessary, further testing on bioaccumulation is required to clarify whether the substance is bioaccumulative or very bioaccumulative.

**T criterion**
Further evaluation and, if necessary, further testing is required to clarify whether the substance is toxic especially on sediment organisms.

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

| | | | |
|---|---|---|---|
| ☒ Harmonised C&L | ☒ Restriction | ☒ Authorisation | ☐ Other (provide further details) |
| If the substance is identified as a PBT/vPvB substance, an analysis of risk management options will be carried out, taking into account information on use and exposure. Potential options are the inclusion in the Candidate List with or without Authorisation, but also Restriction. | | | |