C.I. Acid Black 29: Human health tier II assessment

04 July 2014

CAS Number: 12217-14-0

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	Fast black MB Allilon acid black NB Apollo acid fast black MB
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Appearance and Odour (where available)	Black powder.

Import, Manufacture and Use

Australian

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

The chemical has reported commercial use including:

- textile dyeing in mills;
- wood stains and polishes;
- colour in detergents and crepe paper; and

- as identification in metal castings.

The total volume for the chemical introduced into Australia, reported under previous mandatory and/or voluntary calls for information, was less than 1 tonne.

Whilst no structure information is available, the chemical has been identified as a benzidine-based azo dye (SCCNFP, 2002). Industrial use of benzidine (CAS No. 92-87-5) is prohibited under state and territory workplace health and safety legislation; therefore, manufacture of this chemicals in Australia is not expected.

International

In general, the use of benzidine-based dyes is being phased out internationally and replaced with other types of dye (see **Restrictions (international)**). However, the following potential international uses have been identified through various international assessments (IARC,2010; US EPA, 2010; NTP, 2011; Government of Canada, 2013); the European Commission Cosmetic Ingredients and Substances (CosIng) database; and United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary.

The chemical, along with the related benzidine-based dyes, have reported domestic and commercial use including:

- in ink-jet printers;
- dyes used in the production of textiles, paints, printing inks and paper;
- lasers;
- liquid crystal displays; and
- electro-optical devices.

Restrictions

Australian

No known restrictions have been identified. However several benzidine-based azo dyes are listed in Schedule 7 (effective as of 1 June 2014), following consideration of a NICNAS assessment (NICNAS).

Schedule 7 chemicals are described as 'Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.' Schedule 7 chemicals are labelled with 'Dangerous Poison' (SUSMP, 2013).

International

Cosmetics

No known restrictions have been identified for the chemical. However, the related benzidine-based dyes, Direct Red 28 (CAS No. 573-58-0), Direct Black 38 (CAS No. 1937-37-7), Direct Blue 6 (CAS No. 2602-46-2) and Direct Brown 95 (CAS No. 16071-86-6) are listed on the following (Galleria Chemica):

- ASEAN Cosmetic Directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products;
- EU Cosmetic Directive 76/768/EEC Annex II—List of substances which must not form part of the composition of cosmetic products; and

- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain.

Other

The chemical is not listed on the *Toxic Substances Control Act* (*TSCA)* Chemical Substance Inventory. However, in the United States (US), several benzidine-based dyes are covered by a significant new use rule (SNUR) under section 5(a)(2) of the TSCA (40 CFR section 721.1660). This requires persons to notify the US Environmental Protection Agency (US EPA) at least 90 days before starting to manufacture, import or process these chemicals for any significant new use as described in this rule (use of some of the chemicals as laboratory stains and other analytical reagents are exempted) (US EPA 1996).

In August 2010, the US EPA released an action plan that addresses 48 dyes derived from benzidine and its derivatives (US EPA 2010). As a result of that action plan, on 20 March 2012, the US EPA released a proposed amendment to this SNUR. The amendment would not revoke the exemptions granted for uses as laboratory stains and other analytical reagents; however, it would revoke the exemption for articles. This would require persons who intend to import or process all listed benzidine-based chemical substances as part of an article to notify EPA at least 90 days before starting that activity.

Access to these dyes for home use is no longer permitted in the US (NTP, 2011).

The chemical is restricted by Annex XVII to REACH Regulation as follows:

'1. Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations,

i.e. above 30 ppm in the finished articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as:

- clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags;
- footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck;
- textile or leather toys and toys which include textile or leather garments; and
- yarn and fabrics intended for use by the final consumer.

2. Furthermore, the textile and leather articles referred to in paragraph 1 above shall not be placed on the market unless they conform to the requirements set out in that paragraph.'

Existing Work Health and Safety Controls

Hazard Classification

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

Exposure Standards

Australian

No specific exposure standards are available.

International

An occupational exposure limit (OEL) of 1 or 4 mg/m^3 is listed in Japan. In the US, the Occupational Safety and Health Administration (OSHA) and National Institute for Occupational Safety and Health (NIOSH) concluded that benzidine and benzidine-based dyes were potential occupational carcinogens and recommended that worker exposure be reduced to the lowest feasible level (NIOSH, 2011).

Health Hazard Information

Available data for the chemical are limited. However, the chemical has been identified as a benzidine-based azo dye. The critical concern for this chemical and the focus of this assessment relates to the potential carcinogenic effects following exposure. Data are available for four benzidine-based dyes; Direct Red 28 (CAS no. 573-58-0), Direct Blue 6 (CAS No. 2602-46-2), Direct Black 38 (CAS No. 1937-37-7) and Direct Brown 95 (16071-86-6). Based on the common metabolite, benzidine, the data are considered representative for C.I. Acid Black 29. Local effects are considered a secondary concern for this chemical and, as such, have not been considered as part of this assessment.

Toxicokinetics

Metabolism of benzidine-based dyes to free benzidine and its metabolites has been observed in both humans and animals. In rats and dogs, the amount of free benzidine detected was equivalent to that observed following an equimolar dose of benzidine (NTP, 2011; IARC, 2010; IARC, 2012; Government of Canada, 2013).

In vivo, azo reduction of benzidine-based substances, liberating free benzidine, occurs by an enzyme-mediated reaction. The intestinal microflora have been shown to be particularly active in azo dye reduction, but hepatic enzymes can also catalyse the reductive cleavage (Government of Canada, 2012, IARC, 2010).

Bacteria on the skin have also been shown to possess azoreductase activity (Government of Canada, 2012). In a study in male Fischer 344 (F344) rats and New Zealand White rabbits, radiolabelled Direct Black 38 (CAS No. 1937-37-7) was applied to shaved dorsal skin. Radioactivity in urine and faeces was measured 24–144 hours following dye application. Approximately 3 % of the administered radioactivity was detected in the urine and 5 % in the faeces of rabbits at 144 hours. Excretion of radioactivity was negligible in rats (0.05 % in urine and 0.16 % in faeces). Because skin penetration by the whole dye was considered very unlikely, the absorbed and excreted radioactivity in the rabbits was presumed to represent benzidine liberated by azo-reduction of the dye (ASTDR, 2001).

Acute Toxicity

Oral

No data are available for the chemical. However, similar benzidine-based dyes such as Direct Red 28, Direct Black 38 and Direct Blue 6 showed low acute toxicity in animal tests following oral exposure (NICNAS). The median lethal dose (LD50) in rats was greater than 2000 mg/kg bw. Observed sub-lethal effects included a decrease in motor activity; prostration and convulsions; and congestion of the liver and adrenal glands (HSDB).

Dermal

No data are available for the chemical. However, the related chemicals, Direct Red 28, Direct Black 38 and Direct Blue 6 showed low acute toxicity in animal tests following dermal exposure (NICNAS). The median lethal dose (LD50) in rats was greater than 2000 mg/kg bw. Observed sub-lethal effects included weakness and prostration and staining of organs (HSDB).

Inhalation

No data are available for the chemical. However, the related chemicals, Direct Red 28, Direct Black 38 and Direct Blue 6 showed low acute toxicity in animal tests following inhalation exposure (NICNAS). The median lethal concentration (LC50) was not reported, but was greater than: 50 mg/L (Direct Red 28); "concentrated atmosphere" (Direct Black 38); and 156 mg/L (Direct Blue 6). Observed sub-lethal effects included congestion of both the lungs and adrenal glands and weakness (HSDB).

Repeated Dose Toxicity

Oral

No data are available for the chemical. Due to the scope of studies conducted, limited data are available regarding non-cancer effects following repeated exposure to benzidine-based dyes (NICNAS). Reported non-cancer effects for the related chemicals, Direct Blue 6, Direct Black 38, and Direct Brown 95 include reduced body weight gain (HSDB). Data regarding non-cancer effects for the metabolite benzidine are considered too limited to identify critical target organs or a no observed adverse effect level (NOAEL) (NICNAS). Reported effects include cardiovascular, hepatic, renal, haematological, immunological, or weight-loss effects (ASTDR, 2001).

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

No data are available for the chemical. A dose-related increase in the number of circulating peripheral lymphocytes displaying chromosomal aberrations was observed in workers exposed to benzidine and benzidine-based dyes (Direct Black 38 and Direct Blue 6). The highest frequencies of aberrant lymphocytes were associated with the highest airborne dust concentrations of benzidine (0.42–0.86 mg/m^3) or benzidine-based dyes (7.8–32.3 mg/m^3), and with the highest mean levels of benzidine found in the urine (1.8–2.3 µg/L). The frequency of polyploid lymphocytes was also elevated in workers when compared with controls (ASTDR, 2001; IARC 2010).

Direct Black 38 and Direct Blue 6 have been shown to form adducts with DNA in the livers of rats (HSDB).

Direct Black 38, and urine from animals exposed to Direct Black 38 were mutagenic in *Salmonella typhimurium* in the presence of metabolic activation only. Direct Blue 6 was weakly mutagenic in *S. typhimurium* both in the presence and absence of metabolic activation (HSDB).

Several in vitro assay are available for Direct Brown 95. The chemical was positive in a mouse lymphoma assay in the presence of activation, negative in an in vitro chromosome aberration (with and without activation), and equivocal in a sister chromatid exchange assay (with activation), in Chinese hamster ovary cells. The chemical was negative in vivo in a *Drosophila* sex-linked recessive lethal study.

Direct Black 38 was reported to be negative in an in vitro chromosome aberration assay, and equivocal in a sister chromatid exchange assay in Chinese hamster ovary cells both with and without activation (NTP).

The metabolite benzidine has been shown to induce bone marrow micronuclei in certain strains of mice, and unscheduled DNA synthesis in the livers of rats following oral or intraperitoneal injection exposure (ASTDR, 2001; IARC 2010).

Carcinogenicity

No data are available for the chemical. The chemicals Direct Red 28, Direct Black 38, Direct Blue 6 and Direct Brown 95 are currently classified as hazardous as a Category 2 carcinogen with the risk phrase ‘May cause cancer’ (T; R45) in HSIS (Safe Work Australia). Several other benzidine-based dyes are recommended for classification for carcinogenicity (NICNAS). Based on the common metabolite benzidine, the chemical is also recommended for classification (refer **Recommendation** section).

Three benzidine-based dyes (Direct Black 38, Direct Blue 6 and Direct Brown 95) have been tested for carcinogenicity in animals. The International Agency for Research on Cancer (IARC) concluded that there was sufficient evidence for the carcinogenicity of dyes metabolised to benzidine on the basis of these studies. Observed effects included increased incidence of hepatocellular carcinomas and liver neoplastic nodules with all three dyes, and mammary gland cancers with Direct Black 38. A slight increase in transitional cell carcinoma of the urinary bladder was observed in an implantation study with Direct Blue 6. Hepatocellular carcinomas and liver neoplastic nodules were observed for all three dyes, despite a relatively short exposure period of 13 weeks (NTP, 2011; IARC, 2012; Government of Canada; 2013).

The evidence of bladder cancer for workers exposed to benzidine-based dyes was not consistent across studies. There were limitations in the studies, including coexposure to known carcinogens in humans. Despite this, IARC has classified dyes metabolised to benzidine as carcinogenic to humans (Group 1) and the US National Toxicology Program has also classified dyes metabolised to benzidine as 'known to be human carcinogens'. The findings were based on:

- benzidine is known to be a human carcinogen;
- the metabolism of benzidine-based dyes results in the release of free benzidine and the induction of chromosomal aberration in humans; and benzidine exposure from exposure to benzidine-based dyes is equivalent to exposure to equimolar doses of benzidine.

Reproductive and Developmental Toxicity

No data are available for the chemical. The chemicals Direct Red 28, Direct Black 38 and Direct Blue 6 are classified as hazardous—Category 3 substance toxic to reproduction—with the risk phrase ‘Possible risk of harm to the unborn child’ (T; R63) in HSIS (Safe Work Australia). Several other benzidine-based dyes are recommended for classification for developmental toxicity (NICNAS). Based on the common metabolite, benzidine, the chemical is also recommended for classification (refer **Recommendation** section).

The effects of prenatal exposure to Direct Red 28, Direct Black 38 and Direct Blue 6 on testicular development were studied in mice. Pregnant CD-l mice were administered 0 or l mg/kg azo dye orally on gestational days eight to 12 and were observed for clinical signs of toxicity. Significantly decreased testicular weight and increased seminiferous tubule atrophy was observed. Many of the tubules contained no germ cells (HSDB).

In another study with Direct Red 28 in mice, inhibited testicular and ovarian function was observed in offspring after oral administration of 1 or 0.5 g/kg/day on gestational days 8–12. The testes of male offspring were small and contained hypospermatogenic seminiferous tubules; however, no impact on fertility when mated to untreated females was observed. In contrast, female offspring produced significantly reduced numbers of litters and pups compared with controls. Histological examination of the ovaries revealed that subfertility was correlated with ovarian atrophy (HSDB).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects including carcinogenicity, reproductive toxicity and developmental toxicity. Benzidine based-dyes have been shown to be metabolised to the benzidine, a known human carcinogen.

Public Risk Characterisation

Whilst the use of benzidine-based dyes is being phased out in some countries, use of the chemical in small amounts has been reported to NICNAS under previous mandatory and/or voluntary calls for information. The introduction of this chemical for home use cannot be excluded. In addition, textiles and other products manufactured with these chemicals in other countries could be imported into Australia.

Dermal exposure to the chemical could occur though prolonged contact with dyed textiles and leather. Bacteria on the skin have been shown to possess azoreductase activity, and bioavailability has been demonstrated in animals following dermal exposure. Oral ingestion could also occur in infants through the sucking or chewing of textiles.

Benzidine has been detected in textiles; leaching of benzidine has been demonstrated in the presence of sweat stimulants (DTI, 1998; EurAzos, 2007; RAPEX; Kawakami 2010; Zeilmaker et al, 1999). In some cases, the concentrations of benzidine in samples exceeded the European 30 mg/kg limit by more than tenfold. An international assessment of the risk of cancer caused by textiles and leather goods coloured with certain azo dyes concluded that, while consumer exposure is likely to be 'very low', the associated cancer risks give cause for concern. Although this assessment was not publicly available, the European Scientific Committee on Toxicity, Ecotoxicity and Environment (CSTEE) considers that the report adequately reviews the situation regarding the risk of cancer for consumers as a result of the use of fabrics dyed with azo compounds, and that its conclusions are, in general, acceptable. The CSTEE also supported the recommendation that use of azo dyes that have the potential to give rise to the 14 aromatic amines classified as Category 1 or 2 carcinogens according to Directive 76/769/EEC (these include benzidine), should be restricted to the lowest possible levels or completely eliminated.

The introduction of textiles or leather articles containing benzidine-based dyes is restricted in Europe and proposed to be restricted in the United States. Access to benzidine-based dyes for home use is also prohibited in the United States.

In June 2013, NICNAS completed an assessment of a number of azo dyes which may break down to produce the potent carcinogen, benzidine. The chemicals were recommended for scheduling to prohibit their sale, supply and use in consumer products (NICNAS). The scheduling delegate decided to list the chemicals in Schedule 7 of the Poisons Standard (effective as of 1 June 2014). In the absence of similar regulatory controls, this chemical could also pose an unreasonable risk to the public.

NICNAS also recommended that the Australian Competition and Consumer Commission (ACCC) “consider mechanisms to restrict the supply of textiles and leather articles which may come into direct and prolonged contact with the human skin, that may plausibly result in human exposure to these chemicals at unacceptable levels”. In considering the NICNAS recommendation, the ACCC conducted a market survey to determine if any dyes of concern had been used in the manufacture of consumer goods supplied in Australia. The ACCC has negotiated several recalls of products based on the results of the surveys (ACCC). The testing conducted by the ACCC tested for the concentration of aromatic amines (including benzidine) released from the chemical. This testing is considered appropriate for the chemical.

Occupational Risk Characterisation

During use of the chemical, dermal, ocular and inhalation exposure of workers to the chemical could occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintenance of equipment. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic long-term health effects, the chemical may pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure to the chemicals are implemented. The chemical 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 appropriate controls. Airbourne concentrations of the chemical should be kept as low as resonably practicable to minimise risk. Overseas use of mixtures containing benzidine at concentrations of 0.1 % or more is permitted only in closed systems and all workers must observe special precautions to avoid exposure (NTP, 2011).

The data available support an amendment to the hazard classification in HSIS (refer to **Recommendation section**).

NICNAS Recommendation

Further risk management is required. Sufficient information is available to recommend that risks to public health and safety from the potential use of the chemical in consumer products be managed through changes to poisons scheduling, and risks for workplace health and safety be managed through changes to classification and labelling.

The previous recommendation to the ACCC (NICNAS) is considered to adequately cover this chemical.

Assessment of the chemicals is considered to be sufficient provided that risk management recommendations are implemented and all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Public Health

The chemical is recommended for listing in Schedule 7 consistent with other benzidine-based dyes.

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 hazards and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Carcinogenicity	Carc. Cat 2 - May cause cancer (T; R45)	May cause cancer - Cat. 1B (H350)
Reproductive and Developmental Toxicity	Repro. Cat 3 - Possible risk of harm to the unborn child (Xn; R63)	Suspected of damaging fertility or the unborn child - Cat. 2 (H361)

[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 chemical should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from dermal, ocular and inhalation exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Given the action taken overseas, it is considered that substitutes for the use of benzidine dyes in textiles and leathers should be readily available.

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 chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemical 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;
- air monitoring to ensure control measures in place are working effectively and continue to do so;
- 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 chemical.

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 assist with meeting 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 chemical 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 the chemical has not been undertaken as part of this assessment.

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