



Substance name: [4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride
(C.I. Basic Violet 3) ¹
EC number: 208-953-6
CAS number: 548-62-9

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

[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)
[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

CONTENTS

JUSTIFICATION	6
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES.....	6
1.1 Name and other identifiers of the substance	6
1.2 Composition of the substance.....	7
1.3 Physico-chemical properties	8
2 HARMONISED CLASSIFICATION AND LABELLING.....	9
3 ENVIRONMENTAL FATE PROPERTIES	11
4 HUMAN HEALTH HAZARD ASSESSMENT	11
5 ENVIRONMENTAL HAZARD ASSESSMENT	11
6 CONCLUSIONS ON THE SVHC PROPERTIES.....	11
6.1 CMR Assessment	11

TABLES

Table 1: Substance identity	6
Table 2: Constituents	7
Table 3: Impurities	8
Table 4: Additives	8
Table 5: Classification of C.I. Basic Violet 3 according to Part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008	9
Table 6: Classification of C.I. Basic Violet 3 according to Part 3 of Annex VI, Table 3.2 (list of harmonized classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008	9
Table 7: Classification of C.I. Basic Violet 3 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	10
Table 8: Classification of C.I. Basic Violet 3 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	11

Substance Name(s): [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) ³

EC Number(s): 208-953-6

CAS Number(s): 548-62-9

- 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) ≥ 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

[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) with Michler's ketone ≥ 0.1% is listed as index number 612-205-00-8 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the 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 Regulation (EC) No 1272/2008 is carcinogen, Carc. Cat. 2, R45 ("May cause cancer.")

Therefore, this classification of [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) in Regulation (EC) No 1272/2008 shows that where it contains Michler's ketone ≥ 0.1% it meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.

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 base no specific concentration limit is 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 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.

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) ≥ 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).

Therefore, the above classification of Michler's base in Annex VI to Regulation (EC) No 1272/2008 show that where the substance [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) contains Michler's base $\geq 0.1\%$ it also meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.

Registration dossiers submitted for the substance: Yes

JUSTIFICATION

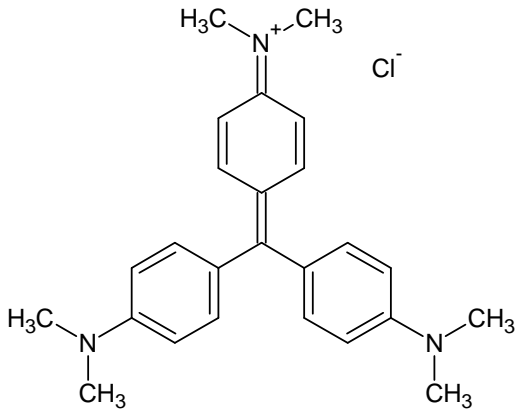
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	208-953-6
EC name:	[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride
CAS number (in the EC inventory):	548-62-9
Deleted CAS numbers:	<ul style="list-style-type: none"> – 7077-31-8 – 23355-47-7
CAS numbers indicated in the Colour Index International for Basic Violet 3	<ul style="list-style-type: none"> – 548-62-9 – 603-48-5 – 14426-25-6
CAS name:	Methanaminium, N-[4-[bis[4-(dimethylamino)phenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, chloride (1:1)
IUPAC name:	4-{Bis[4-(dimethylamino)phenyl]methylidene}-N,N-dimethylcyclohexa-2,5-dien-1-iminium chloride
Index number in Annex VI of the CLP Regulation	612-204-00-2, 612-205-00-8
Molecular formula:	C ₂₅ H ₃₀ ClN ₃
Molecular weight:	408 g/mol
Synonyms:	<ul style="list-style-type: none"> – C.I. Basic Violet 3 – Basic Violet 3 – Crystal Violet Technical – Crystal Violet USP – Gentsal – Gentian violet – Gentian Violet B – Gentiaverm – Genticid – Genticid – Genticid – Genticid – Genticid – Genticid – Hecto Violet R – Hectograph Violet SR – Hexamethyl violet – Hexamethyl-p-rosaniline chloride – Hexamethylpararosaniline chloride

Structural formula:



1.2 Composition of the substance

Name: [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride

Description: ---

Degree of purity: > 76 % - < 90 % (w/w) (according to information received in registration dossiers)

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride EC #: 208-953-6		> 76 % - < 90 %	According to information from registration dossiers.

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
4,4'-bis(dimethylamino)benzophenone EC #: 202-027-5		Confidential information	According to information from registration dossiers.
N,N,N',N'-tetramethyl-4,4'-methylenedianiline EC #: 202-959-2		Confidential information	According to information from registration dossiers.
Further impurities: Confidential information			According to information from registration dossiers.

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
None			According to information from registration dossiers.

1.3 Physico-chemical properties

No information available

2 HARMONISED CLASSIFICATION AND LABELLING

C.I. Basic Violet 3 with Michler's ketone ≥ 0.1%

[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) is listed as index numbers 612-204-00-2 and 612-205-00-8 in Annex VI of Regulation (EC) No 1272/2008 as follows:

Table 5: Classification of C.I. Basic Violet 3 according to Part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

International Chemical Identification	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 Violet 3; 4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride	208-953-6	548-62-9	Carc. 2 Acute Tox. 4 * Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H318 H400 H410	GHS08 GHS05 GHS07 GHS09 Dgr	H351 H302 H318 H410	-	-	-
C.I. Basic Violet 3 with ≥ 0,1 % of Michler's ketone (EC no. 202-027-5)	208-953-6	548-62-9	Carc. 1B Acute Tox. 4 * Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H350 H302 H318 H400 H410	GHS08 GHS05 GHS07 GHS09 Dgr	H350 H302 H318 H410	-	-	-

* Indicates that the classification corresponds to the minimum classification for a category

Table 6: Classification of C.I. Basic Violet 3 according to Part 3 of Annex VI, Table 3.2 (list of harmonized classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008

International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride	208-953-6	548-62-9	Carc. Cat. 3; R40 Xn; R22 Xi; R41 N; R50-53	Xn; N R: 22-40-41-50/53 S: (2-)26-36/37/39-46-60-61	-	-
C.I. Basic Violet 3 with ≥ 0.1 % of Michler's ketone (EC no. 202-027-5)	208-953-6	548-62-9	Carc. Cat. 2; R45 Xn; R22 Xi; R41 N; R50-53	T; N R: 45-22-41-50/53 S: 53-45-60-61	-	E

Note E:

Substances with specific effects on human health (see Chapter 4 of Annex VI to Directive 67/548/EEC) that are classified as carcinogenic, mutagenic and/or toxic for reproduction in categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn). For these substances, the risk phrases R20, R21, R22, R23, R24, R25, R26, R27, R28, R39, R68 (harmful), R48 and R65 and all combinations of these risk phrases shall be preceded by the word 'Also'.

C.I. Basic Violet 3 with Michler's base ≥ 0.1%

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 base no specific concentration limit is 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 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, on such basis, the classification of C.I. Basic Violet 3 where it contains Michler's base ≥ 0.1% (wt/wt) is as follows:

Table 7: Classification of C.I. Basic Violet 3 where it contains Michler's base ≥ 0.1% according to Article 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 Violet 3 with Michler's base ≥ 0.1%	208-953-6	548-62-9	Carc. 1B Acute Tox. 4 * Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H350 H302 H318 H400 H410	GHS08 GHS05 GHS07 GHS09 Dgr	H350 H302 H318 H410	-	-	-

* Indicates that the classification corresponds to the minimum classification for a category

Table 8: Classification of C.I. Basic Violet 3 where it contains Michler's base ≥ 0.1% according to Article 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 Violet 3 with Michler's base ≥ 0.1%	208-953-6	548-62-9	Carc. Cat. 2; R45 Xn; R22 Xi; R41 N; R50-53	T; N R: 45-22- 41-50/53 S: 53-45- 60-61	-	E

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

[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) with Michler's ketone ≥ 0.1% is listed as index number 612-205-00-8 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the 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 Regulation (EC) No 1272/2008 is carcinogen, Carc. Cat. 2, R45 ("May cause cancer.")

Therefore, this classification of [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) in Regulation (EC) No 1272/2008 shows that where it contains Michler's ketone ≥ 0.1% it meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.

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 base no specific concentration limit is 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 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 classification of Michler's base in Annex VI to Regulation (EC) No 1272/2008 shows that where the substance [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) contains Michler's base $\geq 0.1\%$ it also meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.