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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

# DISAZO BLACK DM 5594

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Director
Chemicals Notification and Assessment

# FULL PUBLIC REPORT

# DISAZO BLACK DM 5594

## 1. IMPORTER

Ciba-Geigy Australia Limited of 140 Bungaree Road, Pendle Hill, NSW 2145.

## 2. IDENTITY OF THE CHEMICAL

**Other name:** Disazo Black DM 5594
FAT 40'343/B

**Trade name:** Lanasol Black R

**Molecular weight:** > 1000

**Spectral data:** UV-VIS and Infra-red spectra were supplied.

The notifier has applied for exemption from publication of the following items:

. chemical name;

. CAS number;

. molecular and structural formulae;

. molecular weight;

. spectral data;

. composition of Disazo Black DM 5594;

. estimated manufacture/import volume; and

. number of sites at which the product will be used.

Exemption from publication has been granted as the chemical is considered to be non-hazardous.

## 3. PHYSICAL AND CHEMICAL PROPERTIES

Disazo Black DM 5594 is a dark blue powder with no discernible odour at room temperature and atmospheric pressure. Its physical and chemical properties include:

**Melting Point:** > 300°C

**Density:** $1.83 \times 10^3$ kg/$m^3$ (at 22°C)

**Vapour Pressure:** negligible, as for high molecular weight organic salts

**Water solubility:** > 300 g/L (at 20°C). At concentrations around 2000 g/L the substance forms a paste.

**Degree of hydrolysis:** $t_{1/2}$ = 3220 hours (pH 4, 25°C)

$t_{1/2}$ < 1 day (pH 7, 25°C)

$t_{1/2}$ < 1 day (pH 9, 25°C)

The dye's chemical structure and pH dependence suggest that hydrolysis involves loss of hydrogen bromide.

**Partition co-efficient:** log $P_{OW}$ = -12.7

**Soil adsorption-desorption:** Test not performed. Given the labile nature of the dye under the alkaline conditions prevailing in the dye bath, significant soil exposure appears unlikely.

**Dissociation constant:** The high water solubility of the dye indicates a high degree of dissociation. However, this was not measured as dissociation behaviour will be complex because of the dye's multi-functional chemistry.

**Fat solubility:** < 0.05 mg/100 g fat (at 37°C)

| | |
|---|---|
| **Particle size:** (median mass distribution) | 22.1 µm |
| **Flammability:** | non-flammable |
| **Auto-ignition temperature:** | 270°C |
| **Explosive potential:** | non-explosive |
| **Oxidising properties:** | non-oxidising |
| **Thermal stability:** | stable with or without air at room temperature to 150°C |

## 4. METHOD OF DETECTION AND DETERMINATION

Disazo Black DM 5594 can be separated by High Pressure Liquid chromatography and identified by Infra-red spectroscopy, Nuclear Magnetic Resonance spectroscopy and Ultra-violet/visible spectroscopy.

## 5. PURITY OF THE CHEMICAL

**Degree of purity:**

| | |
|---|---|
| Active material | 50-80% |
| By-products | 10-40% |
| Sodium Bromide | < 10% |
| Dibromopropionic Acid | < 10% |
| Water | < 10% |

The majority of the by-products have similar structures to the main component and can be expected to have similar properties.

The formulated product, Lanasol Black R, will contain approximately 43% Disazo Black DM 5594. Other ingredients of Lanasol Black R will be Lanasol Yellow 4G, Lanasol Scarlet 3G, potassium sulphate, sodium sulphate, sodium chloride and an antidusting agent.

## 6. INDUSTRIAL USES

Disazo Black DM 5594 will be used solely as a reactive dye in the formulated product Lanasol Black R. Lanasol Black R will be used for the colouration of wool in the textile industry in NSW,

Victoria and South Australia. The wool will be dyed by package, hank yarn, tops and piece processes.

The notifier intends to import more than 1 tonne per year of Disazo Black DM 5594 for the first five years.

## 7. OCCUPATIONAL EXPOSURE

Disazo Black DM 5594 will be imported as a constituent of the formulated product Lanasol Black R in sealed, robust 25 kg drums and transported on to the customers without opening or reformulation. Therefore, significant risk of occupational exposure from accidental spillage during transit is unlikely.

The notifier estimates that approximately 25 kg per year of Lanasol Black R may need to be repacked by Ciba-Geigy for customer trials. This would involve two workers weighing and packaging small amounts of the product on a few occasions per year.

Disazo Black DM 5594 will be used in Lanasol Black R for wool dyeing in textile mills in Australia. Approximately three workers at each mill will be involved in the weighing and dissolving of the dye for production batches. Lanasol Black R is usually dissolved in warm water in a side tank and automatically pumped into the dye bath. The dye is permanently fixed to the wool during the dyeing process, thus presenting minimal occupational exposure for workers handling the dyed wool.

Thus workers could be exposed to the dye powder when repacking, weighing and dissolving the dye. Engineering controls, personal protection measures and good personal hygiene should be observed when handling the dye powder. Once the dye has been dissolved the potential for occupational exposure to dust is removed. However, skin contact may result when handling the dye in solution and when spillages occur. Personal protection measures and good personal hygiene should be observed to minimise exposure to the dye solution.

Under correct handling and dyeing conditions, the potential for occupational exposure to Disazo Black DM 5594 should be minimal.

## 8. PUBLIC EXPOSURE

Disazo Black DM 5594 will be imported and distributed as a constituent of Lanasol Black R in sealed drums. Accidental transport spillage is likely to be limited as containers are small and discrete. Public exposure to the dye as a result of being leached from woollen products is expected to be negligible. Once dyeing has occurred Lanasol Black R is permanently fixed to the woollen product, thus presenting minimal public exposure. As indicated by several tests for fastness, Lanasol Black R has very good wet fastness properties. Fixation tests have shown that Lanasol Black R has the highest possible fastness in the perspiration test and has a fixation degree of 95% to wool. Small amounts of the product, which do not react with the wool, would be released to the effluent plant. However, Disazo Black DM 5594 is highly water soluble and will not bioaccumulate in the environment.

Public exposure to the dye is expected to be minimal under normal use conditions.

## 9. ENVIRONMENTAL EXPOSURE

### 9.1 Release

Being a reactive dye, Disazo Black DM 5594 is chemically bound to textiles during use. Reactive dyes are fixed onto fibres under alkaline conditions, with the reactive groups sometimes being generated *in situ* (1). This would appear to be the case for Disazo Black DM 5594, with the reactive groups being vinyl amides formed by rapid elimination of hydrogen bromide under the alkaline conditions of the dye bath.

Disazo Black DM 5594 will be used as a replacement for existing formulations containing sodium dichromate, which give rise to pollution and disposal problems as 20-30% of the chromium is discharged in aqueous effluent and the remainder forms part of the solid waste stream. It is expected that a small number of textile mills will use dye, all discharging waste to municipal sewage works. Unused dyestuff (container residues and spillages) will be disposed of by incineration or secure landfill.

## 9.2 Fate

As Disazo Black DM 5594 contains two reactive termini, it has a high fixation efficiency of around 95% (1). Accordingly, the bulk of the dye will be bound to woollen textiles and in this state is not expected to impact on the environment.

Unfixed residues from dying operations will enter the aquatic environment following discharge from textile mills and subsequent sewage treatment, during which they may be removed through degradation (chemical or biological) or binding to sludge. In view of the ease of hydrolysis under alkaline conditions, it is unlikely that significant quantities of Disazo Black DM 5594 will be discharged from mills. However, as this hydrolysis simply involves loss of hydrogen bromide and possible subsequent hydrolysis of the resultant vinyl amide, no degradation of the essential *bis*(arylazo)naphthalene structure through either biotic or abiotic mechanisms is expected. This prediction is supported by the observation that the related dye, CI Acid Black 1, neither underwent significant transformation nor adsorption to sludge in pilot-scale activated sludge systems (2). Reactive dyes in general have been found not to adsorb to sludge in model systems (3).

In the specific tests on Disazo Black DM 5594, ready biodegradation was not observed when the dye was tested using effluent from a domestic sewage plant according to OECD Guideline 301A (1.1% loss of dissolved organic carbon in 28 days). Testing of biological oxygen demand confirmed this resistance to degradation ($BOD_5$ = 3 mg/g $O_2$) but the dye was susceptible to chemical oxidation (COD = 704 mg/g $O_2$). The slow rate at which this and other highly sulphonated dyes undergo aerobic biodegradation probably reflects the low absorption of these soluble compounds by microbial cells (4).

Residues which survive sewage treatment will enter freshwater or marine environments in solution. Azo dyes are generally stable under aerobic conditions, but are susceptible to reductive degradation under the anaerobic conditions characteristic of sediment (5). Although hydrophilic, Disazo Black DM 5594 and its sulphonated metabolites can be expected to partition to sediment as other highly sulphonated *bis*(azo) dyes have been shown to sorb to sediment (6). Degradation of such dyes in sediment water systems proceeded with a half-life of 2-16 days. Accordingly, no

significant increase in dissolved concentrations over time is predicted, while residues bound to sediment are expected to undergo reductive degradation.

The bioaccumulation potential of Disazo Black DM 5594 was not investigated because of the low partition coefficient. Hydrophilic dyes with log $P_{OW}$ < 3 have been shown not to bioaccumulate (7).

## 10. EVALUATION OF TOXICOLOGICAL DATA

### 10.1 Acute Toxicity

Table 1 Summary of acute toxicity of Disazo Black DM 5594 (FAT 40'343/B)

| Test | Species | Dose | Outcome | Reference |
|---|---|---|---|---|
| Oral | Rat | 5000 mg/kg | LD50>5000 mg/kg | 8 |
| Dermal | Rat | 2000 mg/kg | LD50>2000 mg/kg | 9 |
| Skin irritation | Rabbit | 0.5 g | non-irritant | 10 |
| Eye irritation | Rabbit | 0.1 g | slight irritant | 11 |
| Skin sensitisation | Guinea pig | 5% induction 25% challenge | non-sensitising | 12 |

#### 10.1.1 Oral toxicity

This limit test was performed according to the OECD Guidelines for Testing Chemicals, Section 4: Health Effects, No. 401.

A single 5000 mg/kg dose of Disazo Black DM 5594 was administered by gavage to 5 male and 5 female rats. The dye was suspended in a 4% solution of carboxymethylcellulose (CMC) sodium salt. The animals were observed for 15 days. One male and two female rats died on day two of the study. Clinical symptoms observed in the animals included slight sedation, dyspnea, emaciation (males) and ruffled fur. These symptoms had disappeared by day 9 of the study. Blue discolouration of the extremities was observed in

all test animals. Necroscopy was performed on all animals and bluish discolouration of the skin, liver, stomach and intestines was noted in some animals. The oral rat $LD_{50}$ was greater than 5000 mg/kg (8).

### 10.1.2 Acute Dermal Toxicity

A limit test was carried out according to the OECD Guidelines for Testing Chemicals, Section 4: Health Effects, No. 402.

A single 2000 mg/kg dose of Disazo Black DM 5594 was applied to the shaved backs of 5 male and 5 female rats and covered with an occlusive wrap. The test material was applied in a 4% solution of CMC sodium salt. Twenty-four hours after application the wrap was removed and the treated skin was washed with water. The animals were observed for 15 days. Slight erythema was observed in some of the test animals, from day 2 to day 7. Blue discolouration of the skin was observed from day 2 to 15 in all animals. No deaths occurred and no systemic toxicity was noted. No macroscopic organ changes were observed at necroscopy. The acute dermal rat $LD_{50}$ for Disazo Black DM 5594 was greater than 2000 mg/kg (9).

### 10.1.3 Acute dermal irritation/corrosion

This study was carried out in accordance with the OECD Guidelines for Testing Chemicals, Section 4: Health Effects, No. 404.

A single dose of 0.5 g of Disazo Black DM 5594 was applied to the intact skin of the shaved backs of 3 rabbits (2 males and 1 female). A semi-occlusive wrap was applied for 4 hours. The wrap was removed and the skin was washed with water and then examined at 1, 24, 48 and 72 hours. Blue discolouration of the treated skin was noted in all animals. If necessary the skin was flushed with water prior to observation so that any symptoms, such as erythema, would be clearly visible. No signs of erythema or oedema were observed. The results of this study indicate that Disazo Black DM 5594 is not a skin irritant in rabbits at the concentration tested (10).

### 10.1.4 Acute eye irritation/corrosion

This study was performed in accordance with the OECD Guidelines for Testing Chemicals, Section 4: Health Effects, No. 405.

The test material, O.1 g, was placed in the conjunctival sac of one eye of each of 3 rabbits (2 males and 1 female). The other eye of each animal was not treated and served as the control. All eyes were examined 1, 24, 48 and 72 hours and 7 days after dosing. Oedema was noted at 1 hour and 24 hours in all treated eyes. Slight erythema was noted in the treated eye of two animals from 24 to 72 hours. Blue discharge was noted in all treated eyes at 1 hour. Blue staining of the cornea, iris, nictating membrane, sclera, conjunctivae and eyelashes of the treated eyes were observed in all animals throughout the observation period. No corrosion of the cornea was observed. Disazo Black DM 5594 was a slight eye irritant in rabbits at the concentration tested (11).

**10.1.5 Skin sensitisation**

This study was carried out in accordance with the OECD Guidelines for Testing Chemicals, Section 4: Health Effects No. 406, using the Guinea Pig Maximisation Test.

From a preliminary study, the following suitable concentrations were chosen for the main sensitisation study; 5% Disazo Black DM 5594 in saline for the intradermal injections and 25% Disazo Black DM 5594 for the topical application. In the induction and challenge study, 30 guinea pigs (15 males and 15 females) were used of which 10 (5 males and 5 females) served as controls.

Induction

Three pairs of intradermal injections (0.1ml/site) were made to the clipped scapular area of 20 guinea pigs as follows:

. Freunds' complete adjuvant 50:50 with saline;

. Disazo Black DM 5594 diluted to 5% in saline; and

. 5% concentration Disazo Black DM 5594 emulsified in a 50:50 mixture of Freunds' complete adjuvant and saline.

One week later, the same scapular area was shaved and a 25% concentration of Disazo Black DM 5594 was applied under an occlusive wrap for 48 hours. The control groups were similarly treated, except for the omission of the test material.

Challenge

All animals were challenged two weeks after the topical induction application. A 25% concentration of Disazo Black DM 5594 in saline was applied, under an occlusive wrap for 24 hours, to the left shaved flank of each guinea pig. Saline alone was applied to the other shaved flank. The sites were examined for signs of erythema and oedema immediately, and at 24 hours and 48 hours following removal of the wrapping.

A second challenge was performed two weeks after the first challenge. The challenge method for the treated animals was the same as for the first challenge except the dye solution was applied to the opposite flank (right) and saline to the left flank. The control animals were treated with the saline alone.

Slight erythema was noted in one (of 19) treated guinea pigs at 24 hours after the first challenge. No signs of oedema were observed in any of the test animals after the first or second challenge. One male guinea pig, in the treated group died on day 6 of the test and no macroscopic organ changes were noted upon necroscopy of this animal. Disazo Black DM 5594 is not a skin sensitiser in guinea pigs (12).

**10.2 Five day oral toxicity**

Disazo Black DM 5594 was administered daily by oral gavage to 3 groups of 6 rats (3 of each sex) for 5 days, at dose levels of 0, 200 and 1000 mg/kg. The dye was administered in a solution of 4% CMC. No deaths occurred and no clinical signs were observed in any animals during the study. At necroscopy, liver weights were increased in the male 200 mg/kg dose group and the female 1000 mg/kg dose group. In addition, the liver and kidney weight to body weight ratios were increased in the male 200 mg/kg group. At necroscopy, bluish discolouration was noted in the kidneys of 2 males and 3 females of the 200 mg/kg group and in most of the organs of all rats in the 1000 mg/kg group (13). From the results of this study, the dose levels for the 28-day oral toxicity study were chosen.

**10.3 Twenty eight day Repeat-dose Oral Toxicity**

This study was carried out according to the OECD Guidelines for Testing Chemicals, Section 4, Health Effects, No. 407.

In this repeat-dose oral toxicity study, Disazo Black DM 5594 was administered daily by gavage to rats for 28 days. Four groups of male and female rats were administered 0 mg/kg (20 rats), 50 mg/kg (10 rats), 200 mg/kg (10 rats) or 1000 mg/kg (20 rats) of Disazo Black DM 5594 in a 4% solution of CMC. After completion of the 28-day study, 10 rats from the control group (0 mg/kg) and 10 from the highest dose group (1000 mg/kg) were observed for a further treatment-free 14 days. No deaths occurred during the treatment and recovery periods. In the 1000 mg/kg group, all rats had bluish faeces from day 26 to 29. Also, in this high dose group, bluish discolouration of the extremities was observed from day 26 up to day 14 of the recovery period. Slight changes in the concentrations of blood and urine parameters were noted, however, most findings had been reversed by the end of the recovery period. At necroscopy, bluish discolouration of many organs, including the entire gastrointestinal tract, urinary tract, reproductive organs and subcutaneous tissues was observed in the 1000 mg/kg group, both at 28 days and after the recovery period. A decreased liver to body weight ratio was noted in the 1000 mg/kg female group at the end of the recovery period (14).

**10.4 Mutagenicity**

Table 2 Summary of mutagenicity of Disazo Black DM 5594 (FAT 40'343B)

| **Test** | **Species** | **Dose Range** | **Outcome** | **Reference** |
|---|---|---|---|---|
| Reverse Mutation | Salmonella typhimurium | 10-5000 Êg/plate | negative | 15 |
| In vitro Chromosome Aberration | Chinese Hamster | 30-750 ug/ml | weakly positive | 17 |
| In vivo micronucleus | Chinese Hamster | 1800 mg/kg | negative | 18 |
| In vivo Chromosome Aberration | Chinese Hamster | 5000 mg/kg | negative | 19 |

### 10.4.1 **Salmonella typhimurium, Reverse Mutation Assay** [1]

This Ames test was carried out according to the OECD Guidelines for Testing Chemicals, Section 4, No. 471.

Disazo Black DM 5594 (FAT 40'343/B) at concentrations of 10, 100, 333.3, 1000 and 5000 µg/plate was tested in two independent experiments for gene mutation according to the direct plate incorporation method. *Salmonella typhimurium* strains TA 1535 and TA 100 were used to indicate base pair mutations, and TA 1537, TA 1538 and TA 98 to indicate frame-shift mutations. Untreated and solvent (water) test plates were used as negative controls. The test article plates and the negative control plates were performed both in the presence and absence of microsomal activation (S9 liver microsome mix). Positive controls included sodium azide and 4-nitro-o-phenylene-diamine, both without metabolic activation, and 2-aminoanthracene with metabolic activation. All tests were performed in triplicate. No dose-related increase in the number of revertant colonies was observed in any of the strains exposed to Disazo Black DM 5594 or in the negative controls, in the presence and absence of metabolic activation. In contrast, the positive controls showed marked increases in the number of revertant colonies. Cytotoxic effects, as indicated by a reduction in the number of revertant colonies, was observed in some test groups at the two highest doses, with or without metabolic activation. Disazo Black DM 5594 did not produce point mutations in *Salmonella typhimurium* under the conditions of the study (15).

### 10.4.2 **Salmonella typhimurium, Reverse Mutation Assay** [2]

This Ames test was carried out according to the OECD Guidelines for Testing Chemicals, Section 4, No. 471.

FAT 40'343/A (a research grade of FAT 40'343/B) was tested in this reverse mutation assay. FAT 40'343/A was tested using exactly the same methodology as the above reverse mutation assay for FAT 40'343/B, except that the experiment was only performed once. A decrease in the number of spontaneous revertants in some strains at the highest dose indicated slight toxic effects. No dose-related increase in the number of revertant colonies was observed in any of the strains exposed to FAT 40'343/A, in the presence and absence of metabolic activation. FAT 40'343/A did

not produce point mutations in *Salmonella typhimurium* under the conditions of the study (16).

### 10.4.3 *In vitro* Chromosome Aberration Assay

This study was carried out according to the OECD Guidelines for Testing Chemicals, Section 4, No. 473.

Chinese hamster V79 cells were exposed *in vitro* to Disazo Black DM 5594 over a dose range of 30 to 600 µg/ml in the absence of exogenous metabolic activation and 30 to 750 µg/ml in the presence of metabolic activation (S9 liver microsome mix). Cell samples were taken at 7, 18, and 28 hours after the start of treatment and assayed for structural chromosomal aberrations. The solvent was used as a negative control and ethylmethanesulfonate and cyclophosphamide as positive controls. Plating efficiency was reduced at the highest dose of Disazo Black DM 5594. The mitotic index was reduced by approximately 30 % in the cells treated with 750 µg/ml, in the presence and absence of metabolic activation. In the presence of metabolic activation the test article at 600 and 750 µg/ml induced chromosomal aberrations. A second experiment at 750 µg/ml in the presence of metabolic activation assayed at 18 and 28 hours was inconclusive. A third experiment was performed using 300 µg/ml assayed at 18 hours and 600 µg/ml assayed at 18 and 28 hours in the presence of metabolic activation. At 28 hours a dose-dependant increase in chromosomal aberrations was observed. The positive controls showed distinct increases in cells with structural chromosome aberrations. Therefore, Disazo Black DM 5594 was weakly clastogenic in the V79 Chinese hamster cell line in the presence of metabolic activation (17).

### 10.4.4 Micronucleus Test

This study was carried out according to the OECD Guidelines for Testing Chemicals, Section 4, No. 474.

An 1800 mg/kg dose of Disazo Black DM 5594 was administered to Chinese hamsters (3 males and 3 females). The test material was suspended in a mixture of dimethylsulphoxide and fetal calf serum (1+4) and administered intraperitoneally. The solvent was used as a negative control and cyclophosphamide as the positive control. Bone marrow cells were collected 24 hours after administration for micronuclei analysis. Two males and one female hamster in the test group died. The number of

micronucleated polychromatic erythrocytes was not increased in the surviving animals administered with Disazo Black DM 5594 and in the negative controls. In contrast the positive control showed a distinct increase (18).

### 10.4.5 *In vivo* Chromosome Aberration Assay

This *in vivo* mammalian bone marrow cytogenetic study was carried out according to the OECD Guidelines for Testing Chemicals, Section 4, No. 475.

A 5000 mg/kg dose of Disazo Black DM 5594 was orally administered to 3 groups (6 males and 6 females) of Chinese hamsters. The test material was administered in a 1% CMC suspension. Bone marrow cells were collected for chromosome aberration analysis at 6, 24 and 48 hours after dosing. Cyclophosphamide was administered to the positive control group, and CMC to the negative control group. Two of 36 animals which were administered the test material died during the study. Mitotic depression was observed at 6, 24 and 48 hours after administration of the test material. Disazo Black DM 5594 did not induce chromosome aberrations in bone marrow cells of the Chinese hamster (19).

## 10.5 Overall Assessment of Toxicological Data

Disazo Black DM 5594 exhibited low acute oral toxicity (rat oral $LD_{50}$ > 5000 mg/kg) and low acute dermal toxicity (rat dermal $LD_{50}$ > 2000 mg/kg). Disazo Black DM 5594 was not a skin irritant (rabbit) or skin sensitiser (guinea pig), but was a slight eye irritant (rabbit). A 28-day repeat-dose study in rats showed no evidence of irreversible toxicity. Disazo Black DM 5594 was found to be non-genotoxic in the Ames test, *in vivo* micronucleus test and *in vivo* chromosome aberration assay, but induced chromosome aberrations *in vitro* in Chinese hamster V79 cells at high concentrations in the presence of metabolic activation. Since Disazo Black DM 5594 only tested positive in one of three *in vitro* tests and, significantly, was not genotoxic *in vivo* , the compound is considered to be weakly genotoxic and unlikely to pose a significant genotoxic hazard to man.

## 11. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Table 1 Summary of aquatic toxicity of Disazo Black DM 5594, obtained from tests according to OECD Guidelines 203 and 202.

| Test | Species | Result |
|---|---|---|
| 96h exposure | Zebrafish (*Brachidanio rerio*) | $LC_{50}$ = 485 mg/L |
| Acute immobilization | *Daphnia magna* | 24h $EC_{50}$ > 1000 mg/L |

The above results indicate that Disazo Black DM 5594 has very low toxicity to aquatic fauna. While reproduction tests for daphnids were not conducted, the lack of acute toxicity and the probability that the dye will not undergo cellular absorption indicate that reproductive effects are unlikely to be observed.

Respiratory inhibition of microorganisms in activated sewage sludge was tested according to OECD Guideline 209. The $IC_{50}$ exceeded the highest concentration tested (100 mg/L), indicating that the dye has low toxicity to microbes, as expected for a highly sulphonated compound that is unlikely to be absorbed by microbial cells.

No data were provided for algal growth inhibition on the grounds that "the substance will colour alga strongly, and any growth changes will be masked by this effect and render the test unreliable". Algal growth inhibition tests on 56 dyestuffs showed close parallels with fish toxicity, apart from some acid dyes highly toxic to fish which did not affect algae (20). Accordingly, it appears unlikely that the notified substance will be toxic to algae and the test was not required.

Terrestrial species are unlikely to experience significant exposure to the dye and animal studies show that Disazo Black DM 5594 has low acute toxicity.

## 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Disazo Black DM 5594 was not a skin sensitiser in animal studies and inhalation studies were not carried out. The particle size of the dye is well above the respirable size of 7 µm (21) and Lanasol Black R contains antidusting agents. However, inhalation and skin contact should be avoided as reactive dyes have been linked with respiratory sensitisation and contact dermatitis in humans (22). Disazo Black DM 5594 has been found to be a slight irritant in rabbits, therefore, eye contact should be avoided.

Therefore, due to low public and occupational exposure and low toxicity, it is unlikely that Disazo Black DM 5594 will pose a significant health and safety hazard to the public and to workers when engineering controls, appropriate personal protective clothing and good personal hygiene are observed.

## 13. ASSESSMENT OF ENVIRONMENTAL HAZARD

The main hazard associated with use of Disazo Black DM 5594 will be associated with the release of unfixed residues from sewage treatment works into the aquatic environment. While Disazo Black DM 5594 is unlikely to constitute a significant proportion of these residues, they are likely to retain the essential *bis*(arylazo)naphthalene structure of the dye. If released to the ocean, dilution would be expected to swiftly reduce the environmental concentration to undetectable levels. In the longer term, residues would be expected to bind to sediment and undergo reductive degradation, with amine metabolites being released to the water column where they can undergo further degradation through aerobic processes.

The situation where Disazo Black DM 5594 is discharged to inland waterways, which are likely to periodically experience low flow conditions, requires closer scrutiny. The worst case envisaged by the notifier would occur at the Wangaratta Woollen Mill. Assuming daily use of Disazo Black DM 5594 at the mill would amount to 4 kg (based on the amount imported and number of mills), then a daily release to sewage treatment works of 0.2 kg of Disazo Black DM 5594 can be estimated. For a daily flow rate of 5 ML, the concentration in sewage treatment works would be 40 ppb (or around 30 ppb of Disazo Black DM 5594 and its coloured tribromo impurities). In drought conditions, the dilution factor in receiving waters may be as low as 2. Assuming no degradation

during sewage treatment, the predicted environmental concentration of the dye is 15 ppb. This is more than 4 orders of magnitude lower than concentrations causing acute effects in aquatic fauna, indicating that adverse environmental effects should not occur. The dye has minimal bioaccumulation potential and should not accumulate in sediment, where it is expected to partition through binding, because of reductive cleavage of the azo linkages under anaerobic conditions.

The notifier estimated that environmental concentrations as a result of use at the Wangaratta mill may reach 7 ppb under worst case conditions, but assumed a slightly lower rate of use and some degradation in sewage works. Given that the essential *bis*(arylazo)naphthalene structure of the dye has been shown to survive passage through pilot-scale activated sludge systems (2), it is prudent to assume no such degradation occurs.

Whether the notified substance and its hydrolysis products pass through the sewage treatment works without being removed or are partially removed as assumed by the company, the concentrations reaching the environment should remain well below 100 ppb, a level that is unlikely to present a hazard to the environment based on the ecotoxicity data submitted. In addition, use of the dye should improve environmental quality as it will replace existing chromium based products.

## 14. MATERIAL SAFETY DATA SHEET (MSDS)

The Material Safety Data Sheets (MSDS) for Disazo Black DM 5594 and its product, Lanasol Black R are provided at Attachments 1 and 2. These MSDS were provided by Ciba-Geigy Australia Ltd as part of their notification statement. They are reproduced here as a matter of record. The information and recommended control measures contained in these MSDS generally reflect the hazards associated with use of Disazo Black DM 5594 and its product. The accuracy of this information remains the responsibility of Ciba-Geigy Australia Ltd.

## 15. RECOMMENDATIONS FOR THE CONTROL OF PUBLIC AND WORKER EXPOSURE

To minimise public and worker exposure to Disazo Black DM 5594 and the product, Lanasol Black R, the following guidelines and precautions should be observed:

. a copy of the Material Safety Data Sheet for both Disazo Black DM 5594 and the formulated product should be easily accessible to all employees;

. engineering control measures, such as local exhaust ventilation, should be employed in area where the dry powder dye is handled; and

. workers who frequently come into direct contact with the dye and formulated product should:

  - wear appropriate gloves (such as impervious gloves), which comply with Australian Standards (AS);

  - wear appropriate protective clothing;

  - wear dust masks when handling the powder;

  - observe good personal hygiene practices at work; and

  - avoid the generation of a dust cloud.

## 16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Disazo Black DM 5594 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

## 17. REFERENCES


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