

## Justification Document for the Selection of a CoRAP Substance

**Substance Name (public name):** 4,4'-bis(diethylamino)benzophenone

**EC Number:** 202-025-4

**CAS Number:** 90-93-7

**Authority:** The Netherlands

**Date:** 17/03/2021

### 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: Other Substance identifiers

<b>EC name (public):</b>	202-025-4
<b>IUPAC name (public):</b>	4-[4-(diethylamino)benzoyl]-N,N-diethylaniline
<b>Index number in Annex VI of the CLP Regulation:</b>	-
<b>Molecular formula:</b>	C <sub>21</sub> H <sub>28</sub> N <sub>2</sub> O
<b>Molecular weight or molecular weight range:</b>	-
<b>Synonyms:</b>	<p>Michler's ethylketone  <b>Michler's ethyl ketone</b>            4,4'-Bis(diethylamino)benzophenone            Bis(4-(diethylamino)phenyl)methanone            Methanone, bis[4-(diethylamino)phenyl]-            Bis[4-(diethylamino)phenyl]methanone            4,4'-Bis(diethylamino) benzophenone            4,4'-(Tetraethyldiamino)benzophenone            p,p'-Bis(diethylamino)benzophenone            p,p'-(Tetraethyldiamino)benzophenone            DEAB            Trade name: Omnirad EMK</p>

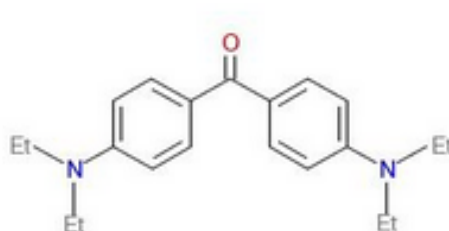
**Type of substance**

Mono-constituent

Multi-constituent

UVCB

**Structural formula:**

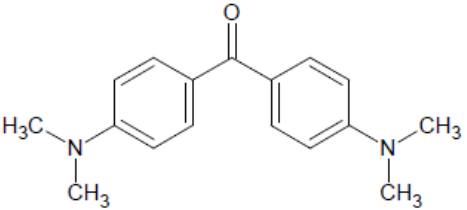
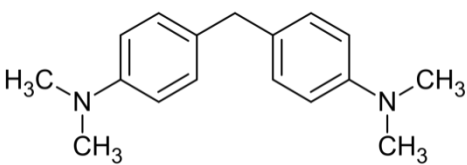


### 1.2 Similar substances/grouping possibilities

The substance is a close structural analogue of 4,4'-bis (dimethylamino) benzophenone (EC 202-027-5; CAS 90-94-8; also known as Michler's Ketone), which is classified as Carc. cat. 1B and Muta.

2. The substance is also an analogue of 4,4'-methylenebis (N,N-dimethyl benzenamine, also known as Michler's Base) (EC 202-959-2; CAS 101-61-1), which is also classified as Carc. Cat. 1B.

Both substances are identified as a Substance of Very High Concern (SVHC).

<b>Name</b>	<b>EC</b>	<b>structural formula</b>
4,4'-bis(dimethylamino) benzophenone	202-027-5	 <p>The structure shows two benzene rings connected by a carbonyl group (C=O) at the para positions. Each benzene ring has a dimethylamino group (-N(CH<sub>3</sub>)<sub>2</sub>) attached at the para position relative to the carbonyl group.</p>
4,4'-methylenebis(N,N-dimethylbenzenamine)	202-959-2	 <p>The structure shows two benzene rings connected by a methylene group (-CH<sub>2</sub>-) at the para positions. Each benzene ring has a dimethylamino group (-N(CH<sub>3</sub>)<sub>2</sub>) attached at the para position relative to the methylene group.</p>

## 2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

**Table: Completed or ongoing processes**

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
Restriction	<input type="checkbox"/> Annex XVII <sup>1</sup>	
CLH	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes/ EU legislation	<input type="checkbox"/> Other (provide further details below)	
Further details	No completed or ongoing processes.	

<sup>1</sup> Please specify the relevant entry.

### **3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)**

#### **3.1 Classification**

##### **3.1.1 Harmonised Classification in Annex VI of the CLP**

Not classified.

##### **3.1.2 Self classification**

- In the registration: no self-classification.
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Skin Irrit. 2 (H315)

Eye Irrit. 2 (H319)

STOT SE 3 (H335)

Carc. 2 (H351)

Aquatic Acute 1 (H440)

Aquatic Chronic 1 (H410)

Aquatic Chronic 2 (H411)

Aquatic Chronic 4 (H413)

##### **3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP**

No proposals.

## 4 INFORMATION ON (AGGREGATED) TONNAGE AND USES<sup>2</sup>

### 4.1 Tonnage and registration status

**Table: Tonnage and registration status**

<b>From ECHA dissemination site *</b>		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 – 10 tpa	<input checked="" type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa
<input 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
Joint submission of four registrations. Total tonnage level is 10-100 tpa.		

\*the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11):

[https://echa.europa.eu/documents/10162/22308542/manual\\_dissemination\\_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0](https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0)

### 4.2 Overview of uses

**Table: Uses**

The substance is formulated for preparations containing photo initiator. There is industrial and professional use of the photo initiator. Product categories used include adhesives and sealants, coatings and paints, ink and toners and paper and board treatment products. These are the uses indicated in the registration dossier. In analogue to the SVHC dossiers for Michler’s ketone and base, it is expected that Michler’s ethyl ketone (and possibly Michler’s ethyl base) will also be used as a starting material in the synthesis of triarylmethane dyes, many of which are used in consumer products (textile dyes, inks). Michler’s ethyl ketone (and base) can therefore be present in these dyes as an impurity.

**Part 1:**

<input type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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<sup>2</sup> The dissemination site was accessed in Sept 2020.

## 5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

### 5.1. Legal basis for the proposal

- Article 44(2)  
 Article 45(5)

### 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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR <sup>1</sup> <input checked="" type="checkbox"/> C <input checked="" type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser <sup>3</sup>	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<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)

<sup>3</sup> 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



Two structural analogues of Michler's ethyl ketone, i.e. Michler's ketone (EC 202-027-5) and Michler's base (EC 202-959-2) have a harmonized classification for Carc Cat 1B and consequently have been identified as a SVHC substances under REACH. In addition, Michler's ketone has a harmonized classification of Muta 2.

All three substances are N-substituted aromatic amines and share the same structural alert for mutagenicity/carcinogenicity (OECD QSAR toolbox, Derek Nexus) which indicates that all three substances could act via the same mechanism.

Based on this information, there is a concern on potential carcinogenicity and mutagenicity of the substance, Michler's ethyl ketone.

For at least one triarylmethane dye registered under REACH, CI Basic Blue 7, EC 219232-0, it has been confirmed that the substance (diethylamino analogue of Michler's ketone) is present as an impurity at concentrations > 1%. CI Basic Blue 7 is used as a dye in ballpoint ink, which implies direct consumer exposure. This contradicts with the intermediate dossier status for CI Basic Blue 7. Furthermore Basic Blue 7 is widely used in for various applications due to its chemical stability and accurate composition. It is used in different industrial applications, which includes carbon paper coloring, ball pen ink and in printing ink.

It is also used to dye anionic substrates, e.g. wool, silk, nylon, and acrylics, where bright dyeing is required. Use as a textile dye potentially leads to direct consumer exposure.

The expected (consumer) exposure to Michler's Ethyl Ketone (and base) is thus not due to intended use of the (registered) substance, but due to its presence as an impurity in dyes synthesized using this substance as a starting material.

Based on the information for Michler's Ethyl Ketone on the IUCLID dissemination site, the reported tonnage level of 10-100 tpa is an aggregated level, and each individual registration dossier is at a level of 1-10 tpa. This means that with respect to mutagenicity, for which only one (negative) Ames test is available, each dossier is in compliance and that a substance evaluation would be needed to request additional information to assess the mutagenic and carcinogenicity potential of the registered substance.

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

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input 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)

Michler's ethyl ketone gives negative results in the Ames test, which is the only information on mutagenicity available in the registration dossiers. However, Michler's Ketone and Michler's Base both showed positive results in the Mouse Lymphoma Assay (MLA) using the Thymidine Kinase (TK) gene. Both substances give mixed results (both positive as well as negative) in the Ames test. It is well known that the mutagenicity of aromatic amines (like Michler's methyl and ethyl ketone) can give rise to false negative results in the Ames test. Therefore, an MLA in vitro assay in addition to the Ames test is

considered necessary as a first step to elucidate the mutagenic and carcinogenic potential of the registered substance (Michler's ethyl ketone).

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

<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>If the substance will be identified in the follow up to the Ames test as mutagenic and/or carcinogenic, it may lead to harmonized classification for these endpoints. Depending on this classification, the substance may be listed as a SVHC, with restriction or authorization as potential follow-up.</p>			