

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

**EC Number(s):** 219-943-6

**CAS Number(s):** 2580-56-5

**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.*

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\* 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)

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## **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-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride<sup>2</sup> (C.I. Basic Blue 26)

**EC Number(s):** 219-943-6

**CAS Number(s):** 2580-56-5

- 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 1B<sup>3</sup> which corresponds to classification as carcinogen category 2<sup>4</sup>.

### **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.

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<sup>2</sup> 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)

<sup>3</sup> 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.

<sup>4</sup> 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).

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ANNEX XV – IDENTIFICATION OF C.I. BASIC BLUE 26 WITH MICHLER'S KETONE OR  
MICHLER'S BASE  $\geq 0.1\%$  AS SVHC

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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 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

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## PART I

### JUSTIFICATION

#### 1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

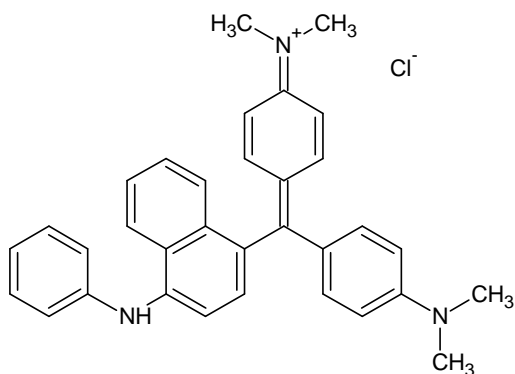
##### 1.1 Name and other identifiers of the substance

Table 1: Substance identity

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

ANNEX XV – IDENTIFICATION OF C.I. BASIC BLUE 26 WITH MICHLER'S KETONE OR  
MICHLER'S BASE  $\geq 0.1\%$  AS SVHC

	<ul style="list-style-type: none"><li>- BTK Victoria Blue</li><li>- Basazol C Blue 57</li><li>- Basic Blue</li><li>- 26; Basic Blue B</li><li>- Basic Victoria Blue B</li><li>- Basonyl Blue 640</li><li>- Basonyl Blue 644</li><li>- Basovict Victoria Blue</li><li>- C-WR Blue 8</li><li>- C.I. 44045</li><li>- Calcozine Blue B</li><li>- Conbasic Blue AK</li><li>- Dycosbasic Victoria Blue B</li><li>- Flexo Blue 630</li><li>- Flexo Blue 640</li><li>- Hecto Blue B</li><li>- Hidaco Victoria Blue B</li><li>- Libbase Victoria Blue LB</li><li>- Lowacryl Blue 26</li><li>- Mitsui Victoria Blue B</li><li>- Ravi Victoria Blue B</li><li>- Tertrophen Blue</li><li>- Victoria Blue</li><li>- Victoria Blue 2B</li><li>- Victoria Blue B 353</li><li>- Victoria Blue B chloride</li><li>- Victoria Blue BA</li><li>- Victoria Blue BH</li><li>- Victoria Blue BN</li><li>- Victoria Blue BN CI 44045</li><li>- Victoria Blue BP</li><li>- Victoria Blue BS</li><li>- Victoria Blue BSA</li><li>- Victoria Blue BX</li><li>- Victoria Blue FB</li><li>- Victoria Pure Blue B</li><li>- Victoria Pure Blue BC</li></ul>
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**Structural formula:**

ANNEX XV – IDENTIFICATION OF C.I. BASIC BLUE 26 WITH MICHLER'S KETONE OR  
MICHLER'S BASE  $\geq 0.1\%$  AS SVHC

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## 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		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	According to the information derived from the C&L notifications.
Further impurities: see confidential Annex			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

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## 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 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. Basic Blue 26 with Michler's ketone $\geq 0.1\%$

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

Table 5: Classification of C.I. Basic Blue 26 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. Basic Blue 26 with Michler's ketone $\geq 0.1\%$	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  $\geq 0.1\%$  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 C.I. BASIC BLUE 26 WITH MICHLER'S KETONE OR MICHLER'S BASE ≥0.1% AS SVHC**

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	-	-
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**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.")

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 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.

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## 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 Basic Blue 26 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)<sup>5</sup>; or in case of manufacture / import at or above 1,000 t/y.

Overall 28 classification & labelling notifications (on behalf of approx. 200 legal entities) had been submitted for Basic Blue 26 at the time of submission of this report for identification of the substance as SVHC. 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 1B.

The potential presence of Michler's ketone as impurity in Basic Blue 26 relates probably to the fact that the latter is manufactured via the ketone. According to Gessner and Mayer (2000), a manufacture process for Basic Blue 26 is by condensation of Michler's ketone with Nphenyl- $\alpha$ -naphthylamine in toluene with phosphorus oxychloride. According to the same source, Basic Blue 26 can also be manufactured via Michler's base: by catalytic oxidation of the leuco base (formed by oxidation of Michler's base in the presence of N-phenyl- $\alpha$ - naphthylamine) with air and catalytic quantities of (dihydrodibenzotetraaza[14]annulene)iron and chloranil.

### 1.2 Data from EU Member States

Of the Member States contacted, six provided responses, with only Sweden indicating the presence of Basic Blue 26 on its market:

- Not registered by Dutch companies;
- Not on the market with Michler's ketone / Michler's base  $\geq 0.1\%$  in Finland;

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<sup>5</sup> 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.

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MICHLER'S BASE  $\geq 0.1\%$  AS SVHC

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- No information on use of C.I. Basic Blue 26 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;
- Chemical products (mixtures) entering Sweden from other Member States contained in total less than 0.1 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 database<sup>6</sup> 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 10-100 ton range. According to information by some of the companies, Basic Blue 26 was imported from countries such as India or China. Most of the accrued amount was imported as substance, with the rest imported as mixture. As about half 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 may be higher. Indeed one importer estimated that the total imported amount in the EU can well be higher, taking into account the type of applications communicated by the suppliers (i.e. as colourant in inks and as dyestuff for textiles).

From the identified imported volume of Basic Blue 26, for approximately one tenth the presence / content of Michler's ketone or Michler's base was stated to be unknown. A similar proportion of the reported volume was reported in the questionnaires to contain Michler's

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<sup>6</sup> 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.

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**ANNEX XV – IDENTIFICATION OF C.I. BASIC BLUE 26 WITH MICHLER’S KETONE OR MICHLER’S BASE  $\geq$ 0.1% AS SVHC**

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ketone or Michler’s base (not specified in the question or response) at or above 0.1%; while the remaining tonnage contained according to the responding companies below 0.1% of each of these impurities (if any – not specified).

The total exported volume reported by the contacted companies was negligible.

## **2. USES**

### **2.1 Uses according to the literature**

Information on potential uses/applications of Basic Blue 26 and the products containing it was retrieved from public on-line sources.

Basic Blue 26 is used in **inks, dyes, paints, and pigments**. Among potential uses registered by companies in the Colour Index (2012)<sup>7</sup>, for products (dyestuff) containing Basic Blue 26, are in printing inks (according to Gessner and Mayer, 2000, melted in oleic or stearic acid), spirit inks, and pigments. According to Denmal et al. (2010), blue and black ball point pen inks may contain Basic Blue 26; with around 80% of blue and black ball point pen inks containing “Basic Violet 3 and its homologues”.

Furthermore, according to information from the Colour Index (2012) Basic Blue 26 or its products are used for **dyeing a variety of materials**, such as paper (also reported by Gessner and Mayer, 2000; according to on-line chemical catalogues paper applications may include: plain, carbon, stencil-, colored, wax-paper etc.), distemper, wood, and fibres/textiles. The commercial product (dyestuff) containing C.I. Basic Blue 26 may be a pure powder, a powder with diluents, or a solution with or without diluents (personal communication with Society of Dyers and Colourists).

Uses relating to **cosmetic products** are also listed in Colour Index, including hair products, crayons, and soaps.

Finally, the literature refers to uses of Basic Blue 26 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 were the following:

- Production of various **inks** (formulation steps may also include mixing with other basic dyes)
- **Cleaners** (e.g. printing plate cleaner and water tank cleaner, for use in the lithographic printing industry)

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<sup>7</sup> 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)

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- **Coating** applications
- Dyeing of various **paper and plastic products** (e.g. paper towel wipes , low grade paper and paper food trays, and other products)
- Dyeing or painting of **other articles**

According to the Swedish Products Register (2009), the mixtures containing Basic Blue 26 are used as ink in printing industry.

### 2.3 Releases from uses

Some companies submitted information on process steps relevant for potential occupational exposure. These include steps during formulation (e.g. of powder dyestuff), such as packing off, weighting, adding, and mixing dye, decanting mixtures, or during end applications, such as during cleaning plates and water tanks.

The relevant routes of exposure are inhalation and skin contact. The total number of employees exposed in the companies that answered the questionnaire is below 30. No data was provided on measured or estimated occupational exposure. Applied Risk Management Measures were mentioned by some of the companies that provided information on exposure, including LEV booth and PPEs such as Self-contained breathing apparatus and full body suit.

Some companies submitted information on estimated environmental releases, identifying as the most relevant receiving flows / compartments the waste flow (minimal releases), the wastewater flow (minimal / below 0.1t/y), and air (minimal).

## 3. ALTERNATIVES

Some companies submitted information in relation to alternatives. Those companies mentioned neither having practical experience nor being aware of alternatives to Basic Blue 26. No company responded that is currently working on the replacement of their substance. A few companies stated that additional R&D would be needed to replace the substance, but possible reformulation would depend on customers' requirements.

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

It appears that grades of Basic Blue 26 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. It is noted that manufacture of Basic Blue 26 seems to be possible also by using alternative intermediates to Michler's ketone (see section 1.1). Nevertheless, for instance the alternative manufacture method cited by Gessner and Mayer (2000) involves Michler's base, which is a substance also with CMR (carcinogenic, mutagenic or reprotoxic) properties and same harmonized CMR classification as Michler's ketone.

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).

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#### 4. REFERENCES

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