

**Substance Name: 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one**

**EC Number: 438-340-0**

**CAS Number: 119344-86-4**

**SUPPORT DOCUMENT FOR IDENTIFICATION OF**

**2-(DIMETHYLAMINO)-2-[(4-METHYLPHENYL)METHYL]-1-[4-(MORPHOLIN-4-YL)PHENYL]BUTAN-1-ONE**

**AS A SUBSTANCE OF VERY HIGH CONCERN  
BECAUSE OF ITS TOXIC FOR REPRODUCTION  
(ARTICLE 57C) PROPERTIES**

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## ABBREVIATIONS

ATP	Adaptation to technical progress
C&L	Classification & Labelling
CLP	Classification, Labelling and Packaging
RAC	Risk Assessment Committee
SVHC	Substance of very high concern

## IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

**Substance name:** 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one

**EC number:** 438-340-0

**CAS number:** 119344-86-4

- The substance is identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class toxic for reproduction category 1B<sup>1</sup>.

### Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one will be covered by index number 606-158-00-2 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it will be classified in the hazard class toxic for reproduction category 1B (H360Df "May damage the unborn child. Suspected of damaging fertility"), anticipated to be included in the 22nd ATP to CLP.

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

**Registration dossiers submitted for the substance:** Yes

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<sup>1</sup> Classification in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008.

## Justification

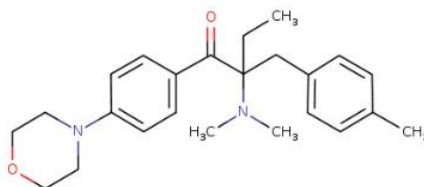
### 1. Identity of the substance and physical and chemical properties

#### 1.1 Name and other identifiers of the substance

**Table 1: Substance identity**

<b>EC number:</b>	438-340-0
<b>EC name:</b>	2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one
<b>CAS number (in the EC inventory):</b>	119344-86-4
<b>CAS number:</b>	119344-86-4
<b>IUPAC name:</b>	2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one
<b>Index number in Annex VI of the CLP Regulation</b>	606-158-00-2 <sup>2</sup>
<b>Molecular formula:</b>	C <sub>24</sub> H <sub>32</sub> N <sub>2</sub> O <sub>2</sub>
<b>Molecular weight range:</b>	380.5
<b>Synonyms:</b>	Omnirad 379 CGI 113 JRCure 379 Keycure 8179 Irgacure 379

#### Structural formula:



(source: European Chemicals Agency, <http://echa.europa.eu/>)

<sup>2</sup> 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one will be covered with this Index No. in the next upcoming ATP

## 1.2 Composition of the substance

**Name:** 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one

**Description:** solid (powder)

**Substance type:** multi-constituent (racemate)

**Table 2: Constituents other than impurities/additives**

Constituents	Typical concentration	Concentration range	Remarks
(R)-2-(4-methylbenzyl)-2-(dimethylamino)-1-[4-(morpholin-4-yl)phenyl]butan-1-one	-	≥ 10% and < 80% (w/w)*	-
(S)-2-(4-methylbenzyl)-2-(dimethylamino)-1-[4-(morpholin-4-yl)phenyl]butan-1-one	-	≥ 10% and < 80% (w/w)*	-

\* Multi constituent substance according to the Guidance for identification and naming of substances under REACH and CLP [new format draft \(europa.eu\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0605-02)

There are no impurities relevant for the identification of the substances as SVHC.

## 1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

## 1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach)

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

## 1.5 Physicochemical properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

## 2. Harmonised classification and labelling

2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one does not yet have a harmonised classification, but according to an adopted opinion from RAC (ECHA, 2022), the substance meets the criteria in the hazard class toxic for reproduction, category 1B. The substance will be covered by Index number 606-158-00-2 in part 3 of Annex VI with the upcoming 22<sup>nd</sup> ATP of the CLP Regulation as follows:

**Table 3: Classification according to Annex VI, Table 3 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008**

Index No	Chemical name	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors and ATEs <sup>3</sup>	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
606-158-00-2	2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one	43-8-34-0-0	11-93-44--86-4	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360Df H400 H410	GHS08 GHS09 Dgr	H360Df H410		M = 1 M = 1	

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<sup>3</sup> Acute Toxicity Estimate

### 3. Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

### 4. Human health hazard assessment

2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one does not yet have a harmonised classification, but according to an adopted opinion from RAC (ECHA, 2022), the substance meets the criteria in the hazard class toxic for reproduction, category 1B. The substance will be covered by Index number 606-158-00-2 in part 3 of Annex VI with the next upcoming 22nd ATP of the CLP Regulation.

### 5. Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

## 6. Conclusions on the SVHC Properties

### 6.1 CMR assessment

2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one will be covered by index number 606-158-00-2 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it will be classified in the hazard class toxic for reproduction category 1B (H360Df "May damage the unborn child. Suspected of damaging fertility") with the upcoming 22<sup>nd</sup> ATP to CLP.

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.



## References

ECHA (2022): RAC Opinion proposing harmonised classification and labelling at EU level of 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one, EC 438-340-0, CAS 119344-86-4. Adopted 2 June 2022. [\[04.01-ML-014.03\] \(europa.eu\)](#).