

9,10-Anthracenedione, 1,4,5,8-tetraamino-: Human health tier II assessment

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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.

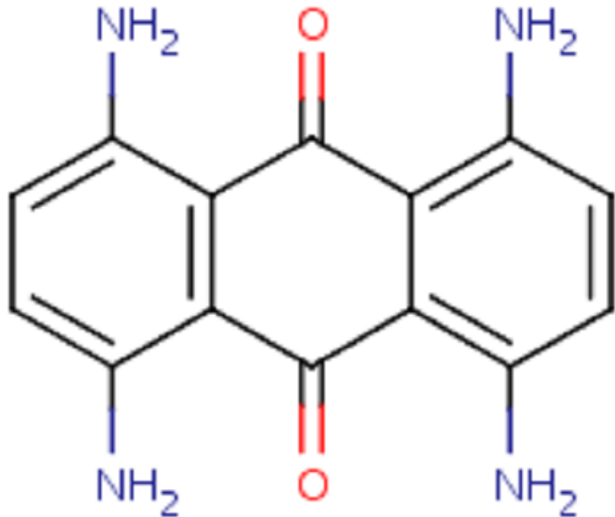
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Acronyms & Abbreviations

Chemical Identity

Synonyms	C.I. Disperse Blue 1 1,4,5,8-tetraaminoanthroquinone 1,4,5,8-tetraamino-9,10-anthracenedione C.I. 64500 C.I. Solvent Blue 18
Structural Formula	
Molecular Formula	C ₁₄ H ₁₂ N ₄ O ₂
Molecular Weight (g/mol)	268.28
Appearance and Odour (where available)	Blue-black solid or deep blue powder.
SMILES	<chem>c12C(=O)c3c(C(=O)c1c(N)ccc2N)c(N)ccc3N</chem>

Import, Manufacture and Use

Australian

The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information:

- textile dyeing in mills;
- wood stains and polishes;
- colour in detergents and crepe paper; and
- as identification in metal castings.

The total volume introduced into Australia, reported under previous mandatory and/or voluntary calls for information, was 0.3 tonnes.

The chemical is not on the 'List of chemicals used as dyes in permanent and semi-permanent hair dyes in Australia' (NICNAS, 2007).

International

The following international uses have been identified through the United States (US) Personal Care Product Council International; the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); and various international assessments (IARC, 1990; CIR, 1995; CIR, 2010; NTP, 2011).

The chemical has reported cosmetic use in direct semi-permanent hair dye preparations at a concentration of less than 1.0 %. The chemical was also reported to be used in a hair colourant mousse and toothpaste, although these were identified as old products (US Household Products Database). Whilst there was no reported use of the chemical in cosmetic products in the US in 2009 and 2010, there was reported use in three products in 2011 (CIR, 2010; Personal Care Products Council, 2011). In 2010, the use of the chemical in hair dye products was banned in the European Union (EU) (see **Restrictions: International**).

The chemical has reported commercial use as a dye in:

- sheepskins, furs, thermoplastic resins, cellulose acetate, nylon, polyester and acrylate fibres and other synthetics; and
- paper printing and photography (Saquib et al., 2008).

In 2009, no commercial manufacturers of the chemical were identified worldwide, but the chemical was available from five suppliers, including three in the USA (NTP, 2011).

Restrictions

Australian

No known restrictions have been identified.

International

The chemical is listed on the following (Galleria Chemica):

- Association of South East Asian Nations (ASEAN) Cosmetic Directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products;
- European Union (EU) Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products;
- EU List of 179 substances banned for use in hair dye products; and
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain.

The US Cosmetic Ingredient Review (CIR) Expert Panel concluded that the chemical is 'safe for use in hair dyes at concentrations up to 1 %.' (CIR, 2011).

The chemical is also restricted by Annex XVII to the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH) Regulations.

The chemical cannot be used in substances and preparations placed on the market for sale to the general public in individual concentrations ≥ 0.1 % (European Parliament & Council, 1999; European Parliament & Council, 2006; European Parliament & Council, 2008).

Existing Work Health and Safety Controls

Hazard Classification

The chemical is classified as hazardous, with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

- R45 Carc. Cat 2 (carcinogenicity);
- Xi; R38 (skin irritation);
- Xi; R41 (serious eye damage); and
- Xi; R43 (sensitisation).

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

Toxicokinetics

The chemical contains two major impurities: an isomer of the chemical and an isomer of nitrotriaminoanthraquinone (CIR, 1995; Doi et al., 2005). The data on absorption and metabolism of the chemical are limited.

Considering its small molecular size, absorption of Disperse Blue 1 is expected following oral, dermal and inhalation exposure. The skin sensitising properties and effects following repeated exposure support the bioavailability of the chemical. However, in vitro dermal absorption data indicate that dermal absorption of the chemical is low. The in vitro penetration of the chemical through human abdominal skin and female fuzzy rat skin was determined using flow-through diffusion cells. Absorption into the receptor fluid over 24 hours was 0.2 % for human skin and 0.7 % for rat skin. Minimal absorption occurred after 24 hours (CIR, 2010). When tested in vitro using the skin of miniature pigs, the chemical showed poor dermal penetration. In this test, sections of skin of approximately one inch in diameter were exposed to 1 % Disperse Blue 1 (in Franz diffusion cells) for 30 minutes or three hours. The amount of the chemical penetrating through the skin after three hours of exposure was only 0.15 % of the applied dose (CIR, 1995).

Based on data for 9,10-anthraquinone (CAS No. 117-79-3) (NICNAS) and given the target organs for toxicity (kidney and urinary bladder), following absorption, the chemical is expected to be transported to and metabolised in the liver, widely distributed and excreted in the urine. Blue urine and staining of the majority of organs were observed in oral toxicity studies (CIR, 1995). Biliary excretion could also be an important pathway for faecal excretion of the chemical (Doi et al., 2005). In an in vitro study with human abdominal skin, no metabolism of the chemical was observed (CIR, 2010).

Metabolism of the chemical is likely to occur via the metabolic pathways observed in other aromatic amines (Doi et al., 2005). Metabolically, aromatic amines undergo ring oxidation, N-glucuronidation, N-acetylation, and N-oxidation (SCCNFP, 2002). The toxicity of these chemicals is largely influenced by N-oxidation, a process primarily mediated by cytochrome P450 enzymes, such as CYP1A2 and CYP3A4, although other enzymes could also play a role. The resulting metabolic products are demonstrated to be highly reactive and are capable of DNA binding. Metabolic processes consistent with the anthraquinone backbone (ring hydroxylation and one-electron reduction of the quinone group (NICNAS)) could also occur, although these are reported to be potentially sterically hindered (Doi et al. 2005).

Acute Toxicity

Oral

The chemical has low acute oral toxicity based on results from animal tests. The reported median lethal dose (LD50) values were >3000 mg/kg for Fischer 344 (F344) rats and >2000 mg/kg for B6C3F1 mice (CIR, 1995). The only observed treatment-related effect was the change of urine colour to blue following exposure to the chemical.

Dermal

No data are available.

Inhalation

No data are available.

Corrosion / Irritation

Skin Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to skin' (Xi; R38) in the (HSIS) (Safe Work Australia). No data are available to evaluate this classification.

Eye Irritation

The chemical is classified as hazardous with the risk phrase 'Risk of serious damage to eyes' (Xi; R41) in the HSIS (Safe Work Australia). No data are available to evaluate this classification.

Sensitisation

Skin Sensitisation

The chemical is classified as hazardous with the risk phrase 'May cause sensitisation by skin contact' (R43) in the HSIS (Safe Work Australia). The positive results reported in a local lymph node assay (LLNA) and guinea pig maximisation test support this classification.

Ahuja et al. (2010) tested the sensitising potential of Disperse Blue 1, at concentrations of 3 % and 10 %, using a modified mouse LLNA (sensitising—challenge or biphasic). In this assay, 50 µL of the chemical was applied daily to the back skin (2 cm²) of female BALB/c mice on days 1–3. On days 15–17 of the assay, 25 µL of the chemical was applied daily to the back of both ears. Evaluation of the effects was conducted at day 19 by assessing changes to: ear thickness and weight; lymph node weight and cell count; and flow cytometry analysis for immune-related cells. Radioactive labelling was not used in this study. Results showed moderate sensitisation reactions at 3 % and 10 % of Disperse Blue 1. Observations were based on the significant increases in:

- cell count and lymph node weight;
- decrease in CD8+ lymphocytes;
- increases in CD19+ lymphocytes (16 % and 18 %) and CD19+ lymphocytes (19 % and 13 % respectively);
- increase in CD45+ cell surface marker (40 % and 15 % respectively); and
- increase in the population of CD45+/1A+ (68 %).

Based on results from an earlier investigation in guinea pigs, Disperse Blue 1 was also classified as a moderate sensitiser (CIR, 1995). During the induction phase of this study, six intradermal injections of the chemical were administered to the clipped and shaved shoulders of female albino Pirbright guinea pigs (n = 10). The total dose received was approximately 4.5 mg. The solution injected was an emulsion of Disperse Blue 1 with Freund's Complete Adjuvant and saline. In the subsequent challenge phase (after 11 days of no treatment), 1 % of the chemical, suspended in acetone, was applied to the right clipped and shaved flank of the animals. The effects were evaluated and scored at 24, 48 and 72 hours after the challenge exposure. On a scale of 0–3 (0 to severe reaction), Disperse Blue 1 scored 1.30 at 24 hours, 1.75 at 48 hours, and 2.00 at 72 hours and was considered as a moderate sensitiser in this test (CIR, 1995).

By contrast, Disperse Blue 1 failed to induce sensitisation reactions in a loose-fit coculture-based sensitisation assay (LCSA) at a concentration of 100 µmol/L (Sonnenburg et al., 2012).

Observation in humans

Disperse blue dyes have been linked to a number of cases of allergic contact dermatitis following exposure to textiles containing these chemicals. Disperse blue dyes are reported to be the most common allergens to cause textile dermatitis (Dawes-Higgs & Freeman, 2004; Jacob & Ramirez, 2007; Caliskaner et al., 2012; Lisi et al., 2014). In Germany, the use of eight disperse dyes in garments, including Disperse Blue 1, is no longer recommended (Platzek, 2012).

The first reported case of a sensitisation reaction to Disperse Blue 1 was from a study that showed 1/15 patients with contact dermatitis from trousers also had positive reaction in a patch test to the chemical (CIR, 1995). No further details were supplied.

Nine cases of sensitisation reactions to black clothes have been investigated. Subsequent patch testing with various dyes was conducted to determine the cause of these reactions. Whilst positive reactions were observed in some subjects following patch testing with Disperse Blue 1, stronger reactions were seen with other disperse dyes. It was also determined that there were low amounts of the Disperse Blue 1 in the black fabrics (CIR, 2010).

Repeated Dose Toxicity

Oral

Considering the lowest observed-adverse effect levels (LOAELs) available from 13 week studies in rats and mice (250–500 mg/kg bw/day), and based on the treatment-related effects reported in various repeated dose toxicity studies, repeated oral exposure to the chemical is not considered to cause serious damage to health.

In a 13-week study, F344 rats and B6C3F1 mice were fed diets containing up to 20000 ppm and 10000 ppm respectively of Disperse Blue 1, commercial grade, without lignosulfonate dispersants (CIR, 1995). The following treatment-related effects were observed in both rats and mice fed diets containing ≥ 2500 ppm (approximately 250 mg/kg bw/day in rats and 500 mg/kg bw/day in mice using conversion factors of 10 and 5, respectively (Derelanko & Auletta, 2014)):

- pigmentation of the thyroid gland follicle;
- renal pigmentation and/or dilation;
- nephrosis;
- chronic inflammation and/or hyperplasia of the urinary bladder transitional epithelium;
- urinary tract calculi (urinary stone);
- focal myocardial necrosis (mice only); and
- mild degeneration of the germinal epithelium of the testis (male rats only).

In another study, Burnett and Squire (1986) reported a number of similar changes in F344 rats exposed to 10000 ppm of Disperse Blue 1 in the diet for six months (approximately 500 mg/kg bw/day using a conversion factor of 20 (Derelanko & Auletta, 2014)) including:

- reduced survival rate;
- formation of large numbers of calculi in the urinary bladder;
- kidney changes (fibrosis and inflammation); and
- chronic nephropathy.

Dark-blue particles and sediments were found in the urinary bladders of many animals during interim examinations at weeks 5, 9 and 17. These particles increased in size with time. The composition of the calculi differed for males and females. The calculi in males consisted mainly of the dye; calculi in female were composed of calcium phosphate. No effects were observed in rats exposed to lower doses (0.1 % and 0.01 %) in the diet (approximately 50 and 5 mg/kg bw/day using a conversion factor of 20) (Derelanko & Auletta, 2014).

In male and female beagle dogs, no significant pathological changes were observed after exposure to 19.5 and 97.5 mg/kg/day, in the diet, for two years (CIR, 1995).

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

Based on the limited data available, it is not possible to draw a definite conclusion regarding the genotoxicity of the chemical. Although available data are neither sufficient nor adequately comprehensive for classification, a genotoxic mode of action cannot be ruled out. Mutagenic responses were observed in in vitro assays. The mutagenic response could be related to the nitrotriaminoanthraquinone impurity (CIR, 2010). Limited in vivo data are available.

Whilst consistent results have not been reported, the chemical was weakly mutagenic in *Salmonella typhimurium* strains TA97 and TA98, with or without metabolic activation and TA1535 with metabolic activation (CIR, 1995). Positive results were also obtained in other in vitro assays including:

- L5178Y mouse lymphoma cell mutation assay without S9 activation;
- chromosome aberration (CA) in Chinese hamster ovary (CHO) cells (with or without activation);
- sister chromatid exchange in CHO cells without activation, weakly positive with activation; and
- induction of morphological transformation in Balb/c-3T3 mouse cells without activation (NTP, 1999).

The genotoxicity of the chemical in vivo has not been adequately characterised. The only available heritable translocation study in vivo in male outbred Sprague Dawley (SD) Charles River CD rats (n = 25) reported a negative result (CIR, 1995). Following single and repeated intraperitoneal injections of the chemical to hamsters (up to 200 mg/kg per day), no significant increase in CA or other abnormalities were seen in the bone marrow (Haws et al., 1994).

Carcinogenicity

The chemical is classified as hazardous—Category 2 carcinogenic substance—with the risk phrase 'May cause cancer' (T; R45) in the HSIS. The available data support this classification.

The carcinogenic potential of Disperse Blue 1 has been investigated using long-term (up to two years) oral feeding studies in F344/N rats and B6C3F1 mice (Burnett & Squire, 1985; IARC, 1990; CIR, 2010; NTP, 2011). Compared with mice, rats were more sensitive to the chemical's carcinogenic effects. The rat urinary bladder was the main target organ of carcinogenicity.

In a National Toxicological Program (NTP)-sponsored study, feeding rats with the chemical in their diet for two years (calculated daily consumption of 45, 95 and 217 mg/kg for the males and 56, 111, and 240 mg/kg for females (CIR, 1995)) resulted in the following urinary bladder tumours:

- benign and malignant transitional-cell tumours (papillomas and carcinomas) in both sexes;
- benign and malignant squamous-cell tumours (papillomas and carcinomas) in females; and
- malignant smooth muscle and smooth muscle connective tissue combined (leiomyoma and leiomyosarcoma) in both sexes.

No tumours were observed in the low dose animals: 45 mg/kg bw/day (males); and 56 mg/kg bw/day (females).

In addition to urinary bladder tumours, a small number of rats showed a dose-related increase in the incidence of pancreatic islet-cell adenoma and carcinoma (IARC, 1990).

In mice, liver and lung tumours were identified following oral exposure for two years with calculated daily doses of 112, 239 and 540 mg/kg in male mice and 108, 235 and 520 mg/kg in females. These include hepatocellular adenoma and carcinoma; and alveolar/bronchioalveolar adenoma and carcinoma; however, the increase in the combined incidences of these tumours was considered marginal (NTP, 2011).

In another long-term oral study, F344 rats were exposed to the chemical in a diet containing 0.01 %, 0.1 % and 1 % (100, 1000 and 10000 ppm or mg/kg) for 19 months or 1 % for six months. Tumours in the urinary bladder were only observed in 10000 mg/kg group: squamous cell papilloma (male); and transitional cell carcinoma (female) (Burnett & Squire, 1985). No treatment-related tumours were seen in lower dose animals.

There are no epidemiological data or human case reports indicating a link between human exposure to the chemical and tumour development. The International Agency for Research on Cancer (IARC) has classified the chemical as 'possibly carcinogenic to humans' (Group 2B), based on sufficient evidence for carcinogenicity in animal testing (IARC, 1990).

Mechanism of action

It has been suggested that the increased incidence of urinary bladder tumours in male and female rats could be associated with the calculi formation in the urinary bladder and the ensuing inflammation. Therefore, the carcinogenicity of Disperse Blue 1 in rats is via a secondary mechanism (operationally non-genotoxic) (Burnett & Squire, 1985; CIR, 1995; NTP, 2011). However a large number of the tumours in the NTP study were of smooth muscle origin rather than epithelial. There is no compelling evidence for a causal relationship between urinary-bladder calculi and development of smooth muscle tumours (CIR, 2010; NTP, 2011).

Reproductive and Developmental Toxicity

Limited data are available.

No effects on fertility were observed in a cross-fertilisation study in SD rats exposed to a composite dye containing 1.54 % Disperse Blue 1, at concentrations of 0.195 % and 0.78 % (composite dye) in the diet. No teratogenic effects were observed in Carworth Farm's CFE-S rats following exposure on days 6–15 of gestation to the same composite dye (CIR, 1995). In addition, daily oral gavage of the chemical (doses: 19.5 or 97.5 mg/kg) on gestation days 6–18 did not cause foetal abnormalities in New Zealand White rabbits (CIR, 1995).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (carcinogenicity) and local effects (skin sensitisation). The chemical could produce eye damage and skin irritation.

Public Risk Characterisation

Cosmetic

Whilst the chemical had historical use in hair dyes internationally, only minimal use of the chemical is reported recently. In addition, the chemical is not on the 2007 'List of chemicals used as dyes in permanent and semi-permanent hair dyes in Australia' (see **Import, manufacture and use** section). Therefore, based on the available data, significant cosmetic use of the chemical is not expected, and the risk to the public from this route of exposure is not considered to be unreasonable.

Dyed textiles and paper products

Generally, disperse blue dyes, such as Disperse Blue 1, are partially soluble in water and display poor wetfastness (Hatch & Magee, 1998). These properties could potentially lead to significant leaching from the fabric to the skin under moist conditions (Hatch & Magee, 1998; Jacob & Ramirez, 2007). In addition, there may be increased exposure if the disperse dyeing is not done in accordance with best practice (OEHHA, 2012).

Therefore, the public could be exposed to the chemical by:

- dermal contact with the chemical from prolonged exposure to articles of clothing containing the dye, particularly tight fitting synthetic garments; and
- oral exposure by young children sucking textiles containing the dye.

If the chemical is used in paper products, sucking them is also a potential route of exposure.

However, the risk to the public from these routes of exposure is not considered to be unreasonable based on the following:

- limited worldwide production of the chemical has been reported (see **Import, manufacture and use** section);
- the chemical has low dermal absorption;
- whilst positive reactions were observed in some subjects following patch testing with the chemical, stronger reactions were seen with other disperse dyes; and
- whilst a genotoxic mode of action has not been completely ruled out, a threshold for the formation of the best-characterised tumours was established in carcinogenicity studies.

If information becomes available to indicate significant use of the chemical in Australia in cosmetics or in textile and paper products, a Tier III assessment is recommended to further characterise the exposure and risks from these uses.

Occupational Risk Characterisation

During product formulation, exposure of workers to the chemical may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemical at lower concentrations may also occur while using formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic long-term and local 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.

The *Guidance on the interpretation of workplace exposure standards for airborne contaminants* advises that 'exposure to carcinogens should be eliminated or minimised so far as is reasonably practicable' (Safe Work Australia, 2012).

Based on the available data, the hazard classification in the HSIS (Safe Work Australia) is considered appropriate.

NICNAS Recommendation

Current risk management measures are considered adequate to protect public and workers' health and safety, provided that all requirements are met under workplace health and safety, and poisons legislation as adopted by the relevant state or territory.

If information becomes available to indicate significant use of the chemical in Australia in cosmetics or in textile and paper products, a Tier III assessment is recommended to further characterise the exposure and risks from these uses.

Regulatory Control

Work Health and Safety

The chemical is 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	Risk of serious eye damage (Xi; R41)* Irritating to skin (Xi; R38)*	Causes serious eye damage - Cat. 1 (H318) Causes skin irritation - Cat. 2 (H315)

Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Sensitisation	May cause sensitisation by skin contact (Xi; R43)*	May cause an allergic skin reaction - Cat. 1 (H317)
Carcinogenicity	Carc. Cat 2 - May cause cancer (T; R45)*	May cause cancer - Cat. 1B (H350)

^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 industry

Control measures

Control measures to minimise the risk from oral, dermal, ocular and inhalation 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 which could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemicals from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemical, 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.

References

Ahuja V, Platzek T, Fink H, Sonnenburg A, Stahlmann R 2010. Study of the sensitising potential of various textile dyes using a biphasic murine local lymph node assay. *Archives of Toxicology* 84(9) pp. 709-718.

Burnett CM& Squire RA 1986. The effect of dietary administration of Disperse Blue 1 on the urinary system of the Fischer 344 rat. *Food and Chemical Toxicology* 24 (4) pp. 269-276.

Caliskaner Z, Kartal O, Baysan A, Yesillik S, Demirel F, Gulec M, Sener O 2012. A case of textile dermatitis due to disperse blue on the surgical wound. *Human& Experimental Toxicology*. 31(1) pp. 101-103.

ChemIDPlus Advanced. Accessed January 2015 at <http://chem.sis.nlm.nih.gov/chemidplus/>

Cosmetic Ingredient Review (CIR) 1995. Final report on the safety assessment of Disperse Blue 1. *Journal of the American College of Toxicology* 14 (6) pp. 433-451.

Cosmetic Ingredient Review (CIR) 2010. Disperse Blue 1 CIR Expert Panel Meeting December 13-14-2010. Accessed February 2015 at http://www.cir-safety.org/sites/default/files/117_draft_dpb1.pdf

Cosmetic Ingredient Review (CIR) 2011. Annual Review of Cosmetic Ingredient Safety Assessments: 2007-2010. *International Journal of Toxicology* 30 (Supplement 2) 735-1275

Dawes-Higgs E& Freeman S 2004. Allergic contact dermatitis caused by the clothing dye, disperse blue 106, an important contact allergen that may be frequently missed. *Australasia Journal of Dermatology* 45 pp. 62-65.

Derelanko& Auletta (2014). Approximate conversion factors (ppm to mg/kg/day) in *Handbook of Toxicology*, Third Edition, p84. Boca Raton: Taylor and Francis.

Doi AM, Irwin RD, Bucher JR 2005. Influence of functional group substitutions on the carcinogenicity of anthraquinone in rats and mice: analysis of long-term bioassays by the National Cancer Institute and the National Toxicology Program. *Journal of Environmental Health, Part B Critical Reviews* 8 (2) pp. 109-126.

European Parliament and Council 1999. Directive 1999/45/EC, Official Journal of the European Union, Publications Office of the European Union, Luxembourg. Accessed January 2015 at http://www.biosafety.be/PDF/1999_45.pdf.

European Parliament and Council 2006. Annex XII: Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles. Regulation (EC) No 1907/2006, Accessed January 2015 at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20130701:EN:PDF#page=234>

European Parliament and Council 2008. Annex 1 to Directive 67/548/EEC, Regulation (EC) No 1272/2008, Official Journal of the European Union, Publications Office of the European Union, Luxembourg. Accessed January 2015 at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2014:163:FULL&from=EN>.

Galleria Chemica. Accessed January 2015 at <http://jr.chemwatch.net/galleria/>

Hatch K & Magee P 1998. A discriminant model for allergic contact dermatitis in anthraquinone disperse dyes. *Quantitative Structure-Activity Relationships* 15 (1) pp. 20-25.

Haws LC, Jackson BA, Turnbull D, Dressler WE 1994. Two approaches for assessing human safety of disperse blue 1. *Regulatory Toxicology and Pharmacology* 19(1) pp. 80-96.

International Agency for Research on Cancer (IARC) 1990. Some Flame Retardants and Textile Chemicals, and Exposures in the Textile Manufacturing Industry. IARC Monographs Volume 48. Accessed January 2015 at <http://monographs.iarc.fr/ENG/Monographs/vol48/>

Jacob S & Ramirez C. 2007. Focus on 2000 Allergen of the Year: Textile Dyes. *The Dermatologist* 15(1). Accessed January 2015 at <http://www.the-dermatologist.com/article/6760>

Lisi P, Stingeni L, Cristaudo A, Foti C, Pigatto P, Gola M, Schena D, Corazza M, Bianchi L 2014. Clinical and epidemiological features of textile contact dermatitis: an Italian multicentre study. *Contact Dermatitis* 70 (6) pp. 344-350.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) 2007. List of Chemicals used as Dyes in Permanent and Semi-Permanent Hair Dyes in Australia.

National Toxicology Program (NTP) 1999. Final report on carcinogens background document for Disperse Blue 1. Accessed January 2015 at http://ntp.niehs.nih.gov/ntp/newhomeroc/other_background/disperse_blue_508.pdf

New Zealand (NZ) Environmental Protection Agency (EPA) 2006. Cosmetic Products Group Standard. Accessed January 2015 at <http://www.epa.govt.nz/Publications/Cosmetic%20Products%20Group%20Standard.pdf>

NTP 2011. Report on Carcinogens. Thirteenth Edition. Disperse Blue 1 (CAS No. 2475-45-8). Accessed January 2015 at [http://ntp.niehs.nih.gov/ntp/roc/content/profiles/disperseblue1.pdf#search=disperse blue 1](http://ntp.niehs.nih.gov/ntp/roc/content/profiles/disperseblue1.pdf#search=disperse%20blue%201)

Office of Environmental Health Hazard Assessment (OEHHA) 2012. Evidence on the carcinogenicity of C.I. Disperse Yellow 3. Accessed January 2015 at http://www.oehha.ca.gov/Prop65/hazard_ident/pdf_zip/081012CIYHID.pdf

Personal Care Products Council (INCI Dictionary). Accessed January 2015 at <http://www.ctfa-gov.org/jsp/gov/GovHomePage.jsp>

Platzek T 2012. Chemical risk assessment implications for product safety. Federal Institute for Risk Assessment, Germany. Accessed February 2015 at <http://www.oecd.org/internet/consumer/50195102.pdf>

Safe Work Australia (SWA). Hazardous Substances Information System (HSIS). Accessed January 2015 at <http://hsis.safeworkaustralia.gov.au/HazardousSubstance>

Safe Work Australia 2012. Guidance on the interpretation of workplace exposure standards for airborne contaminants. Accessed January 2015 at <http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/interpretation-airborne-contaminants-guide>

Saquib M, Abu Tariq M, Haque MM, Muneer M 2008. Photocatalytic degradation of disperse blue 1 using UV/TiO₂/H₂O₂ process. *Journal of Environmental Management* 88 (2) pp. 300-306.

Sonnenburg A, Ahuja V, Schreiner M, Platzek T, Stahlmann R 2012. Assessment of the sensitizing potential of textile disperse dyes and some of their metabolites by the loose-Wt coculture-based sensitization assay (LCSA). *Archives of Toxicology* 86 pp. 733-740.

The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) 2002. Opinion on the Safety Review of the Use of Certain Azo-Dyes in Cosmetics Products. SCCNFP/0495/01, final. Accessed February 2015 at http://ec.europa.eu/health/archive/ph_risk/committees/sccp/documents/out155_en.pdf

United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary. Accessed January 2015 at <http://gov.personalcarecouncil.org/jsp/gov/GovHomePage.jsp>

US Household Products Database (HPD). US Department of Health and Human Services. Accessed January 2015 at <http://householdproducts.nlm.nih.gov/advancedsearch.htm>

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