

Substance name: [4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26)¹

EC number: 219-943-6
CAS number: 2580-56-5

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

[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26)
[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
CMR² PROPERTIES**

Adopted on 7 June 2012

¹ 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)

² CMR means carcinogenic, mutagenic or toxic for reproduction

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Substance Name(s): [4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride³ (C.I. Basic Blue 26)

EC Number(s): 219-943-6

CAS Number(s): 2580-56-5

- 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 1B⁴ which corresponds to classification as carcinogen category 2⁵.

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 Annex VI to the CLP Regulation show that where the substance [4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) 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

³ 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)

⁴ 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.

⁵ 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

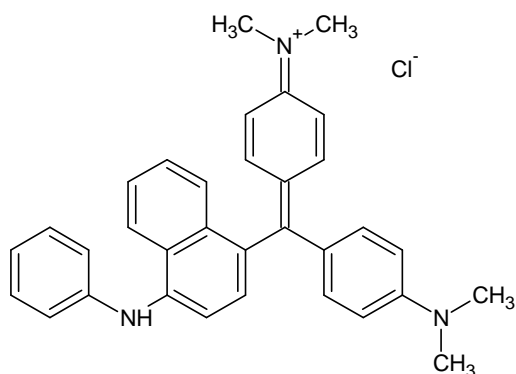
1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	219-943-6
EC name:	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride
CAS number (in the EC inventory):	2580-56-5
Deleted CAS number:	97930-07-9
CAS name:	Methanaminium, N-[4-[[4-(dimethylamino)phenyl][4-(phenylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, chloride (1:1)
IUPAC name:	4-{[4-(Dimethylamino)phenyl][4-(phenylamino)naphthalen-1-yl]methylidene}-N,N-dimethylcyclohexa-2,5-dien-1-iminium chloride
Index number in Annex VI of the CLP Regulation	
Molecular formula:	C ₃₃ H ₃₂ ClN ₃
Molecular weight:	506.1 g/mol
Synonyms:	<ul style="list-style-type: none"> – C.I. Basic Blue 26 – Methanaminium, N-[4-[[4-(dimethylamino)phenyl][4-(phenylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, chloride – Victoria Blue B – ADC Victoria Blue B – Aizen Victoria Blue BH – BTK Victoria Blue – Basazol C Blue 57 – Basic Blue – 26; Basic Blue B – Basic Victoria Blue B – Basonyl Blue 640 – Basonyl Blue 644 – Basovict Victoria Blue – C-WR Blue 8 – C.I. 44045

	<ul style="list-style-type: none"> – Calcozine Blue B – Conbasic Blue AK – Dycosbasic Victoria Blue B – Flexo Blue 630 – Flexo Blue 640 – Hecto Blue B – Hidaco Victoria Blue B – Libbase Victoria Blue LB – Lowacryl Blue 26 – Mitsui Victoria Blue B – Ravi Victoria Blue B – Tertrophen Blue – Victoria Blue – Victoria Blue 2B – Victoria Blue B 353 – Victoria Blue B chloride – Victoria Blue BA – Victoria Blue BH – Victoria Blue BN – Victoria Blue BN CI 44045 – Victoria Blue BP – Victoria Blue BS – Victoria Blue BSA – Victoria Blue BX – Victoria Blue FB – Victoria Pure Blue B – Victoria Pure Blue BC
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Structural formula:



1.2 Composition of the substance

Name: [4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride

Description: ---

Degree of purity: see confidential Annex

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride EC #: 219-943-6		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	According to the information derived from the C&L notifications.
Further impurities: Confidential information			According to the information derived from the C&L notifications.

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
None			According to the information derived from the C&L notifications.

1.3 Physico-chemical properties

No information available

2 HARMONISED CLASSIFICATION AND LABELLING

[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) 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. Basic Blue 26 with Michler's ketone ≥ 0.1%

Therefore, on such basis, the classification of C.I. Basic Blue 26 where it contains Michler's ketone ≥ 0.1% (wt/wt) is as follows:

Table 5: Classification of C.I. Basic Blue 26 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. Basic Blue 26 with Michler's ketone ≥ 0.1%	219-943-6	2580-56-5	Carc. 1B Muta. 2 Eye Dam. 1	H350 H341 H318	GHS08 GHS05 Dgr	H350 H341 H318	-	-	-

Table 6: Classification of C.I. Basic Blue 26 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. Basic Blue 26 with Michler's ketone ≥ 0.1%	219-943-6	2580-56-5	Carc. Cat. 2; R45 Muta. Cat. 3; R68 Xi; R41	T R: 45-41-68 S: 53-45	-	-

C.I. Basic Blue 26 with Michler's base ≥ 0.1%

On the same basis, the classification of C.I. Basic Blue 26 where it contains Michler's base ≥ 0.1% (wt/wt) is as follows:

Table 7: Classification of C.I. Basic Blue 26 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. Basic Blue 26 with Michler's base ≥ 0.1%	219-943-6	2580-56-5	Carc. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H400 H410	GHS08 GHS09 Dgr	H350 H410	-	-	-

Table 8: Classification of C.I. Basic Blue 26 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. Basic Blue 26 with Michler's base ≥ 0.1%	219-943-6	2580-56-5	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.")

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Therefore, the above classifications of Michler's ketone and Michler's base in Annex VI to the CLP Regulation show that where the substance [4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) contains Michler's ketone or Michler's base ≥ 0.1% it meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.