

Annex XV dossier

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR 1A OR 1B, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name(s): 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol*

EC Number(s): 209-218-2

CAS Number(s): 561-41-1

Submitted by: European Chemicals Agency at the request of the European Commission

PUBLIC VERSION: *This version does not include the confidential annexes to Parts I and II.*

* The substance is proposed only where it contains Michler's ketone (EC Number: 202-027-5) or/and Michler's base (EC Number: 202-959-2) \geq 0.1% (wt/wt)

CONTENTS

PART I.....	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	9
2 HARMONISED CLASSIFICATION AND LABELLING.....	10
3 ENVIRONMENTAL FATE PROPERTIES.....	12
4 HUMAN HEALTH HAZARD ASSESSMENT	12
5 ENVIRONMENTAL HAZARD ASSESSMENT	12
6 CONCLUSIONS ON THE SVHC PROPERTIES.....	12
6.1 CMR Assessment	12
PART II.....	13
1 Manufacture, import, export.....	13
2 Uses.....	14
3 Alternatives.....	16
4 References.....	16

TABLES

Table 1: Substance identity.....	6
Table 2: Constituents.....	8
Table 3: Impurities	8
Table 4: Additives	8
Table 5: Overview of physicochemical properties	9
Table 6: <i>Classification of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) where it contains Michler's ketone $\geq 0.1\%$ 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.....</i>	10
Table 7: <i>Classification of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) where it contains Michler's ketone $\geq 0.1\%$ 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.....</i>	10
Table 8: <i>Classification of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) where it contains Michler's base $\geq 0.1\%$ 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.....</i>	11
Table 9: <i>Classification of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) where it contains Michler's base $\geq 0.1\%$ 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.....</i>	11

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR 1A OR 1B, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name(s): 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol)²

EC Number(s): 209-218-2

CAS Number(s): 561-41-1

- The substance is proposed to be 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/and Michler's base (EC Number: 202-959-2) $\geq 0.1\%$, owing to its classification as carcinogen category 1B³ which corresponds to classification as carcinogen category 2⁴.

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 Art. 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

² The substance is proposed 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)

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.

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).

ANNEX XV – IDENTIFICATION OF 4,4'-BIS(DIMETHYLAMINO)-4''-(METHYLAMINO)TRITYL
ALCOHOL WITH MICHLER'S KETONE OR MICHLER'S BASE $\geq 0.1\%$ AS SVHC

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 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) 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

PART I

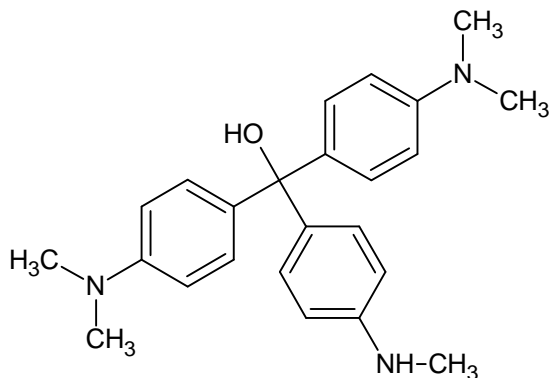
JUSTIFICATION

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:	209-218-2
EC name:	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol
CAS number (in the EC inventory):	561-41-1
CAS number:	561-41-1
CAS name:	Benzenemethanol, α,α -bis[4-(dimethylamino)phenyl]-4-(methylamino)-
IUPAC name:	Bis[4-(dimethylamino)phenyl][4-(methylamino)phenyl]methanol
Index number in Annex VI of the CLP Regulation	
Molecular formula:	$C_{24} H_{29} N_3 O$
Molecular weight range:	375.5 g/mol
Synonyms:	The information is derived from the C&L notification received. Some notifiers indicated as a synonym of the substance Solvent Violet 8. However the Colour Index International identifies Solvent Violet 8 with the CAS numbers 52080-58-7 and 67989-22-4 as well with the EC number 268-006-8 which does not match the numerical identifiers with which the substance is notified.

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

For each constituent/ impurity/ additive, fill in the following tables. The information is particularly important for the main constituent(s) and for the constituents (or impurities) which influence the outcome of the evaluation.

Name: 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol

Description: ---

Degree of purity: see confidential Annex

ANNEX XV – IDENTIFICATION OF 4,4'-BIS(DIMETHYLAMINO)-4''-(METHYLAMINO)TRITYL ALCOHOL WITH MICHLER'S KETONE OR MICHLER'S BASE $\geq 0.1\%$ AS SVHC

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
4,4'-bis (dimethylamino)-4''-(methylamino)trityl alcohol EC #: 209-218-2		See confidential Annex	Information from C&L notifications

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
4,4'-bis(dimethylamino)benzophenone EC #: 202-027-5		See confidential Annex	Information derived from the C&L notifications
N,N,N',N'-tetramethyl-4,4'-methylenedianiline EC #: 202-959-2		See confidential Annex	Information derived from the C&L notifications
Further impurities: see confidential Annex			Information derived from the C&L notifications

Table 4: Additives

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

ANNEX XV – IDENTIFICATION OF 4,4'-BIS(DIMETHYLAMINO)-4''-(METHYLAMINO)TRITYL ALCOHOL WITH MICHLER'S KETONE OR MICHLER'S BASE $\geq 0.1\%$ AS SVHC

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	575.3 °C at 1013 hPa	Calculated using Advanced Chemistry Development (ACD/Labs) Software V11.02 (© 1994-2012 ACD/Labs)
Vapour pressure	6×10^{-11} Pa at 25 °C	Calculated using Advanced Chemistry Development (ACD/Labs) Software V11.02 (© 1994-2012 ACD/Labs)
Water solubility at 25 °C	1.8 g/l at pH 4 1.7 mg/l at pH 7 1.5 mg/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)	3.926 at 25 °C	Calculated using Advanced Chemistry Development (ACD/Labs) Software V11.02 (© 1994-2012 ACD/Labs)
Density at 20 °C	1.152 gcm ⁻³	Calculated using Advanced Chemistry Development (ACD/Labs) Software V11.02 (© 1994-2012 ACD/Labs)

2 HARMONISED CLASSIFICATION AND LABELLING

4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) is not itself listed in Annex VI of Regulation (EC) No 1272/2008.

However, according to Art. 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.

4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) with Michler's ketone $\geq 0.1\%$

Therefore, on such basis, the classification of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) where it contains Michler's ketone $\geq 0.1\%$ (wt/wt) is as follows:

Table 6: Classification of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) where it contains Michler's ketone $\geq 0.1\%$ 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)		
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol)with Michler's ketone $\geq 0.1\%$	209-218-2	561-41-1	Carc. 1B Muta. 2 Eye Dam. 1	H350 H341 H318	GHS08 GHS05 Dgr	H350 H341 H318	-	-	-

Table 7: Classification of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) where it contains Michler's ketone $\geq 0.1\%$ 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

ANNEX XV – IDENTIFICATION OF 4,4'-BIS(DIMETHYLAMINO)-4''-(METHYLAMINO)TRITYL ALCOHOL WITH MICHLER'S KETONE OR MICHLER'S BASE ≥0.1% AS SVHC

4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) with Michler's ketone ≥ 0.1%	209-218-2	561-41-1	Carc. Cat. 2; R45 Muta. Cat. 3; R68 Xi; R41	T R: 45-41-68 S: 53-45	-	-
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4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) with Michler's base ≥ 0.1%

On the same basis, the classification of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) where it contains Michler's base ≥ 0.1% (wt/wt) is as follows:

Table 8: *Classification of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) 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)		
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) with Michler's base ≥ 0.1%	209-218-2	561-41-1	Carc. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H400 H410	GHS08 GHS09 Dgr	H350 H410	-	-	-

Table 9: *Classification of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) 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
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) with Michler's base ≥ 0.1%	209-218-2	561-41-1	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 Art. 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 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) 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.

PART II

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

1. MANUFACTURE, IMPORT, EXPORT

1.1 REACH Registration and C&L notification data

No registration had been submitted for 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol by the time of submission of this report for identification of the substance as SVHC. As the substance is not itself listed in Annex VI of Regulation (EC) No 1272/2008 as CMR, the registration deadline of 2010 was relevant for that substance only in case of impurities (/constituents / additives) above the thresholds which lead to a CMR (cat. 1A or 1B) classification (and tonnage at or above 1 t/y)⁵; or in case of manufacture / import at or above 1,000 t/y.

Overall 7 classification & labelling notifications (on behalf of approx. 200 legal entities) had been submitted for 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol at the time of the development of this report. The notifications included also case(s) with Michler's ketone and/or Michler's base as impurity, and classification(s) as Carcinogen 1B.

1.2 Data from EU Member States

Of the Member States contacted, six provided responses, which though were negative as regards the presence of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol on their market:

- Not registered by Dutch companies;
- Not on the market with Michler's ketone / Michler's base $\geq 0.1\%$ in Finland;
- No information on use of the substance on the Nordic SPIN database or on Denmark's database on substances in consumer products (i.e. database on substances identified in consumer products in various Danish projects conducted during the last 10-15 years);
- No import to / export from Estonia has been registered to customs authorities;
- No info held on the substance by the United Kingdom;
- No manufacture / import of substance or mixture above 0.1 t/y in Sweden (Swedish Products Register, 2009)

⁵ or in cases of self-classification of the substance itself as CMR (cat. 1A or 1B) or dangerous to aquatic organisms or the environment, and annual tonnages at or above 1t/y or 100t/y respectively.

1.3 Consultation with industry stakeholders

Questionnaires were sent to companies identified in ECHA's classification & labelling notifications database⁶ or from other sources on the internet. Furthermore, questionnaires were sent to industry associations, including four trade associations (ETAD, VdMi, CEPE, EuPIA) and six pulp and paper associations (CEPI, INTERGRAF, CEPIPRINT, EADP, FAEP, ENPA).

CEPE (European Council of producers and importers of paints, printing inks and artists' colours) performed a survey with a negative result as results uses in coatings or inks. No information was directly available to INTERGRAF (International confederation for printing & allied industries). It was noted that EuPIA (the European Printing Ink Association) has published an "Exclusion List for Printing inks and Related Products" (EuPIA, 2011), which is a commitment of ink manufacturers not to use dangerous substances. It is a list that describes "substances previously used or relevant in the formulation of printing inks that must be avoided and which under normal established and foreseeable conditions of use in the manufacture and application of printing inks would cause a risk to health". This list includes, among others, substances / mixtures with CMR 1A/1B classification as well as explicitly Michler's ketone. In that publication it is mentioned that the majority of raw materials used in printing inks are produced under commercial industrial conditions and may contain unavoidable impurities, mostly in small quantities. As some of these impurities may be on the exclusion list, every effort is made to ensure that they are at a minimum level. The EuPIA Exclusion List is by its nature a recommendation and does not constitute legal obligations. It is though reported by the Association to have the full support of all of its printing ink manufacturer members.

The accrued amount of the substance imported in 2011 into the EU by the responding companies was >10 tons. It is noted that only part of the contacted notifying companies replied and filled in the questionnaire, while this consultation did not cover all notifying companies (see footnote).

The tonnage that was identified by the responding companies was reported to be with a content of Michler's ketone and Michler's base below 0.1%.

A fraction of the products containing 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol was exported from the EU.

2. USES

2.1 Uses according to the literature

Although some companies that submitted classification and labelling notifications indicated "Solvent Violet 8" as a synonym of the substance 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol, the Colour Index International identifies Solvent Violet 8 with EC and CAS numbers which do not match the numerical identifiers of the substance 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol. In the paragraphs of this section (2.1),

⁶ During the consultation, only companies which had submitted single-substance notifications (i.e. not bulk notifications) were contacted. Companies were contacted regardless of the notified impurity profile. When the submission had been made by a group of Manufacturers / Importers, only the submitting legal entity was contacted.

ANNEX XV – IDENTIFICATION OF 4,4'-BIS(DIMETHYLAMINO)-4''-(METHYLAMINO)TRITYL ALCOHOL WITH MICHLER'S KETONE OR MICHLER'S BASE $\geq 0.1\%$ AS SVHC

the information on potential uses/applications refers to Solvent Violet 8 and the products containing, as it is cited by public on-line sources.

According to Gessner and Mayer (2000), Solvent Violet 8 is used in **inks and dyes**, e.g. in the production of stamping inks, hectographic inks, and inking ribbons. Among potential uses registered by companies in the Colour Index (2012)⁷, for products (dyestuff) containing Solvent Violet 8 are uses in inks such as for ball point pens, computer cartridges, typewriter ribbons, as well as in spirit inks and rotogravure inks.

Solvent Violet 8 (/its products) are also used **dyeing a variety of materials**: In Colour Index the materials listed include paper (copying, carbon), packaging, distemper, wood, lacquers, plastics, and feathers; while chemical catalogues refer additionally to uses in leather, as well as in candle and rubber; moreover, Gessner and Mayer (2000) refer also to use in black dyes for polyacrylonitrile materials. Furthermore, according to the Colour Index potential uses include also dyeing of **oil and fat products**, as well as **soaps**.

The products (dyestuff) containing Solvent Violet 8 could have a diluent, but it would have to be soluble in solvents that are used to dissolve the dye. The commercial products listed can be supplied as powders or as pastes used for ballpoint pens, coatings on carbon paper, spirit inks etc. (personal communication with Society of Dyers and Colourists).

At the website of an Indian company Solvent Violet 8 is reported to being extensively used in **fertilizers**.

Finally, the literature refers to uses of Solvent Violet 8 in **diagnostic, analytical, and R&D applications**, such as biological stain, while in chemical catalogues it is also reported to be used as **anti-allergen** and **bactericide**.

2.2 Identified uses in the EU

The individual EU companies consulted reported uses of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol such as formulation and production of **writing inks**.

2.3 Releases from uses

In the information provided during the consultation, as relevant routes of occupational exposure during formulation inhalation and skin contact were mentioned. However not detectable exposure levels were reported. Risk Management Measures applied included exhaust, filters, and protective clothing. The total number of employees exposed in the companies that answered the questionnaire and provided relevant information is below 100.

As regards environmental releases, the amount going to waste was estimated to be negligible, with otherwise no releases anticipated for the environmental compartments.

⁷ The registrations made / applications listed by some companies in the Colour Index database may some times be inaccurate / refer to a wider range of products (personal communication with Society of Dyers and Colourists)

3. ALTERNATIVES

Some information was provided during the consultation in relation to alternatives. According to this information, no practical experience with alternatives could be reported; work on alternatives had been done in the past, but without success in the past.

As limiting factors, that could not be overcome, price, technical, or performance-related issues were listed.

It appears that grades of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol not containing Michler's ketone or Michler's base at or above the CMR threshold are available on the market, as the consulted companies indicated to be using such grades. It is not known whether these grades are the result of alternative reaction, alternative synthesis conditions, or better purification of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol.

Purification appears at least to be a main option. Purification of triarylmethane dyes usually involves physical processes such as membrane filtration or chemical processes such as salting the mother liquors (Thetford, 2000).

4. REFERENCES

Colour Index International (2012), Society of Dyers and Colourists and American Association of Chemists and Colourists, www.colour-index.com

EuPIA (2011) Exclusion List for Printing inks and Related Products (7th edition revised http://cepe-myeteam.eudata.be/EPUB//easnet.dll/GetDoc?APPL=1&DAT_IM=104F19&DWNLD=2011-04-07_Exclusion_List_for_Printing_Inks_and_Related_Products_7th_edition_corr_Nov2011.pdf as of November 2011

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Thetford, D. (2000) Triphenylmethane and related dyes. In: Kirk-Othmer Encyclopedia of Chemical Technology. John Wiley & Sons, Inc.
