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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

MONOAZO RED TZ 3369

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**MONOAZO RED TZ 3369****1. APPLICANT(S)**

Ciba-Geigy Australia Limited, 235 Settlement Road, Thomastown
VICTORIA 3074

2. IDENTITY OF THE CHEMICAL

Chemical name(s): Monoazo Red TZ 3369, F.A.T 40'405/A,
Reactive Red 244

Trade name(s): CIBACRON RED C-4G

Method of detection and determination:

High pressure liquid chromatography, thin layer chromatography, gas chromatography, atomic absorption spectroscopy and volumetry can be used to identify and determine the concentration of Monoazo Red TZ 3369.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: dark red powder

Melting Point/Boiling Point: >300 °C

Gravity/Density: $1.83 \times 10^3 \text{ kg/m}^3$

Water Solubility: >350 g/L at 20°C

Surface Tension: 10 g/L solution = 65.7-71.0 mNm⁻¹
(Water = 72 mNm⁻¹)

Fat Solubility: <0.05 mg/100g at 37°C

Partition Co-efficient: log p_{ow} ~ -14. (calculated)
(n-octanol/water)

Hydrolysis as a function of pH: 1/2 life at:
pH4 and 25°C = 36.5 hrs
pH7 and 25°C = 2245 hrs
pH9 and 25°C = 142 hrs

Flash Point: not applicable

Flammability Limits: not applicable

Autoignition Temperature: 350°C

Explosive Properties: not explosive

Reactivity/Stability: not an oxidiser

Particle size distribution: range - 20-1000 µm
median - 164 µm

Soil adsorption/desorption : Given the low entry of the substance into the soil and its stated improved fixation properties the test was considered unnecessary. This test was not required for notification in the EEC. As noted below strong adsorption to sediment may be expected.

Dissociation constant : The high water solubility of the dye, multi-functional chemistry and four sulphonate groups indicates a

high degree of dissociation. This was not measured as the test was not required for notification to the EEC.

Thermal stability : No peak was recorded when the dye was heated to 150°C.

Vapour pressure : As the dye is a salt and has a high molecular weight (>1000), the vapour pressure is expected to be negligible.

4. PURITY OF THE CHEMICAL

Degree of purity: >60%

Impurities consist of :

byproducts:	known, uncoloured	0.4%
	known coloured	10 - 30%
	unknown coloured	5.0%

Toxic or hazardous additives:

. **Chemical name:** sodium fluoride
CAS No.: 7681-49-4
Weight percentage: 0.5%

Additives/Adjuvants:

. **Chemical name:** sodium tripolyphosphate
CAS No.: 7758-29-4
Weight percentage: <10%

. **Chemical name:** sodium fluoride
CAS No.: 7681-49-4
Weight percentage: 0.5%

. **Chemical name:** sodium sulfate
CAS No.: 7757-82-6
Weight percentage: <10%

Comments on Chemical Identity

The company has supplied the structural formulae for the above known by-products. There are 7 known coloured by-products that have similar structures to the notified substance, 2 known uncoloured by-products and 8 unknown coloured by-products.

Sodium fluoride is present in Monoazo Red TZ 3369 at a level of 0.5% and in the commercial product Cibacron Red C-4G at a concentration of 0.3%. This value is comparable to the typical fluoride content of household toothpaste. The company has calculated that the treatment of the commercial product in the sewer system will dilute the NaF content to ppb levels. This would have no significant effect on aquatic invertebrates (*Daphnia magna* LC50 > 1000 mg.L⁻¹) (1).

5. INDUSTRIAL USES

Monoazo Red will be imported as an ingredient which comprises more than 60% of a powder formulation for the colouration of textiles by the cold pad-batch or pad-steam method.

6. OCCUPATIONAL EXPOSURE

Repacking of the imported powder is expected to be minimal and not to produce significant exposure.

Workers at sites where the chemical is to be used will weigh and dissolve the material. The use of an antidust agent in the powder formulation is expected to minimise dust and exposure. Dwindraught local ventilation or the use of respirators is advised to further reduce the exposure to dust. The importer/manufacturer will provide material safety data sheets, advice on good work practices and safety seminars and will carry out industry surveys.

7. PUBLIC EXPOSURE

Monoazo Red TZ 3369 is a reactive dye intended for use solely within the textile industry. The product is claimed to have very good wet fastness properties, so that none to minimal transfer from the dyed fabric will occur. The product is imported in fibre-board containers with polythene plastic liners, using Ciba Geigy accredited carriers for transportation.

The applicant states that the product is to be a replacement of existing dyestuffs and as a result of its higher degree of fixation, there will be up to 30% less unfixed dye passing to the effluent in a washing-off operation. The applicant's projections indicated that <14 kg per annum of the dyestuff will be lost to each user's treatment plant (or municipal water authority) from the dyeing operations. The maximum averaged daily discharge into municipal sewage works was calculated to be between 0.18 to 11.25 ppb. Disposal of unused dyestuff (contaminated or spillage) and containers will be by incineration or secure landfill.

By-products of the dye, in particular sodium fluoride, are not considered to present risks to the public when released to waterways or treated as secure landfill. The estimated release of sodium fluoride is 37 g/day/site which is equivalent in a worse case scenario to 0.0092 mg/litre in effluent.

8. ENVIRONMENTAL EXPOSURE

Environmental Release

- **Volume and Use**

Monoazo Red TZ 3369 will take the place of products already used.

Monoazo Red TZ 3369 is used as a reactive dye for the coloration of cellulosic textiles by the cold-pad batch or pad-steam dyeing method. This kind of dye becomes attached to the fibre through the formation of a covalent bond. The notified substance has a higher fixation degree than existing dyes in use due to the fact that it is a bifunctional dye - ie it contains two types of reactive group that will bind to the fibre.

The dyestuff will be used in the textile industry in NSW, Victoria, South Australia and Tasmania. The processing mills are located in the city and several in country areas.

- **Formulation, handling and disposal**

Monoazo Red TZ 3369 will be imported in containers (size not stated) and transported from point of entry to Thomastown Victoria where it will be reformulated to the sales product Cibacron Red C-4G and packaged in 30 kg drums for distribution, by Ciba-Geigy accredited road carriers, to customers in NSW, Victoria, South Australia and Tasmania. Barring the unlikely event of a major road or sea transport accident, spillages during

product distribution are not expected. Disposal of unstated but probably low quantities of unused dyestuff (container residues and spillages) is expected to be by incineration or secure landfill.

Environmental Fate

As Monoazo Red TZ 3369 will replace existing dyestuffs and the use pattern of dyed textiles is expected to remain unchanged, there will be no increase in the release of dyestuff to the environment. It is projected that with an even use of the substance per customer and a high dye fixation rate (measured by the colorimetric analysis of the liquors from the dyeing process), about 14 kg.year⁻¹ of substance will be lost to each user's treatment plant or municipal water authority.

The notified substance will be released in the effluent from the sewage treatment works treating the waste from the dye factories. In general, dyestuffs are practically not biologically degraded during the short residence times characteristic of most sewage treatment plants (2). A study which mimicked the mixing of dyewastes with the biomass in an activated sludge plant showed that dyes similar to the notified substance either do not adsorb or show variable adsorptive properties to sludge (3).

The notified substance can also enter the soil compartment when effluent containing the notified substance is used for the irrigation of agricultural or municipal land (eg golf courses, racecourses). The likely concentration of the notified substance in effluent irrigation water is likely to be in the order of ppb, based on the company predicted concentration of the notified substance in sewage treatment works as 11.25 ppb.

- **Hydrolysis**

Hydrolytic degradation studies indicate a hydrolytic half-life of the substance of 93 days at pH 7.0. Although at pH 4.0 and 9.0 the hydrolytic half-life of the substance was significantly lower, 1.5 and 6 days, respectively, likely environmental pH conditions are in the known sewer range of 6 to 10 which indicates that hydrolytic degradation of the substance is possible, though the extent is uncertain.

- **Bioaccumulation**

The notified substance's high water solubility, very low partition coefficient ($\log P_{ow} = -10$) and low fat solubility indicate that it is unlikely to bioaccumulate. Hydrophilic dyes with $\log P_{ow} < 3$ have been shown not to bioaccumulate (4).

- **Biodegradation**

No ready biodegradation was observed when the dye was tested using effluent from a domestic sewage plant according to OECD Guideline 301A (0.0% loss of dissolved organic carbon in 28 d). Testing of biological oxygen demand indicates a resistance to degradation ($BOD_5 = 0 \text{ mg/g O}_2$) and, although the dye was susceptible to chemical oxidation ($COD_5 = 723 \text{ mg/g O}_2$), the BOD/COD ratio of 0 supports suggestions that the dye is likely to be relatively undegradable (5). Highly sulphonated dyes are known to degrade slowly under aerobic conditions (6).

Many dyes, especially the azo dyes (as this is) are degraded under anaerobic conditions and form sulphonated or other hydrophilic aromatic amines or lipophilic aromatic amines (6). In general, aromatic amines are degraded under aerobic conditions but not under anaerobic conditions. Desorption of aromatic amines back into aerobic environment does occur resulting in further biodegradation and complete mineralization (6).

Due to the azo dye's reactivity, the unfixed dye, when discharged with sewage effluent, may bind to waterway sediment and, in the long term, undergo gradual long-term anaerobic biodegradation. Biodegradation under anaerobic conditions is expected to be an important environmental fate mechanism for azo dyes (4).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Test	Species	Outcome	Ref
Oral	rat	LD ₅₀ > 5000 mg/kg	(7)
Dermal	rat	LD ₅₀ > 2000 mg/kg	(8)
Skin irritation	rabbit	non irritant	(9)
Eye irritation	rabbit	slightly irritant	(10)
Skin sensitisation	guinea pig	slight sensitiser	(11)

9.1.1 Oral Toxicity OECD Guideline #401 (12)

Single oral doses of Monoazo Red TZ 3369 were administered as an aqueous solution by gavage. Groups of five male and five female Wistar Han (outbred SPF-quality) rats received doses of 2000mg/kg or 5000mg/kg. Animals were observed for a 15 day period.

Four animals receiving 2000mg/kg and nine animals receiving 5000mg/kg had diarrhoea from the first or second day of the study which cleared by day five. One female, receiving 5000mg/kg, died on day two of the study without any previous clinical signs or symptoms. Necropsy showed that this animal had pale discolouration of the lungs. This finding had been noted in all animals of the high dose group.

The oral LD₅₀ in rats was determined to be greater than 5000mg/kg in this study.

9.1.2 Dermal Toxicity OECD Guideline #402 (13)

An area of skin on the backs of five male and five female Han IBM Wistar (SPF) was shaved 24 hours before application of an aqueous solution of Monoazo Red TZ 3369 at a dose of 2000mg/kg. The site was covered with a semi-occlusive dressing which was held in place for 24 hours. After removal, the skin was washed. No comment was made on whether all red colouration was removed by this. Animals were observed during the application and for 14 days after removal of the dressing.

All animals were reported to have red and scaling skin at the application site which persisted until the end of the observation period at 15 days. Two females showed a slight weight loss at day 8. All other animals gained weight. No abnormalities were reported at necropsy.

The dermal LD50 was greater than 2000mg/kg in this study.

9.1.3 Skin Irritation OECD Guideline #404 (14)

Five hundred mg of Monoazo Red TZ 3369 was applied to an area of skin (shaved 24 hours previously) of 3 New Zealand White rabbits and covered with a semi-occlusive dressing which was held in place for 4 hours. At the end of this period, the skin was flushed with water and observations taken after 1, 24, 48, and 72 hours.

The skin in all animals was stained red by the dye where the chemical had been applied. This may have obscured any erythema of irritation. No oedema or other effect on the skin was noted.

Monoazo Red TZ 3369 was concluded to be non irritating to the skin.

9.1.4 Eye Irritation OECD Guideline #405 (15)

One hundred mg of Monoazo Red TZ 3369 powder was instilled into the conjunctival sac of the left eye of 3 New Zealand White rabbits. The right eye was not treated and served as a control. Eyes were not washed and were examined 1, 24, 48, and 72 hours after administration of the test substance.

The conjunctiva, sclera, eye lashes and nictitating membrane were stained red by the dye stuff. Staining persisted throughout the whole 72 hour observation period. Any erythema caused by the test substances would therefore have been obscured. One hour after instillation, slight oedema of the conjunctiva was reported in two animals. The oedema resolved before 24 hours. No signs of corneal opacity or damage were reported.

Monoazo Red TZ 3369 was slightly irritating to the eye in this study.

9.1.5 Skin Sensitisation

OECD Guideline #406 (16)

Pilot studies were conducted in IBM GOHI (SPF quality) guinea pigs to determine a suitable nonirritant intradermal and epidermal concentration for the study. Epidermal application sites were depilated to clean away red stains from the dye before observations. No concentration produced irritation. For the maximisation test, the test article was used diluted to 5% in saline for intradermal injection and to 15% or 25% in Vaseline for epidermal application.

Induction phase

Three pairs of intradermal injections (0.1ml/site) were made into the clipped region of the back of 10 male and 10 female guinea pigs. Injections were:

- . Freund's complete adjuvant 50:50 with distilled water.
- . The notified chemical 5% in physiological saline.
- . The notified chemical 5% in Freund's complete adjuvant 50:50 with physiological saline.

A control group of 5 male and 5 female animals received the vehicle without the notified chemical. Six days later the area was clipped, shaved free of hair and pretreated with 10% sodium-lauryl-sulfate to produce a mild inflammatory reaction. The following day the test article (25% in Vaseline) was applied on a patch of filter paper over the injection site of the test group and left in place for approximately 48 hours. Control animals received identical treatment except they did not receive the test article. After removal of the dressing, sites were reviewed for irritation immediately and after 24 and 48 hours.

Challenge

Two weeks after the epidermal application animals were challenged by the application of test article (15% in Vaseline) on filter paper applied to the left flank sites. Filter paper saturated with the vehicle only was applied to the right flank sites. Dressings remained in place for 24 hours and sites were assessed for a reaction immediately, and 24 and 48 hours after removal. Control animals were treated identically. Sites were depilated as an aid in assessing erythema by removal of staining from the red dye.

Animals in the control group showed no signs of erythema or oedema at any time interval after challenge. In the test group 3 females and 2 males showed barely perceptible erythema after removal of the challenge patch. One male animal showed well defined erythema which diminished but was still perceptible at 24 and 48 hours. Readings at 24 hours were used to assess whether the chemical was a sensitiser. On this basis, one animal was considered sensitized and the chemical was concluded to be a weak sensitiser in guinea pigs.

9.2 Repeated dose toxicity

OECD Guideline #407 (17)

9.2.1 Five day dose ranging study in rats (18)

Aqueous solutions of Monoazo Red TZ 3369 were administered daily by gavage to groups of three male and three female Han Wistar rats at doses of 0, 200 mg/kg/day or 1000 mg/kg/day. Animals were observed for five days.

During the study, males in the higher dose group had slightly reduced food consumption and a decreased gain in body weight. High dose females and rats of both sexes receiving 200mg/kg did not show these signs. No other clinical symptoms were reported during the study and no deaths occurred. At autopsy, males and females receiving 1000mg/kg day had discoloured mucosa in the upper part of the gastrointestinal tract in two out of three animals of either sex. Males receiving 1000 mg/kg/day also showed discolouration of the testes. These signs were considered to be related to the dye properties of the test compound, not to its toxicological properties. Isolated dark red foci were reported in the fundus of two high dose males. This was considered not significant in the terms of selection of dose for the 28 day oral toxicity study.

Doses selected for the 28 day study were 0, 50, 200, and 1000mg/kg.

9.2.2. 28 Day oral toxicity study in rats (19)

Groups of five male and five female HanIbm Wistar (SPF) rats received daily oral doses of 0, 50, 200, and 1000mg/kg/day for 28 days. An additional five males and five females were added to the group receiving 0 and 1000mg/kg/day and were observed for two weeks after dosage had been discontinued. In this report, they are designated as the recovery groups.

Animals were observed daily, food consumption and body weights were recorded weekly. Haematology, serum chemistry, and urinalysis was carried out at the termination of the study either after the 28 day exposure or at the end of the two week recovery period. At necropsy, gross examination was performed and tissues taken for histopathology as follows:

- . Adrenals;
- . heart;
- . kidneys;
- . liver;
- . spleen; and
- . stomach

from all animals in the control and in the high dose group. In addition, all gross lesions noted at autopsy were taken for histopathological examination.

After one week on the study, all male and female animals in the high dose group had reddish discolouration of the extremities. This persisted until the end of the dosing and until the end of the recovery period in that group. Animals receiving 1000mg/kg/day also had dark reddish faeces on day four of the study.

No mortalities occurred during the study. However, one female in the low dose group died during blood sampling immediately before termination of the study. Food consumption in the high dose males was increased during the first three weeks of the studies and then normalised. Animals in other dose groups were not affected. Ophthalmological examination at the termination of the study showed no abnormalities in treated rats.

Haematology findings at the termination of the study included an increase in platelet count and scattered other abnormalities in both sexes receiving 1000mg/kg/day. These abnormal findings were not seen in the 1000mg/kg/day recovery group but haematocrit was decreased in both sexes in this group. Clinical biochemistry changes reported in both sexes receiving 1000 mg/kg/day were increased uric acid, markedly increased total bilirubin, increases in triglycerides and decreases in alanine aminotransferase. Changes occurring in only one sex receiving the high dose were increased total cholesterol concentrations in males (not statistically significant in females), increased phospholipids in males and increased potassium in females. These findings were not observed in the group receiving 1000mg/kg/day recovery group.

Urinalysis showed a light red to red discolouration of urine in rats receiving 200mg/kg/day and 1000mg/kg/day. Some urinary abnormalities were noted in both sexes of the high dose group.

Apart from a orange urine discolouration, these abnormalities were not observed in the recovery group.

Many of the clinical biochemistry and urinalysis abnormalities were considered to be related to interference with the test by red dye colouration in the plasma or urine. Rats of both sexes receiving 200mg/kg and 1000mg/kg showed a red discolouration of the plasma which was dose related in intensity. The presence of a red colour in the plasma was considered to affect the readings for cholesterol, triglyceride, phospholipids, uric acid and bilirubin. Discolouration of the urine potentially affected the positive finding for protein, glucose, ketone, bilirubin, blood and urobilinogen for high dose rats of both sexes.

At the end of the two week recovery period, abnormalities in the clinical biochemistry and urinalysis were comparable to those in the control group.

At autopsy, red staining was widely distributed in the tissues of both males and females receiving 1000mg/kg/day in both the 28 day test group and the recovery group. This staining was not associated with any histopathological changes. Males receiving 1000mg/kg/day showed an increased severity of renal tubular hyaline droplets. The severity at the end of the recovery period and in males receiving 50 and 200mg/kg/day was comparable to that in control animals. In females these droplets were not found in control, 50mg/kg or 200mg/kg/day dose groups. They were reported in the 1000mg/kg/day but were not as severe as in males. At the end of the two week recovery period, the severity of renal droplets in females which had received 1000 mg/kg/day was very slight.

9.3 Genotoxicity

9.3.1. Reverse Mutation Assay in *Salmonella typhimurium* (20)

Monoazo Red TZ 3369, in aqueous concentrations, of 10-5000µg/plate, with and without metabolic activation, was incubated for 72 hours at 37°C with *S.typhimurium* strains TA98, TA100, TA1535, TA1537, TA1538.

Untreated plates and plates treated with double distilled water served as negative controls. Positive controls were

sodium azide	10µg/plate	TA100, TA1535
4-nitro-o-phenylene-diamine	50µg/plate	TA1537, TA1538 TA98

2-aminoanthracene, 10µg/plate, was used as positive control to check the metabolic activation.

All positive controls produced increase in revertant counts. There was no increase with any concentration of Monoazo Red TZ 3369 either in the presence or absence of metabolic activation.

Monoazo Red TZ 3369 was not found to be mutagenic to *Salmonella typhimurium* in this test.

9.3.2. Chromosome Aberration Assay (21)

Monoazo Red TZ 3369 was incubated for four hours *in vitro* in concentrations of 0.03 - 3.0 mg/ml with Chinese Hamster V79 cells, with and without metabolic activation. Positive controls were ethylmethanesulfonate without metabolic activation and cyclophosphamide with metabolic activation.

Cells were harvested at the following intervals after treatment commenced:

without metabolic activation

7 hours	Monoazo Red TZ 3369, 0.1; 0.3; 1.0; 3.0 mg/ml;
18 hours	Monoazo Red TZ 3369, 0.01; 0.03; 0.1; 0.3; 1.0; 3.0 mg/ml, ethylmethanesulfonate;
28 hours	Monoazo Red TZ 3369, 0.1; 0.3; 1.0; 3.0 mg/ml;

with metabolic activation:

7 hours	Monoazo Red TZ 3369, 0.1; 0.3; 1.0; 3.0 mg/ml;
18 hours	Monoazo Red TZ 3369, 0.01; 0.03; 0.1; 0.3; 1.0; 3.0 mg/ml, cyclophosphamide;
28 hours	Monoazo Red TZ 3369, 0.1; 0.3; 1.0; 3.0 mg/ml.

Aberrations which included gaps were recorded separately and not included in the evaluation of the effect of the test compound. Examination of chromosomes revealed that there was an increase in chromosomal aberrations, excluding gaps, with the positive controls. No effect of the test compound in increasing the number of aberrations excluding gaps was reported at any concentration at any time interval.

9.3.3 Mouse Micronucleus Assay (22)

Groups of six male and six female mice received single oral doses of 5000 mg/kg Monoazo Red TZ 3369, previously determined to be the maximum attainable dose. Distilled water served as a negative control. Twenty four , 48 and 72 hours after administration animals were sacrificed and femoral bone marrow samples from five animals prepared for examination.

Another group of six males and six females received a single oral dose of cyclophosphamide, 30 mg/kg. Bone marrow samples were prepared after 24 hours exposure.

Samples were examined microscopically to determine whether there was any increase in micronucleus formation or whether any cytotoxic effects were shown by changes in the ratio of polychromatic erythrocytes / normochromatic erythrocytes.

There was no increase in micronucleus formation in animals treated with the notified chemical. In contrast, administration of cyclophosphamide was associated with an increase in micronuclei formation. No cytotoxic effects were reported.

The notified chemical was not found to be clastogenic in this study.

9.4 Overall Assessment of Toxicological Data

Monoazo Red TZ 3369 has a low oral and dermal toxicity in rats. No signs of skin irritation were reported in rabbits although the dye colouration would have obscured erythema. In the guinea pig sensitisation pre-study to determine irritant potential, sites were depilated to remove any staining and concentrations of 25% of Monoazo Red TZ 3369 were nonirritant . Monoazo Red TZ 3369 was considered non-irritant to the skin. It was found to be

slightly irritating to the rabbit eye and therefore can reasonably be assumed to be slightly irritating to the respiratory tract. No inhalation study was available.

Monoazo Red TZ 3369 is a weak skin sensitiser in guinea pigs. The notification states that many reactive dyes are respiratory sensitisers and that appropriate precautions should be implemented.

The 28 day feeding study in rats revealed abnormalities considered likely to be caused by discolouration of samples of body fluids. On histopathological examination of tissues male rats receiving 1000mg/kg/day exhibited an increased severity of renal tubular hyaline droplets. Droplets were reported in females in the 1000mg/kg/day dose group but not in those rats receiving lower doses. In both sexes, the severity/incidence of droplets was reduced in the recovery group, indicating the effect to be reversible.

Monoazo Red TZ 3369 was not mutagenic towards *S.typhimurium* in the Ames test or clastogenic in the mouse micronucleus test.

It was not considered to cause chromosomal aberrations in the V-79 cells.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following test results, obtained according to OECD Guidelines 203 and 202, were provided for aquatic species.

Test	Species	Result
Acute toxicity	Zebrafish	96h LC50 > 1000 ppm
Acute Immobilization	<i>Daphnia magna</i>	48h EC50 > 1000 mg.L ⁻¹

The above results indicate that Monoazo Red TZ 3369 is practically nontoxic to aquatic fauna. While reproduction tests for daphnids were not conducted, the lack of acute toxicity and the probability that the dye, given its high molecular weight, 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^{-1}), indicating that the dye is practically nontoxic to microbes, and should not affect sewerage micro-organisms.

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". While there are other methods of measuring changes in algal growth, a survey of fish toxicity data on over 3000 commercial products by ETAD (Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry) indicates that the majority of dyes are not very toxic to fish (6). 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 (23). Accordingly, it appears unlikely that the notified substance will be toxic to algae and a test will not be required.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The main route of environmental exposure for the notified substance will occur when unfixed dye in the effluent from sewage plants is released to the aquatic compartment where it may persist owing to its lack of biodegradation under aerobic conditions. It is unlikely to undergo volatilisation given expected low vapour pressure.

The effluent from dye factories that are discharged to rivers or streams may present a greater hazard to the environment, than the effluent from dye factories which are discharged to the ocean. Thus the potential hazard is greater in inland areas because of the lower volume of the receiving waters.

. Predicted environmental concentrations

A large dilution of the notified substance will occur at dye factories whose waste is treated by sewage treatment plants that dispose of effluent into the oceans. However, in the case of the dye factories that have their waste treated by sewage treatment plants that dispose of effluent into inland waters, the dilution will be significantly lower, particularly in drought conditions, requiring closer scrutiny.

Two detailed cases for receiving water concentrations of Monoazo Red TZ 3369 have been provided with calculations based on the following:

- discharges from dye-works solely involved with pad batch operation (the dyeing technique most suited for use with Monoazo Red TZ 3369);
- an even use of Monoazo Red TZ 3369 at seven dyeworks;
- a high fixation level and 50% removal at the municipal sewage plant;
- use of the dye on 310 days of the year; and
- a worst case 4 ML.day⁻¹ at Seymour dyeworks and 250 ML.day⁻¹ at Werribee via the Melbourne Water Board.

The company states that discharge, from all sites likely to use the notified substance, will be to municipal sewage works where they estimate municipal streams' volumes to vary from several to 500 megalitres.day⁻¹. The notifier predicts the concentration in receiving waters to be 11.25 ppb under low flow conditions and 0.18 ppb under high flow conditions.

It should be noted the company assumes that 50% of the notified substance is removed during the sewage treatment process, suggesting that it expects the notified substance to undergo abiotic hydrolysis due to alkalinity typical of effluent from sewage works (23). This level of removal is unlikely due to the short residence times of most sewage treatment plants (2) and the hydrolytic half-life (~ 1 week) of the substance in alkaline conditions. Despite its water solubility the dye may, however, bind to sediment due to its reactivity.

. Ecotoxicity hazard

These concentrations are at least 3 orders of magnitude less than the ecotoxicity results presented above and indicate Monoazo Red TZ 3369 is unlikely to present either an acute or chronic hazard to aquatic invertebrates, freshwater fish and micro-organisms at likely environmental levels. Although no algal toxicity results were provided for Monoazo Red TZ 3369, the notified substance is also unlikely to present a hazard to algae. While Monoazo Red TZ 3369 may persist in the aquatic compartment, its very high water solubility and low octanol water partition coefficient both indicate that bioaccumulation to toxic levels is extremely unlikely.

If the notified substance does bind to sediment to some extent, the hazard presented to benthic organisms is unclear. However, it

is unlikely that significant toxic levels of the notified substance will occur due to its high water solubility and lack of bioaccumulation potential.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY

Exposure to the notified chemical will occur when repacking, weighing and dissolving the chemical by exposure to the dust via skin contact or inhalation. Repacking is not expected to occur frequently. The use of antidust agents in the currently proposed formulation will reduce the formation of and exposure to dusts. Exposure may also occur to the dissolved dye if an aerosol is formed or splashing occurs.

Exposure during transport and storage would occur only in the event of an accidental spill.

13. RECOMMENDATIONS FOR THE CONTROL OF PUBLIC AND WORKER EXPOSURE

To minimise public and worker exposure to Monoazo Red TZ 3369 the following guidelines and precautions should be observed:

- . workers repacking or weighing and dissolving the dyestuff should wear a class M particulate respirator (half face) of Class M category conforming to Australian Standard 1715-1991 (25).

- workers should wear elbow length PVC gloves conforming to Australian Standard 2161-1978 (26) protective clothing to minimise skin contact with Monoazo Red TZ 3369.

- good housekeeping practices should be observed to minimise accumulation of dust layers in work areas, to avoid generation of mists or splashing of the dyestuff solution.

- . workers using Monoazo Red TZ 3369 and products containing it should have access to MSDS.

- . workers who have been sensitised to other reactive dyes should not be exposed to Monoazo Red TZ 3369 or products containing it.

14. MATERIAL SAFETY DATA SHEET(S)

The Material Safety Data Sheet (MSDS) for Monoazo Red TZ 3369 was provided in Worksafe format. (24)

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Monoazo Red TZ 3369 will be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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