

Triarylmethane dyes – Solvent Blue 2, 4 and 5: Human health tier II assessment

25 November 2016

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
1-Naphthalenemethanol, .alpha.,.alpha.-bis[4-(dimethylamino)phenyl]-4-(methylphenylamino)-	1325-85-5
1-Naphthalenemethanol, .alpha.,.alpha.-bis[4-(diethylamino)phenyl]-4-(ethylamino)-	1325-86-6
1-Naphthalenemethanol, .alpha.,.alpha.-bis[4-(dimethylamino)phenyl]-4-(phenylamino)-	6786-83-0

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit: www.nicnas.gov.au

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ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals in this group belong to the class of triarylmethane colourants. The chemicals have similar structure with alkyl or aryl amino groups attached to the 1-naphthyl(diphenyl)methanol backbone at the para ring positions. The chemicals have the same core structure and differ only in the amine substitution. All three chemicals have similar physico-chemical properties and are mainly used in printing inks. The chemicals are expected to have toxicological properties similar to those of other members of the triarylmethane colourants; with major concerns for carcinogenicity and reproductive toxicity (NICNASa; NICNASb).

Based on the similar physico-chemical and toxicological properties as well as their similar use pattern, these chemicals were grouped for this assessment.

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified.

International

The following international uses of these chemicals have been identified through the European Union Registration, Evaluation and Authorisation of Chemicals (REACH) dossier, COWI Consultation (2013), Galleria Chemica, Substances in Preparations in Nordic countries (SPIN) database, United States Occupational Health database (HazMap), United States Environmental Protection Agency (US EPA) Chemical and Product Categories (CPCat) database, European Chemicals Agency Annex XV dossier for Solvent Blue 4 (Annex XV dossier), and Colour Index Online.

The chemical Solvent Blue 4 (CAS No 6786-83-0) may have cosmetic use in soaps. However, the chemicals are not reported as being used in: cosmetic products in the US (CIUCUS, 2011); in the European Commission Cosmetic Substances and Ingredients (CosIng) database; or in the US Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) directory.

The chemicals Solvent Blue 4 or Solvent Blue 5 (CAS No 1325-86-6) have reported domestic uses as dyes in:

- ballpoint pens;
- shoe polish;
- candles;
- cleaning and washing agents; and
- coatings and paints.

However, there is currently no documented use of the chemicals in the United States Household Products Database (US HPD).

The chemicals have reported commercial uses in:

- dyes used for paper, distemper, wood, feathers, silk and plastic;
- printing inks; and
- fuels (Solvent Blue 4).

The chemical Solvent Blue 4 has non-industrial use in fertilisers.

Restrictions

Australian

No known restrictions have been identified.

International

The chemical Solvent Blue 4 (CAS No 6786-83-0) with Michler's ketone or Michler's base $\approx 0.1\%$ is on the candidate list of substances of very high concern (SVHC) for eventual inclusion in Annex XIV (ECHA, 2016). In the European union (EU), companies could have legal obligations if the chemical that they produce, supply or use is included on the candidate list whether on its own, in mixtures, or present in articles.

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals are not listed on the Hazardous Substances Information System (HSIS)(Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

Limited health hazard information is available for Solvent Blue 4 (CAS No 6786-83-0), while no health hazard information was identified for the other two chemicals. Health hazard information from structurally related chemical Solvent Violet 8 (CAS No 561-41-1) is used for certain endpoints. Solvent Violet 8 is not listed on Australian Inventory of Chemicals Substances (AICS).

Acute Toxicity

Oral

The chemicals are expected to have low acute toxicity via oral route.

In an Organisation for Economic Cooperation and Development (OECD) Test Guideline (TG) study, female Wistar rats (n=6) received a single oral dose of 2000 mg/kg bw of Solvent Blue 4 (CAS No 6786-83-0). No deaths occurred. The acute oral median lethal dose (LD50) was greater than 2000 mg/kg bw (limit value) (REACH).

No data are available for the other chemicals in this assessment.

Dermal

The chemicals are expected to have low acute toxicity via the dermal route.

Based on an OECD TG study, male and female Wistar rats (n=5/sex) were exposed to 2000 mg/kg bw dose of Solvent Blue 4 (CAS No 6786-83-0). The chemical was applied uniformly over clipped dorsal area of the skin and removed using distilled water 24 hours after application. The acute dermal LD50 was >2000 mg/kg bw (cut-off value) (REACH).

No data are available for the other chemicals in this assessment.

Inhalation

No data are available for the chemicals.

Corrosion / Irritation

Skin Irritation

The chemicals are not expected to be skin irritants.

In an OECD TG study, male New Zealand White (NZW) Rabbit (n=3) were treated with 500 mg of pulverised Solvent Blue 4 (CAS No 6786-83-0) moistened with 0.5 ml distilled water for 4 hours, covered with porous gauze dressing and non-irritating tape. The rabbits were observed for 72 hours. The residual test item was removed by using cotton soaked in distilled water. The individual mean score at 24, 48 and 72 hours for animal nos. 1, 2 and 3 were 0.33, 0.67, 0.67 and 0.00, 0.00, 0.33 (Draize method), for erythema and oedema formation, respectively. It was concluded that the chemical was non-irritating to the skin of male NZW rabbits under the experimental conditions (REACH).

This is supported by another OECD TG study in male NZW rabbits where no erythema and oedema (skin irritation) were found at the end of 72 hour observation period following dermal exposure (patch) to a structurally related chemical, Solvent Violet 8 (CAS No 561-41-1) (REACH).

No data are available for the other chemicals in this assessment.

Eye Irritation

The chemical Solvent Blue 4 (CAS No 6786-83-0) is irritating to the eyes with reversible effects observed only after 21 days. While no data are available for the other chemicals, due to structural similarity, the other chemicals in this group are also expected to be irritating to the eyes. Therefore, the chemicals are recommended to be classified as hazardous with the risk phrase 'Irritating to eyes' (Xi; R36) in the HSIS.

In an OECD TG study, female NZW rabbits (n=3) were exposed to 100 mg of Solvent Blue 4 (CAS No 6786-83-0) instilled into the conjunctival sac of the right eye for 24 hours. The treated eyes of rabbits were washed with normal saline. The animals were observed at 1, 24, 48, 72 hours and at day 7 and 21 after application of the chemical. Opacity, chemosis and corneal epithelium cell damage were observed in all animals. However, effects in all animals were fully reversible within an observation period of 21 days (REACH).

This is supported by another OECD TG study in male NZW rabbits when eye irritation was reported during the 72 hour observation period following installation of structurally related chemical, Solvent Violet 8 (CAS No 561-41-1), into conjunctival sac of right eye. The effects were fully reversible within an observation period of 21 days (REACH).

No data are available for the other chemicals in this assessment.

Sensitisation

Skin Sensitisation

No experimental data for skin sensitisation were identified for these chemicals.

Based on the QSAR toolbox version 3.4, the chemicals are not predicted to be skin sensitisers.

This is supported by findings in a structurally related chemical Malachite Green (CAS No 569-64-2) which is not a skin sensitiser (NICNASa).

Repeated Dose Toxicity

Oral

Limited information is available for the repeated dose toxicity of the chemicals. However, Solvent Blue 4 (CAS No 6786-83-0) was lethal to all rats in a subchronic (28-day) toxicity study at doses 150 mg/kg bw/day and above. Therefore, these chemicals can damage health by prolonged oral exposure. The chemicals are recommended to be classified as harmful with the risk phrase 'Danger of serious damage to health by prolonged exposure if swallowed' (T; R48/22) in the HSIS.

In a OECD TG subacute toxicity study using Solvent Blue 4 (CAS No 6786-83-0), male and female Sprague-Dawley (SD) rats (n=7/sex/dose) were exposed (oral gavage) daily with 0 (corn oil), 50, 150 or 450 mg Solvent Blue 4/kg bw for 28 days. Doses of 450 and 150 mg/kg/bw/day were lethal to all rats by day five and 11, respectively. All rats treated with 50 mg/kg/bw/day survived throughout the treatment period. However, significant decrease in body weights was observed in treated male and female rats when compared to the control group. Male rats had significantly increased brain weights when treated with 50 mg/kg/bw/day as compared to the control group. Therefore, the lowest observed effect level (LOEL) is considered to be 50 mg/kg bw/day in male and female SD rats exposed daily to Solvent Blue 4 via oral route for 28 days (REACH).

This is supported by another OECD Test Guideline subchronic toxicity study using a related chemical Solvent Violet 8 (CAS No 561-41-1). Male and female SD rats (n=6/sex/dose) were exposed (oral gavage) to 0 (corn oil), 25, 50 or 100 mg/kg bw/day. No mortality was observed in any of the rats. Significantly reduced body weight gain was observed in both sexes when treated with 50 or 100 mg/kg bw/day. Increased relative weights of the brain after treatment with 50 and 100 mg/kg bw/day were observed in male rats. Increased relative weights of the liver were observed in male and female rats treated with 100 mg/kg bw/day. A no-observed adverse effect level (NOAEL) of 25 mg/kg bw/day was determined for the chemical (REACH).

No data are available for the other chemicals in this assessment.

Dermal

No data are available for the chemicals.

Inhalation

No data are available for the chemicals.

Genotoxicity

No experimental data are available for the genotoxicity of the assessed chemicals. However, the chemicals have mechanistic alerts for mutagenicity using the profiling functionality of the OECD QSAR Toolbox v3.2 (see **Carcinogenicity** section).

Carcinogenicity

No experimental data is available for the carcinogenicity of the assessed chemicals. Based on the available information from structurally similar chemicals and Quantitative Structure Activity Relationship (QSAR) modelling, the carcinogenic potential of these chemicals cannot be ruled out.

Two structurally related chemicals, Malachite Green chloride (CAS No. 569-64-2) and Crystal Violet (CAS No 548-62-9) are genotoxic and carcinogenic, respectively (NICNASa, NICNASb).

The chemicals in this category and the structurally-related chemicals have mechanistic alerts for mutagenicity and carcinogenicity using the profiling functionality of the OECD QSAR Toolbox v3.2. Additional QSAR modelling was undertaken using the Optimized Approach software based on Structural Indices Set—Tissue Metabolism Simulator (OASIS–TIMES) v2.27.19, to predict the genotoxicity and consequent carcinogenicity potential of the chemicals. For all chemicals, positive QSAR predictions were obtained for one or more of the following genotoxicity models:

- in vitro Ames;
- in vitro chromosomal aberration;
- in vivo micronucleus test; and
- in vivo liver genotoxicity.

All chemicals were outside the structural applicability domain of the models. However, the alerts are based on a common mechanism to “N-Substituted Aromatic Amines” driving the prediction. The positive QSAR findings are supported by the listing of Solvent Blue 2 (CAS No 1325-85-5) and Solvent Blue 5 (CAS No 1325-86-6) in Annex III inventory of REACH with concerns including carcinogenicity and mutagenicity (Annex III).

These dyes can also contain carcinogenic impurities, such as Michler's ketone (CAS No 90-94-8) and Michler's base (CAS No 101-61-1) (Annex XV dossier).

Reproductive and Developmental Toxicity

No experimental reproductive or developmental toxicity data are available for the assessed chemicals. Due to insufficient information, the chemicals are not recommended for classification.

In a non-guideline, subchronic toxicity study, male and female SD rats (n=7/sex/dose) were treated daily (gavage) with Solvent Blue 4 (CAS No 6786-83-0) for 28 days with 0 (corn oil), 50, 150 or 450 mg/kg bw/day. Doses of 150 and 450 mg/kg bw/day were lethal to all rats (see **Repeated dose toxicity** section). No significant changes were detected in the weights of testes and epididymides (males) or of uterus and ovaries (females) at dose of 50 mg/kg bw/day when compared to the control animals. No changes were reported in oestrous cycles in females. Based on this short-term study, a NOAEL of greater than 50 mg/kg/day is considered for reproductive toxicity (REACH).

No data are available for the other chemicals in this assessment.

It should be noted that the structurally related chemical, Malachite Green chloride (CAS No. 569-64-2), is classified for reproductive toxicity (Repro. Cat 3 - Possible risk of harm to the unborn child (Xn; R63)) (NICNASa), and Solvent Blue 5 (CAS No 1325-86-6) is listed on the Annex III of REACH with concerns for reproductive toxicity (ECHA).

Risk Characterisation

Critical Health Effects

Limited health hazard data is available for these chemicals. The critical health effects include eye irritation and toxicity by repeated oral exposure. The systemic long-term effect of carcinogenicity and/or reproductive toxicity cannot be excluded.

Public Risk Characterisation

Cosmetic and domestic

Although the use of these chemicals in cosmetic or domestic products in Australia is not known, the chemicals may be used in products overseas such as soaps, paints and cleaning agents (SPIN, REACH, Annex XV dossier). The introduction of these dyes for home use cannot be excluded, but is expected to be low as these chemicals are not listed in CIUCUS (2011), CosIng database or INCI directory, and there is no documented domestic use in US HPD (see **Import, Manufacture and Use** section).

Dyed products and printing inks

The chemicals are reported to be used for colouring paper, feathers, plastic and wood. However, the prevalence of these chemicals in such products in Australia is unknown. Oral ingestion could occur in infants through: sucking or chewing dyed paper; migration from food packaging; and accidental ingestion of inks contained in ballpoint pens. NICNAS has recommended further assessment for some carcinogenic and mutagenic chemicals used in printing inks and in paper products (NICNASc).

The Solvent Blue 4 (CAS No 6786-83-0) is reported to be used for coating of carbon paper (Annex XV dossier) which is expected to be rarely accessible for children. In addition, based on questionnaires for companies in Europe, majority of Solvent Blue 4 imported from India or China in 2010 or 2011 was reported to not contain carcinogenic impurities (Michler's ketone CAS No 90-94-8 or Michler's base CAS No 101-61-1) above 0.1% (Annex XV dossier).

Overall consumer exposure is likely to be low. However, the associated risks of prolonged exposure as well as uncertainty in carcinogenic potential give cause for concern. Therefore, it is recommended that further assessment or changes in risk management may be required should:

- information become available to indicate significant consumer exposure to the chemical in Australia (i.e. higher concentrations or quantities in cosmetics or domestic products);
- NICNAS determine a substantial risk for carcinogenic and mutagenic chemicals present in printing inks or paper products; or
- further information become available on the reproductive toxicity or mutagenic/carcinogenic potential of these chemicals.

Occupational Risk Characterisation

Given the critical systemic long-term health effects, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise exposure are implemented. The chemicals should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine the appropriate controls. While the data are insufficient to fully characterise the hazards of the chemicals, the concerns for associated risks on prolonged exposure and uncertainty in carcinogenic potential should be considered.

NICNAS Recommendation

Assessment of these chemicals are considered to be sufficient, provided that the recommended amendment to the classification is adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Based on the structurally related chemicals, these chemicals may have carcinogenicity and reproductive toxicity concerns. However, the available data is insufficient to conclusively demonstrate that these chemicals cause these adverse effects.

Overall consumer exposure is likely to be low. However, the associated risks of prolonged exposure as well as uncertainty in carcinogenic potential give cause for concern.

It is recommended that further assessment or changes in risk management may be required should:

- information become available to indicate significant consumer exposure to the chemical in Australia (i.e. higher concentrations or quantities in cosmetics or domestic products);
- NICNAS determine a substantial risk for carcinogenic and mutagenic chemicals present in printing inks or paper products; or
- further information become available on the reproductive toxicity or mutagenic/carcinogenic potential of these chemicals.

Regulatory Control

Public Health

Products containing the chemical should be used according to the instructions on the label.

Work Health and Safety

The chemicals are recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical and environmental hazards.

Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Irritation / Corrosivity	Irritating to eyes (Xi; R36)	Causes serious eye irritation - Cat. 2A (H319)
Repeat Dose Toxicity	Harmful: danger of serious damage to health by prolonged exposure if swallowed (Xn; R48/22)	May cause damage to organs through prolonged or repeated exposure - Cat. 2 (H373)

^a Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

^b Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

* Existing Hazard Classification. No change recommended to this classification

Advice for consumers

Products containing the chemicals should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from oral, dermal, and ocular exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemicals are used. Examples of control measures that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- health monitoring for any worker who is at risk of exposure to the chemicals, if valid techniques are available to monitor the effect on the worker's health;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemicals.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to help meet obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((M)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemicals are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (M)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals—Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of these chemicals has not been undertaken as part of this assessment.

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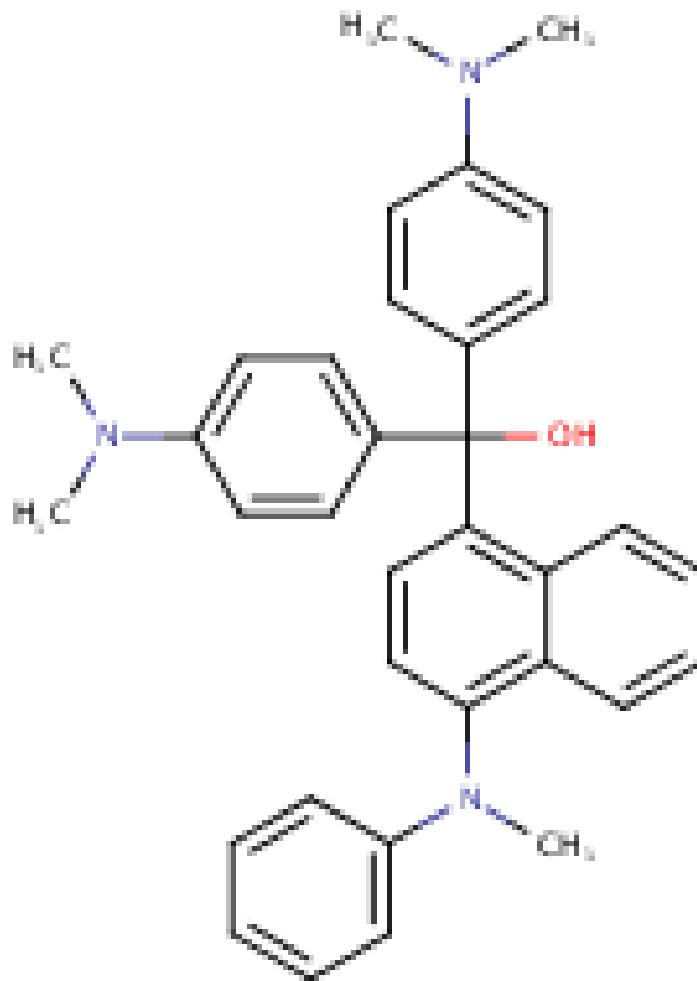
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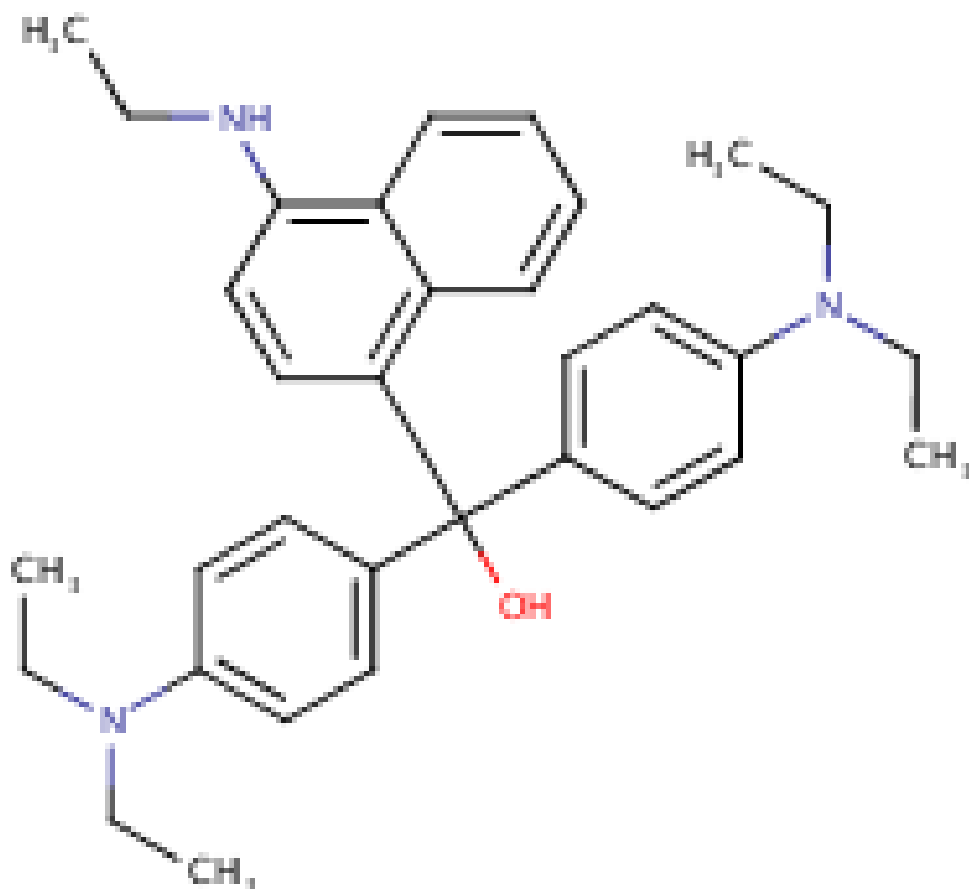
Chemical Identities

Chemical Name in the Inventory and Synonyms	1-Naphthalenemethanol, .alpha.,.alpha.-bis[4-(dimethylamino)phenyl]-4-(methylphenylamino)-C.I. Solvent Blue 2
CAS Number	1325-85-5
Structural Formula	



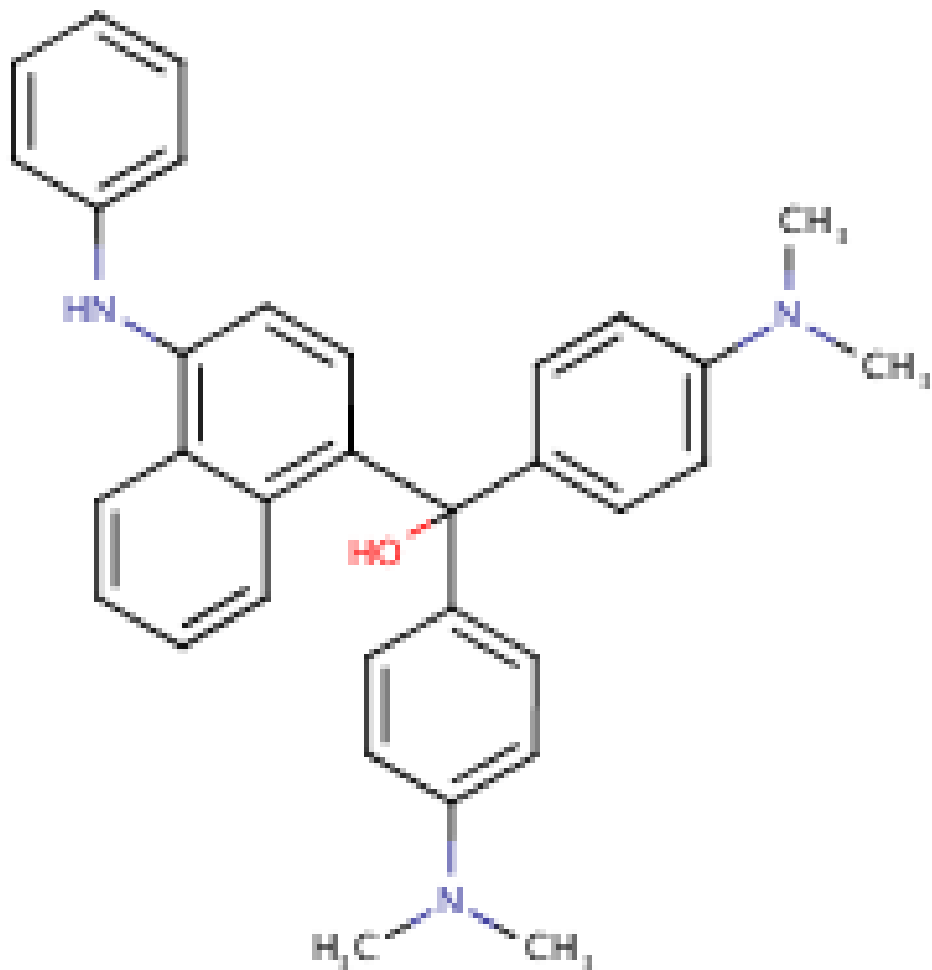
Molecular Formula	C ₃₄ H ₃₅ N ₃ O
Molecular Weight	501.6

Chemical Name in the Inventory and Synonyms	1-Naphthalenemethanol, .alpha.,.alpha.-bis[4-(diethylamino)phenyl]-4-(ethylamino)- C.I. Solvent Blue 5
CAS Number	1325-86-6
Structural Formula	



Molecular Formula	C33H41N3O
Molecular Weight	495.7

Chemical Name in the Inventory and Synonyms	1-Naphthalenemethanol, .alpha.,.alpha.-bis[4-(dimethylamino)phenyl]-4-(phenylamino)- C.I. Solvent Blue 4
CAS Number	6786-83-0
Structural Formula	



Molecular Formula	C ₃₃ H ₃₃ N ₃ O
Molecular Weight	487.6

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