



**Substance name:**  $\alpha,\alpha$ -Bis[4-(dimethylamino)phenyl]-4  
(phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) <sup>1</sup>

**EC number: 229-851-8**  
**CAS number: 6786-83-0**

**MEMBER STATE COMMITTEE  
SUPPORT DOCUMENT FOR IDENTIFICATION OF**

**$\alpha,\alpha$ -Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-  
methanol (C.I. Solvent Blue 4)**

*[with ≥ 0.1% of Michler's ketone (EC no. 202-027-5) or Michler's base (EC no. 202-959-2)]*

**AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS  
CMR<sup>2</sup> PROPERTIES**

**Adopted on 7 June 2012**

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<sup>1</sup> The substance is identified as SVHC only where it contains Michler's ketone (EC Number: 202-027-5) or Michler's base (EC Number: 202-959-2) ≥ 0.1% (wt/wt)

<sup>2</sup> CMR means carcinogenic, mutagenic or toxic for reproduction

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**Substance Name(s):**  $\alpha,\alpha$ -Bis[4-(dimethylamino)phenyl]-4  
(phenylamino)naphthalene-1-methanol<sup>3</sup> (C.I. Solvent Blue 4)

**EC Number(s):** 229-851-8

**CAS Number(s):** 6786-83-0

- The substance is identified as substance meeting the criteria of Article 57 (a) of Regulation (EC) 1907/2006 (REACH) where it contains Michler's ketone (EC Number: 202-027-5) or Michler's base (EC Number: 202-959-2)  $\geq 0.1\%$ , owing to its classification as carcinogen category 1B<sup>4</sup> which corresponds to classification as carcinogen category 2<sup>5</sup>.

### Summary of how the substance meets the Carcinogen 1B criteria

Michler's ketone (4,4'-bis(dimethylamino)benzophenone; EC Number: 202-027-5) is listed as Index number 606-073-00-0 in Regulation (EC) No 1272/2008 (the CLP Regulation) and classified in Annex VI, part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as carcinogen, Carc. 1B (H350: "May cause cancer.") The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of the CLP Regulation is carcinogen, Carc. Cat. 2, R45 ("May cause cancer.")

Michler's base (N,N,N',N'-tetramethyl-4,4'-methylenedianiline; EC Number: 202-959-2) is listed as Index number 612-201-00-6 in the CLP Regulation and classified in Annex VI, part 3, Table 3.1 as carcinogen, Carc. 1B (H350: "May cause cancer.") The corresponding classification in Annex VI, part 3, Table 3.2 of the CLP Regulation is carcinogen, Carc. Cat. 2, R45 ("May cause cancer.")

According to Article 10(1) of the CLP Regulation, specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance (or in a mixture) as an identified impurity, additive or individual constituent leads to the classification of the substance (or mixture) as hazardous.

For Michler's ketone and Michler's base no specific concentration limits are set in Annex VI of the CLP Regulation and therefore the generic concentration limit is to be used for the purpose of determining classification of substances (or mixtures) containing Michler's ketone and/or Michler's base. The generic concentration limit for carcinogens, Carc. 1B is 0.1%, as set out in Table 3.6.2 in Part 3 of Annex I to the CLP Regulation.

Therefore, the above classifications of Michler's ketone and Michler's base in Regulation (EC) No 1272/2008 show that where the substance  $\alpha,\alpha$ -Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) contains Michler's ketone or Michler's base  $\geq 0.1\%$  it meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.

**Registration dossiers submitted for the substance:** No

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<sup>3</sup> The substance is identified as SVHC only where it contains Michler's ketone (EC Number: 202-027-5) or Michler's base (EC Number: 202-959-2)  $\geq 0.1\%$  (wt/wt)

<sup>4</sup> Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances.

<sup>5</sup> Classification in accordance with Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.2 List of harmonised classification and labelling of hazardous substances (from Annex I to Council Directive 67/548/EEC).

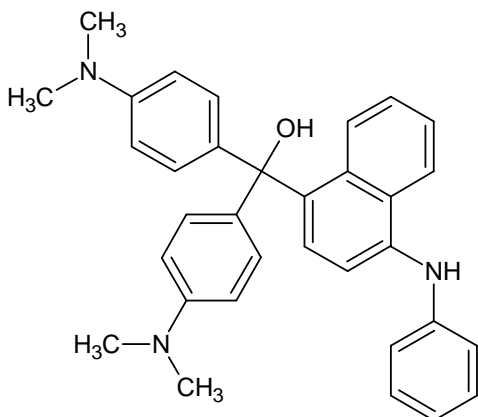
## JUSTIFICATION

### 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>	229-851-8
<b>EC name:</b>	$\alpha,\alpha$ -bis[4-(dimethylamino)phenyl]-4-(phenylamino)naphthalene-1-methanol
<b>CAS number (in the EC inventory):</b>	6786-83-0
<b>CAS number:</b>	6786-83-0
<b>Deleted CAS number(s):</b>	1325-91-3
<b>CAS name:</b>	1-Naphthalenemethanol, $\alpha,\alpha$ -bis[4-(dimethylamino)phenyl]-4-(phenylamino)-
<b>IUPAC name:</b>	[4-(Dimethylamino)-5,8-dihydronaphthalen-1-yl]{bis[4-(dimethylamino)phenyl]}methanol
<b>Index number in Annex VI of the CLP Regulation</b>	
<b>Molecular formula:</b>	C <sub>33</sub> H <sub>33</sub> N <sub>3</sub> O
<b>Molecular weight range:</b>	487.6 g/mol
<b>Synonyms:</b>	<ul style="list-style-type: none"> <li>– C.I. Solvent Blue 4</li> <li>– Victoria Blue B</li> <li>– Base B</li> <li>– Baso Blue 645;</li> <li>– Aizen Victoria Blue B Base;</li> <li>– Brilliant Oil Blue B Base;</li> <li>– C.I. 44045B;</li> <li>– Fast Oil Blue B Base</li> <li>– Victoria Blue B Base</li> <li>– Victoria Blue BA Base</li> <li>– Victoria Blue BDP Base</li> <li>– Victoria Blue Base</li> <li>– Victoria Blue Base B</li> <li>– Victoria Blue Base FB</li> <li>– Waxoline Victoria Blue B</li> </ul>

**Structural formula:****1.2 Composition of the substance**

**Name:** α,α-bis[4-(dimethylamino)phenyl]-4-(phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4)

**Description:** ---

**Degree of purity:** see confidential Annex

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
α,α-bis[4-(dimethylamino) phenyl]-4-(phenylamino)naphthalene-1-methanol EC #: 229-851-8		Confidential information	Information from C&L notifications

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
4,4'-bis(dimethylamino)benzophenone EC #: 202-027-5		Confidential information	Information derived from the C&L notifications
Further impurities: Confidential information			Information derived from the C&L notifications

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
None			Information derived from the C&L notifications

### 1.3 Physico-chemical properties

Table 5: Overview of physicochemical properties

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	solid	
Boiling point	682.7 °C at 1013 hPa	Calculated using Advanced Chemistry Development (ACD/Labs) Software V11.02 (© 1994-2012 ACD/Labs)
Water solubility at 25 °C	0.13 mg/l at pH 4 1.6 µg/l at pH 7 1.6 µg/l at pH 9	Calculated using Advanced Chemistry Development (ACD/Labs) Software V11.02 (© 1994-2012 ACD/Labs)
Partition coefficient n-octanol/water (log value)	7.492 at 25 °C	Calculated using Advanced Chemistry Development (ACD/Labs) Software V11.02 (© 1994-2012 ACD/Labs)
Density at 20 °C	1.199 gcm <sup>-3</sup>	Calculated using Advanced Chemistry Development (ACD/Labs) Software V11.02 (© 1994-2012 ACD/Labs)

## 2 HARMONISED CLASSIFICATION AND LABELLING

$\alpha,\alpha$ -Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) is not itself listed in Annex VI of Regulation (EC) No 1272/2008 (the CLP Regulation).

However, according to Article 10(1) of the CLP Regulation, specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance (or in a mixture) as an identified impurity, additive or individual constituent leads to the classification of the substance (or mixture) as hazardous.

For Michler's ketone and Michler's base no specific concentration limits are set in Annex VI of the CLP Regulation and therefore the generic concentration limit is to be used for the purpose of determining classification of substances (or mixtures) containing Michler's ketone and/or Michler's base. The generic concentration limit for carcinogens, Carc. 1B is 0.1%, as set out in Table 3.6.2 in Part 3 of Annex I to the CLP Regulation.

### C.I. Solvent Blue 4 with Michler's ketone ≥ 0.1%

Therefore, on such basis, the classification of C.I. Solvent Blue 4 where it contains Michler's ketone ≥ 0.1% (wt/wt) is as follows:

Table 6: Classification of C.I. Solvent Blue 4 where it contains Michler's ketone ≥ 0.1% according to Art. 10 and Table 3.6.2 in Part 3 of Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), on the basis of the entry with index number 606-073-00-0 in Part 3 of Annex VI to CLP Regulation, Table 3.1

Substance name	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	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)		
C.I. Solvent Blue 4 with Michler's ketone ≥ 0.1%	229-851-8	6786-83-0	Carc. 1B Muta. 2 Eye Dam. 1	H350 H341 H318	GHS08 GHS05 Dgr	H350 H341 H318	-	-	-

Table 7: Classification of C.I. Solvent Blue 4 where it contains Michler's ketone ≥ 0.1% according to Art. 10 and Table 3.6.2 in Part 3 of Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), on the basis of the entry with index number 606-073-00-0 in Part 3 of Annex VI to CLP Regulation, Table 3.2

Substance name	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
C.I. Solvent Blue 4 with Michler's ketone ≥ 0.1%	229-851-8	6786-83-0	Carc. Cat. 2; R45 Muta. Cat. 3; R68 Xi; R41	T R: 45-41-68 S: 53-45	-	-



**C.I. Solvent Blue 4 with Michler's base ≥ 0.1%**

On the same basis, the classification of C.I. Solvent Blue 4 where it contains Michler's base ≥ 0.1% (wt/wt) is as follows:

Table 8: Classification of C.I. Solvent Blue 4 where it contains Michler's base ≥ 0.1% according to Art. 10 and Table 3.6.2 in Part 3 of Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), on the basis of the entry with index number 612-201-00-6 in Part 3 of Annex VI to CLP Regulation, Table 3.1

Substance name	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	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)		
C.I. Solvent Blue 4 with Michler's base ≥ 0.1%	229-851-8	6786-83-0	Carc. 1B Aquatic Acute 1  Aquatic Chronic 1	H350 H400 H410	GHS08 GHS09 Dgr	H350 H410	-	-	-

Table 9: Classification of C.I. Solvent Blue 4 where it contains Michler's base ≥ 0.1% according to Art. 10 and Table 3.6.2 in Part 3 of Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), on the basis of the entry with index number 612-201-00-6 in Part 3 of Annex VI to CLP Regulation, Table 3.2

Substance name	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
C.I. Solvent Blue 4 with Michler's base ≥ 0.1%	229-851-8	6786-83-0	Carc. Cat. 2; R45 N; R50-53	T; N R: 45-50/53 S: 53-45-60-61	-	-

### **3 ENVIRONMENTAL FATE PROPERTIES**

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

### **4 HUMAN HEALTH HAZARD ASSESSMENT**

See section 2 on harmonised classification and labelling.

### **5 ENVIRONMENTAL HAZARD ASSESSMENT**

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

## **6 CONCLUSIONS ON THE SVHC PROPERTIES**

### **6.1 CMR Assessment**

Michler's ketone (4,4'-bis(dimethylamino)benzophenone; EC Number: 202-027-5) is listed as Index number 606-073-00-0 in Regulation (EC) No 1272/2008 (the CLP Regulation) and classified in Annex VI, part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as carcinogen, Carc. 1B (H350: "May cause cancer.") The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of the CLP Regulation is carcinogen, Carc. Cat. 2, R45 ("May cause cancer.")

Michler's base (N,N,N',N'-tetramethyl-4,4'-methylenedianiline; EC Number: 202-959-2) is listed as Index number 612-201-00-6 in the CLP Regulation and classified in Annex VI, part 3, Table 3.1 as carcinogen, Carc. 1B (H350: "May cause cancer.") The corresponding classification in Annex VI, part 3, Table 3.2 of the CLP Regulation is carcinogen, Carc. Cat. 2, R45 ("May cause cancer.")

According to Article 10(1) of the CLP Regulation, specific concentration limits and generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in another substance (or in a mixture) as an identified impurity, additive or individual constituent leads to the classification of the substance (or mixture) as hazardous.

For Michler's ketone and Michler's base no specific concentration limits are set in Annex VI of the CLP Regulation and therefore the generic concentration limit is to be used for the purpose of determining classification of substances (or mixtures) containing Michler's ketone and/or Michler's base. The generic concentration limit for carcinogens, Carc. 1B is 0.1%, as set out in Table 3.6.2 in Part 3 of Annex I to the CLP Regulation.

Therefore, the above classifications of Michler's ketone and Michler's base in Regulation (EC) No 1272/2008 show that where the substance  $\alpha,\alpha$ -Bis[4-(dimethylamino)phenyl]-4-(phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) contains Michler's ketone or Michler's base  $\geq 0.1\%$  it meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.