

AGREEMENT OF THE MEMBER STATE COMMITTEE

**ON THE IDENTIFICATION OF
[4-[4,4-BIS(DIMETHYLAMINO) BENZHYDRYLIDENE]CYCLOHEXA-2,5-DIEN-1-
YLIDENE]DIMETHYLAMMONIUM CHLORIDE (C.I. BASIC VIOLET 3)
[with $\geq 0.1\%$ 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

**According to Articles 57 and 59 of
Regulation (EC) 1907/2006¹**

Adopted on 7 June 2012

This agreement concerns

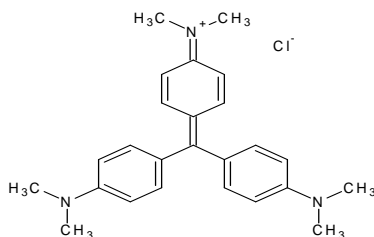
Substance name: [4-[4,4-bis(dimethylamino)
benzhydrylidene]cyclohexa-2,5-dien-1-
ylidene]dimethylammonium chloride (C.I. Basic
Violet 3)²

EC number: 208-953-6

CAS number: 548-62-9

Molecular formula: C₂₅H₃₀ClN₃

Structural formula:



¹Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

² 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)

European Chemicals Agency on behalf of the European Commission presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (27 February 2012, submission number CT011701-41) on identification of *[4-[4,4-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)* as a substance of very high concern due to its carcinogenic properties.

The Annex XV dossier was circulated to Member States on 27 February 2012 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received by both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 14 May 2012 and was discussed in the meeting on 6-8 June 2012 of the Member State Committee.

Agreement of the Member State Committee in accordance with Article 59(8):

[4-[4,4-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Violet 3) where it contains Michler's ketone (EC Number: 202-027-5) or Michler's base (EC Number: 202-959-2) ≥ 0.1% is identified as a substance meeting the criteria of Article 57 (a) of Regulation (EC) 1907/2006 (REACH) owing to its classification as carcinogen category 1B³. This classification corresponds to classification as carcinogen category 2⁴.

³ 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 [as amended and adapted to technical and scientific progress by Commission Regulation (EC) No 790/2009, OJ No L 235, p. 1, 5.9.2009].

⁴ 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), [as amended and adapted to technical and scientific progress by Commission Regulation (EC) No 790/2009, OJ No L 235, p. 1, 5.9.2009]

**UNDERLYING ARGUMENTATION
FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN**

Carcinogenicity:

[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) with Michler's ketone $\geq 0.1\%$ 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 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 $\geq 0.1\%$ 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, 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 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 [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.

Reference:

1. Support Document [4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)⁵ (MSC, 7 June 2012)

⁵ The substance is identified as SVHC only where it contains Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2) $\geq 0.1\%$ (wt/wt)