

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

EC Number(s): 229-851-8

CAS Number(s): 6786-83-0

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 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.....	6
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.....	15
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 C.I. Solvent Blue 4 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 C.I. Solvent Blue 4 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 C.I. Solvent Blue 4 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 C.I. Solvent Blue 4 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

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Substance Name(s): α,α -Bis[4-(dimethylamino)phenyl]-4(phenylamino)naphthalene-1-methanol² (C.I. Solvent Blue 4)

EC Number(s): 229-851-8

CAS Number(s): 6786-83-0

- 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 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 of determining classification of substances (or mixtures) containing Michler's ketone and/or

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 C.I. SOLVENT BLUE 4 WITH MICHLER'S KETONE OR
MICHLER'S BASE $\geq 0.1\%$ AS SVHC

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 α,α -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

PART I

JUSTIFICATION

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

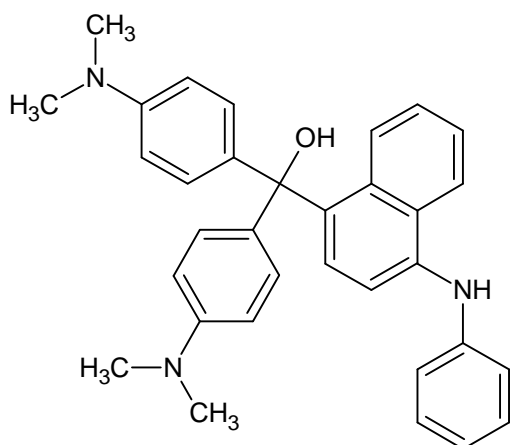
Table 1: Substance identity

EC number:	229-851-8
EC name:	α,α -bis[4-(dimethylamino)phenyl]-4-(phenylamino)naphthalene-1-methanol
CAS number (in the EC inventory):	6786-83-0
CAS number:	6786-83-0
Deleted CAS number(s):	1325-91-3
CAS name:	1-Naphthalenemethanol, α,α -bis[4-(dimethylamino)phenyl]-4-(phenylamino)-
IUPAC name:	[4-(Dimethylamino)-5,8-dihydronaphthalen-1-yl]{bis[4-(dimethylamino)phenyl]}methanol
Index number in Annex VI of the CLP Regulation	
Molecular formula:	$C_{33} H_{33} N_3 O$
Molecular weight range:	487.6 g/mol
Synonyms:	<ul style="list-style-type: none"> – C.I. Solvent Blue 4 – Victoria Blue B – Base B – Baso Blue 645; – Aizen Victoria Blue B Base; – Brilliant Oil Blue B Base; – C.I. 44045B; – Fast Oil Blue B Base – Victoria Blue B Base

ANNEX XV – IDENTIFICATION OF C.I. SOLVENT BLUE 4 WITH MICHLER'S KETONE OR
MICHLER'S BASE $\geq 0.1\%$ AS SVHC

	<ul style="list-style-type: none"> - Victoria Blue BA Base - Victoria Blue BDP Base - Victoria Blue Base - Victoria Blue Base B - Victoria Blue Base FB - Waxoline Victoria Blue B
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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

ANNEX XV – IDENTIFICATION OF C.I. SOLVENT BLUE 4 WITH MICHLER'S KETONE OR
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Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
α,α -bis[4-(dimethylamino)phenyl]-4-(phenylamino)naphthalene-1-methanol EC #: 229-851-8		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
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

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 ⁻³	Calculated using Advanced Chemistry Development (ACD/Labs) Software V11.02 (© 1994-2012 ACD/Labs)

2 HARMONISED CLASSIFICATION AND LABELLING

α,α -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 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.

C.I. Solvent Blue 4 with Michler's ketone $\geq 0.1\%$

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

Table 6: Classification of C.I. Solvent Blue 4 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)		
C.I. Solvent Blue 4 with Michler's ketone $\geq 0.1\%$	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 $\geq 0.1\%$ 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
C.I. Solvent Blue 4 with Michler's ketone $\geq 0.1\%$	229-851-8	6786-83-0	Carc. Cat. 2; R45 Muta. Cat. 3; R68 Xi; R41	T R: 45-41-68 S: 53-45	-	-

ANNEX XV – IDENTIFICATION OF C.I. SOLVENT BLUE 4 WITH MICHLER'S KETONE OR
MICHLER'S BASE $\geq 0.1\%$ AS SVHC

C.I. Solvent Blue 4 with Michler's base $\geq 0.1\%$

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

Table 8: *Classification of C.I. Solvent Blue 4 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*

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 $\geq 0.1\%$	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 $\geq 0.1\%$ 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*

Substance name	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
C.I. Solvent Blue 4 with Michler's base $\geq 0.1\%$	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.")

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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 α,α -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.

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 Solvent Blue 4 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 18 classification & labelling notifications (on behalf of approx. 50 legal entities) had been submitted for Solvent Blue 4 at the time of the development of this report. The notifications submitted did in the vast majority not indicate the presence of Michler's ketone or Michler's base as impurity. Nevertheless, the notifications included also composition(s) with Michler's ketone as impurity, and classification(s) as Carcinogen 1A and 1B.

It is noted that Solvent Blue 4 is a derivative of Basic Blue 26 (Gessner and Mayer, 2000).

1.2 Data from EU Member States

Of the Member States contacted, six provided responses, with only Sweden indicating the presence of Solvent Blue 4 on its 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 C.I. Solvent Blue 4 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);

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.

ANNEX XV – IDENTIFICATION OF C.I. SOLVENT BLUE 4 WITH MICHLER'S KETONE OR MICHLER'S BASE $\geq 0.1\%$ AS SVHC

- No import to / export from Estonia has been registered to customs authorities;
- No info held on the substance by the United Kingdom;
- Chemical products (mixtures) entering Sweden from other Member States contained in total less than 1 ton of the substance (Swedish Products Register, 2009)

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 2010 or 2011 into the EU by the responding companies was in the 100 -1,000 ton range, and mainly imported as such. According to information by some of the companies, Solvent Blue 4 was imported from countries such as India or China. As about one third of the contacted notifying companies replied and filled in the questionnaire, and as this consultation did not cover all notifying companies (see footnote), the actual amount imported / manufactured in the EU might be higher.

The volume of Solvent Blue 4 currently imported into the EU which was identified on the basis of the questionnaires contains in its vast majority below 0.1% of each of these impurities (if any – not specified). For the remaining volume (not higher than 1t) no information was provided on the presence / content of those impurities.

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.

2. USES

2.1 Uses according to the literature

Information on potential uses/applications of Solvent Blue 4 and the products containing it was retrieved from public on-line sources.

Solvent Blue 4 is used in **inks and dyes**. Among potential uses registered by companies in the Colour Index (2012)⁷, for products (dyestuff) containing Solvent Blue 4 are printing inks (such as rotogravure inks, typewriter ribbons, computer cartridge, etc.), ball point pen inks, and stamping inks.

Furthermore, according to Colour Index (2012) Solvent Blue 4 or its products are used for **dyeing a variety of materials**, such as paper (e.g. carbon paper), distemper, wood, lacquers, feathers, and plastic.

Products containing Solvent Blue 4 could have a diluent, but it would have to be soluble in solvents that are used to dissolve the dye. The commercial products listed in Colour Index 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).

Solvent Blue 4 may also be used in **fuel** (Colour Index, 2012), while at the website of an Indian company it is reported to being extensively used in **fertilizers**.

Uses relating to **cosmetic products** are also listed in Colour Index, such as in soaps.

Finally, the literature refers to uses of Solvent Blue 4 in **diagnostic, analytical, and R&D applications**, such as biological stain.

2.2 Identified uses in the EU

The uses/applications reported during consultation with individual EU companies or Member States were the following:

- Production of various **inks**, e.g. for printing (inks in publication gravure printers) or writing
- Dyeing of **paper**
- Use in mixtures such as **windscreen washing agents** (Swedish Products Register, 2009)

According to information by some companies which responded to the questionnaire, the main use of the substance is probably in the production of inks.

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)

2.3 Releases from uses

Some companies provided information related to the potential for environmental releases. The amount going to waste was estimated to be negligible / below 0.1t/y by the companies that responded. According to one company, dust filters are employed for controlling air releases.

Some information was also provided in regard to the potential for occupational exposure (see confidential Annex).

3. ALTERNATIVES

Some of the companies which submitted information in relation to alternatives. Part of them mentioned having tried alternatives but without success in the past. No company responded that is currently working on the replacement of their substance, for which R&D would be needed. Among limiting factors, that could not be overcome, technical performance-related issues were listed.

It appears that grades of Solvent Blue 4 not containing Michler's ketone at or above the concentration limit for classification as CMR are available on the market, as some of the 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 C.I. Solvent Blue 4.

Purification appears at least to be a main option. 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

Gessner, T. and Mayer, U. (2000) Triarylmethane and Diarylmethane Dyes. Ullmann's Encyclopedia of Industrial Chemistry.

Personal communication with Society of Dyers and Colourists, February 2012.

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