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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

CIBACRON ORANGE TZ 3538

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Cibacron Orange TZ 3538

1. APPLICANT

Ciba-Geigy Australia Ltd; 235 Settlement Road, Thomastown, Victoria 3074.

2. IDENTITY OF THE CHEMICAL

- Cibacron Orange TZ3538 has been classified as hazardous by Worksafe Australia due to its skin sensitisation properties. However, for commercial reasons, the identity, impurities, methods of detection and determination, estimated import volumes and number of sites at which the chemical will be used have been granted exemption from the Full Public Report and Summary Report. The conditions of this being permitted are:

- The descriptive generic name **DISAZOFLUORTRIAZINE TRISULFONIC ACID, SODIUM SALT DERIVATIVE** be used to identify the substance in the MSDS,

- The relevant employee unions shall be informed of the conditions of use of Cibacron Orange TZ 3538,

- The full chemical name shall be provided to any health professionals in the case of a legitimate need where exposure to the chemical may involve a health risk,

- The full chemical name shall be provided to those on site who are using the chemical and to those who are involved in planning for safe use, etc. in the case of a legitimate need,

- The Director of NICNAS will release the full chemical name etc in the case of a request from a medical practitioner,

- Confidentiality will expire after a 3 year period,

- That the chemical be identified as a sensitiser in the Health Effects Section of the MSDS, and that reference to its assessment by NICNAS be made on the MSDS,

- These conditions shall be published in the Chemical Gazette.

Trade names: FAT 40'436/A
Cibacron Orange TZ 3538
Reactive Orange TZ 3538

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: Brown powder

Odour: None

Melting Point: None up to 400°C

Density: 1.65 x 10^3 kg/m^3 at 20°C

Vapour Pressure: Not determined. The vapour pressure for a high molecular weight salt is expected to be negligible.

Water Solubility: > 700 g/L at 20°C

Fat Solubility: 0.37 mg/100 g at 37°C

Partition Co-efficient (n-octanol/water) log $P_{O/W}$: Û-5

Hydrolysis as a function of pH: Hydrolytically stable at pH 4 and 7 and unstable at pH 9.

pH	Temperature [°C]	rate constant K_{obs} [hours^{-1}]	Half-life time ($t_{1/2}$) [hours]
4	50	---	> 1 year
7	50	---	> 1 year
9	25	1.16×10^{-4}	5974
9	60	1.59×10^{-2}	44
9	70	5.41×10^{-2}	13

Adsorption/Desorption: Not determined. The notifier argues that the method of use will not present any opportunities for release of any significant quantity of the substance into the environment which could result in contamination of soil. (See comments in Environmental Fate section).

Dissociation Constant pKa**:** 3.05 ± 0.05 at 20°C

Flash Point: Not determined.

Flammability Limits: Not highly flammable.

Combustion Products: Oxides of sulfur likely, and brominated compounds may be generated if combustion is incomplete.

Decomposition Temperature: > 290°C

Decomposition Products: Not provided.

Autoignition Temperature: None up to 400°C test maximum.

Explosive Properties: Not sensitive to heat, shock or friction.

Particle size distribution: 85.8% > 50 µm
1.1% < 10 µm

Surface Tension: 72.3 mN/m at 1.8 g/L at 20°C (not a surfactant).

4. PURITY OF THE CHEMICAL

Degree of purity:

Component	Content
Cibacron Orange TZ 3538 main component	high (> 40%)
Reaction homologues, by-products and organic impurtities	med (< 30%)
Inorganic salts	low (< 5%)
water	6.3%

5. INDUSTRIAL USE

Cibacron Orange TZ 3538 is a cellulose textile dye which will be introduced as a major component of Cibacron Orange F-BR in ready to sell packages. It is a high light-fast dye for which exhaust dye methods will be used. It will be chemically bound to the cellulose fibres, and has been introduced in order to replace existing dyes.

The dye will not be manufactured in Australia but repackaging will occur when supplies of smaller quantities are required.

There have not been any reported human health effects involving the notified chemical during its use overseas.

6. OCCUPATIONAL EXPOSURE

Repackaging of < 100 kg/yr may be carried out at the Ciba-Geigy premises in Victoria where a maximum of two people will be involved in packaging for approximately 15 - 20 minutes on each of 10 days per year.

Forty to fifty workers categorized as plant operators, batch weighers and laboratory technicians will be potentially exposed to the dye. During the dyeing operation the powdered Cibacron Orange TZ 3538 will be weighed out and added to a blending vessel to be dissolved. It will then be added to a vat already containing the fabric, salts and a wetting agent at an elevated temperature. The fabric is thus dyed and the dye is then fixed with alkali. It is estimated that the batch weighers will weigh out five 2 kg batches per day on 36 days of a year, and that this will take 15 minutes on each occasion. On this basis it has been calculated by Ciba-Geigy that these workers will be exposed to a daily level of 2.53 mg Cibacron Orange TZ 3538 on the days of weighing, and an annual level of 91 mg Cibacron Orange TZ 3538.

7. PUBLIC EXPOSURE

There is low potential for public exposure to the notified chemical during transport and distribution. The exhaust dye method used is not expected to result in significant public exposure.

Disposal of waste notified chemical will be limited to traces remaining from the cleanup of any spills, trace residues in empty packaging and discharges to dye effluent systems, and will be by incineration. The notifier claims that approximately 50% of notified chemical discharged into the dyehouse effluent system is expected to be retained in the sludge in biological treatment effluent works. There is therefore low potential for public exposure resulting from disposal of the notified chemical.

The notified chemical will be used to dye fabrics and other products. However, public exposure to the dye in the final product is expected to be negligible as the dye exhibits a high level of fastness to the fibres used.

8. ENVIRONMENTAL EXPOSURE

. Release

Spills generated during repackaging will be cleaned up according to the MSDS and consigned to secure landfill or incinerated, as will residues from cleaning equipment or containers etc.

Cibacron Orange TZ 3538 is a variant on dyes already in use in Australia and it is claimed that using it instead of older dyes should reduce the quantity of dye released into the environment.

The notifier has indicated that the dye has a 71% level of fixation on the fibres by the exhaust method. The remainder will be discharged into the sewer. The notifier has estimated the concentration in the receiving waters, after treatment in a sewage treatment plant, at between 0.0012 $mg.L^{-1}$ and 0.018 $mg.L^{-1}$. CEPA's calculations (see below) are higher than this.

. Fate

The bulk of the dye will become chemically bound to fibres and in this state is not expected to adversely impact on the environment.

The unfixed residues from dyeing operations will enter the aquatic environment after discharge from the textile mills and subsequent treatment at sewage treatment plants. The dye may be removed by degradation (chemical or biological) and sorption to sludge. As a result of its low K_{ow} and hydrolytic stability, it is likely that significant quantities of the dye will remain in the aquatic phase. Furthermore, reactive dyes have been found not to strongly adsorb to sludge (1) in model systems.

The dye was tested for its biodegradability, according to OECD test guideline 301D, and found to be not biodegradable. This test uses activated sludge from a domestic sewage plant in a closed bottle test and was performed at a concentration of 1.5 and 3.8 ppm (nominal). The results, -39% and -4% (compared to controls) change in biological oxygen demand for the low and high concentration respectively indicate there was no degradation of the dye and its not ready biodegradable.

Residues that survive treatment in the sewage plant, which is likely, will enter either freshwater or marine environments in solution. The dye is stable to aerobic conditions but azo dyes are susceptible to reductive degradation under anaerobic conditions, characteristic of sediments (2). The half life of this degradation was found to be between 2 and 16 days for several sulphonic azo dyes (3), thus no significant increase in concentration over time is expected. One possible route for the dye to enter the sediments is by precipitation of its calcium salts, as several calcium salts of sulphonic dyes are known to be insoluble (3) at modest concentrations. However, apart from precipitation as the calcium salt, the hydrophilic nature of Cibacron Orange TZ 3538 should limit the affinity for soil and sediment and thus the dye should remain mainly in the aquatic compartment.

The bioaccumulation potential of the dye was not investigated due to its very low partition coefficient ($\log P_{ow} < -5$), as allowed by the *Act.* This, together with the high water solubility and low fat solubility, indicate that bioaccumulation should not occur.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1Summary of the acute toxicity of Cibacron Orange TZ 3538

Test	Species	Outcome	Ref
oral	rat	LD_{50} > 2000 mg/kg	4
dermal	rat	LD_{50} > 2000 mg/kg	5
skin irritation	rabbit	slight irritant	6
eye irritation	rabbit	non irritant	7
skin sensitization	guinea pig	sensitizer	8

9.1.1 Oral Toxicity (4)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 401*.

Rats (5 per sex) of a Wistar derived strain were administered a single dose of 2000 mg/kg Cibacron Orange TZ 3538 dissolved in water by oral gavage. Animals were observed for a period of 15 days after which necropsy was performed.

No deaths, clinical signs, macroscopic changes or changes in body weight were observed in any animals.

It was concluded that the oral LD_{50} of Cibacron Orange TZ 3538 was > 2000 mg/kg.

9.1.2 Dermal Toxicity (5)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 402*.

Rats (5 per sex) of a Wistar derived strain were administered Cibacron Orange TZ 3538 by dermal application.

On day one of the procedure the test substance was applied evenly to a portion of the shaved area. This was covered by a semi-occlusive dressing. Cibacron Orange TZ 3538 was diluted in water and animals received 4 ml of the substance at a dose of 2000 mg/kg. Twenty four hours after application the skin was washed and dried. The animals were then observed for a period of 15 days after which necropsy was performed.

No mortality or macroscopic abnormalities were observed during the study. The skin of all animals become slightly brown coloured. One female lost weight between days 1 and 8 of the study and the female rats in general showed minimal weight gain.

It was concluded that the dermal LD_{50} of Cibacron Orange TZ 3538 was > 2000 mg/kg.

9.1.3 Skin Irritation (6)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 404.*

New Zealand White rabbits (one male and two female) were administered by dermal application a single dose of 0.5 g of Cibacron Orange TZ 3538 moistened with water.

On day one of the procedure the test substance was applied to a portion of the shaved area and covered with a semi-occlusive dressing.

The test substance remained on the skin for four hours after which time it was removed with lukewarm tap water. Animals were then observed at 1, 24, 48 and 72 hours and 7 days after removal of the dressing.

All animals showed skin discolouration which lasted for 7 days. One female showed very slight erythema without oedema for 48 hours. The male showed well defined erythema and very slight oedema which continued for 48 hours before diminishing by 72 hours.

Body weights were normal and no other clinical symptoms were observed.

Cibacron Orange TZ 3538 was concluded to be a slight irritant to the skin under the conditions of this study.

9.1.4 Eye Irritation (7)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 405.*

New Zealand White rabbits (two female and one male) were administered a single dose of 0.1 g of neat Cibacron Orange TZ 3538 into the conjunctival sac of the left eye. The right eye was untreated and used as a control. Animals were observed at 1, 24, 48 and 72 hours after administration of Cibacron Orange TZ 3538.

Application of the test substance resulted in orange staining of the lid hair of all three rabbits which persisted for 48 hours. One female showed slight reddening and swelling of the conjunctivae, slight reddening of the nictitating membrane and a slight discharge 1 hour after treatment. Reddening of the conjunctivae and nictitating membrane were observed in the male animal one hour after treatment. These symptoms were not present 24 hours after treatment and no other clinical signs were observed. Body weights remained normal during the study.

Cibacron Orange TZ 3538 was concluded to be a non-irritant to the eye of the rabbit under the conditions of the study.

9.1.5 Skin Sensitisation (8)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 406.*

The test used was the guinea-pig maximisation test of Magnusson and Kligman.

Preliminary study

To determine the dose level for intra-dermal injection in the main study, 0.1 ml of 1%, 3% and 5% solutions of Cibacron Orange TZ 3538 in saline were injected into the clipped flank of two Himalayan spotted guinea-pigs. The resulting dermal reactions were assessed 24 hours later. All three

concentrations produced very slight oedema and erythema. A dose of 5% w/v was selected for intra-dermal induction in the main study as mild to moderate irritation was observed at this dose level.

To determine the dose level for topical induction and challenge in the main study, 25%, 15%, 10% and 5% of Cibacron Orange TZ 3538 in vaselinum album was applied to the clipped and shaved flanks of 4 guinea-pigs. Filter paper saturated with the test substance was applied to the skin under occlusive bandage. The dressings were removed after 24 hours and assessments were made immediately and at 24 hours after removal of the bandage. After removal of the filter paper patches the hair of the animals was depilated to clean the site of staining. No irritation could be observed in any animal after any dose level. A concentration of 25 % was chosen for both the induction and challenge procedures.

Induction Study

Thirty female guinea-pigs of the Himalayan strain (20 test and 10 control animals) were used.

On day 1 three pairs of intra-dermal injections (volume 0.1 ml) were made into the clipped inter-scapular region of each guinea-pig. The injected solutions were:
. Freund's Complete Adjuvant 50:50 with physiological saline,
. Cibacron Orange TZ 3538 diluted to 5% with saline,
. Cibacron Orange TZ 3538 diluted to 5% by emulsion in a 50:50 mixture of saline and Freund's Complete Adjuvant: physiological saline (1:1).

Control animals received the same treatment but without the test substance.

On day 7 of the test, 24 hours prior to the epidermal application the scapular region was clipped and shaved and pretreated with 10 % sodium laurylsulfate (SLS) in petroleum oil. The SLS enhances sensitization by provoking a mild inflammatory reaction.

On day 8 the SLS pretreated area was treated with an occlusive epidermal application of 25% Cibacron Orange TZ 3538 in vaselinum album in the same manner as described above for topical application in the pretest. The bandage remained in place for 48 hours. Control animals were similarly treated but without the use of the test substance. The sites were evaluated 24 and 48 hours after removal of the patches.

Challenge Study

Two weeks after the epidermal induction application, the test and control animals were challenged topically with 25% Cibacron Orange TZ 3538. The test substance was applied to the left flank of each guinea pig and vaselinum album alone was applied to the right flank. The techniques used were the same as those described above. The bandages remained for 24 hours and assessment was made of the skin reactions at 24 and 48 hours after removal of the bandages.

Results

During the induction phase, no oedema was observed in any animal. Erythema could not be determined due to staining of the skin by the test substance.

Following challenge slight (5/20 animals) to well defined (3/20 animals) erythema but no oedema was observed in test animals 24 hours after removal of the bandages. This persisted and was present undiminished at the 48 hour observation time point. No positive reactions were present in the control group. Body weight gains in the test group were comparable to those observed in the control group. No toxic symptoms were observed in any animals.

As a positive result was observed after challenge in 40% of treated animals Cibacron Orange TZ 3538 was concluded to be a skin sensitiser in guinea-pigs.

9.2 Repeated Dose Toxicity (9)

After a preliminary range finding study, groups of 10 rats (5 of each sex) of a Wistar derived strain were treated orally by gavage, once daily, 7 days a week for 4 weeks. Animals received 0, 50, 200 or 1000 mg/kg of Cibacron Orange TZ 3538 dissolved in distilled water at 10 ml/kg. In a recovery study 5 animals of each sex were treated with 0 or 1000 mg/kg. The animals were allowed a 14 day recovery period prior to analyses being performed.

There were no deaths, ophthalmic abnormalities or any other clinical signs of toxicity in any of the treated animals. Body weights of all animals remained within the control values, but food consumption varied slightly in a random manner.

Slight changes were measured in a number of haematological parameters in the 1000 mg/kg treatment group. Those observed in males included slight increases in platelet count, (also in the 200 mg/kg group), in nucleated erythrocyte in males, and in methemoglobin concentration in males. Both sexes were found to have shorter thromboplastin time and lower haemoglobin concentration and haematocrit. Females were found to have a lower erythrocyte count. At the end of the recovery period none of these observations were found to be present.

A number of changes were observed in the clinical biochemistry of animals treated with 1000 mg/kg Cibacron Orange TZ 3538. In males, slightly lower glucose concentrations and slightly higher uric acid and phospholipid concentrations were measured. Slightly higher triglyceride concentrations were found in the females. Both sexes were observed to have slight increases in the cholesterol concentration. Moderate increases were also found in some parameters. These included a 1.9 and 2.4 fold increase in creatinine in females and males respectively and 4.3 and 7.2 fold increase in bilirubin concentration in females and males respectively. The study authors state that the high bilirubin and creatinine levels were likely to have been due to the orange colour of Cibacron Orange TZ 3538 which interfered with the reading of the reaction complex measured in these spectrophotometric assays.

The only change noted in the urine analysis was a deep orange /yellow colouration of the urine in 8 males and 6 females of the higher treatment group. The colouring had reverted to normal by the end of the recovery period.

Slight statistically significant changes in organ to body weight changes were present. These were apparently incidental as they exhibited no relationship to the dose.

Examination at necropsy revealed yellow/orange discolouration of the gastrointestinal tract of animals treated with 1000 mg/kg Cibacron Orange TZ 3538. In this same treatment group an increase in the number of red/brown inclusions in the glandular stomach was observed. These regressed to a large extent after the recovery period. Similar inclusions were observed in the caecum of some animals of this treatment group.

No macroscopic or microscopic findings were noted in animals treated with 50 or 200 mg/kg Cibacron Orange TZ 3538.

The results of this study indicate that the gastrointestinal tract is the likely target for toxicity and that administration of Cibacron Orange TZ 3538 at 200 mg/kg or below does not cause any notable changes.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium and Escherichia coli Reverse Mutation Assay (10)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 471.*

Cibacron Orange TZ 3538 was tested in the reverse mutation assay on *S. typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 and *E. coli* strain WP2uvrA in the presence or absence of liver microsomal S9 activation. As a result of a preliminary study the concentrations selected for the main study were 0, 10, 100, 333.3, or 1000 µg Cibacron Orange TZ 3538 /plate. Positive controls used in the absence of activation were 4-nitro-o-phenylenediamine, sodium azide, and methyl methane sulfonate. 2-Aminoanthracene was used as the positive control in experiments including the liver S9 mix. All positive control substances produced marked increases in the number of revertant colonies within the anticipated range.

No significant and repeatable increases in the number of revertant colonies of bacteria were recorded for any of the strains of *S. typhimurium* or *E. coli* used, at any dose level of the test substance, with or without metabolic activation. The only incident noted was an increase in the number of revertants of TA98 only at 100 µg/plate and only in one of the two experiments. The test substance caused no toxicity to the bacterial lawn.

The results of this study indicate that Cibacron Orange TZ 3538 is not genotoxic toward *Salmonella typhimurium* or *Escherichia coli*.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (11)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 474*.

Cibacron Orange TZ 3538 was investigated for its potential to induce micronuclei in bone marrow polychromatic erythrocytes of Charles River mice.

A single preliminary experiment was performed to determine the dosing protocol for the main experiment. In the main study six animals of each sex were allocated to different treatment groups and administered a single dose of Cibacron Orange TZ 3538 dissolved in water by the intraperitoneal route at a rate of 10 ml/kg body weight. Bone marrow cells from five animals per group were collected for micronuclei analysis 24 or 48 hours after the treatment. The doses employed for the 24 hour preparation interval were 100, 333, or 1000 mg/kg body weight. For the 48 hour preparation interval, 1000 mg/kg body weight was used.

Cyclophosphamide administered intraperitoneally at 30 mg/kg body weight was the positive control, and distilled water was the negative control.

One thousand polychromatic erythrocytes (PCEs) were scored per animal, and the number of micronucleated PCEs recorded. No cytotoxic effects were observed as indicated by the absence of an increase in the ratio of polychromatic to normochromatic erythrocytes in treated animals compared to controls. No increase in the frequency of micronucleated polychromatic erythrocytes occurred in animals treated with Cibacron Orange TZ 3538 compared to controls. In contrast a distinct increase in the number of micronuclei was noted in animals treated with the positive control cyclophosphamide.

The results of this study indicate that Cibacron Orange TZ 3538 does not cause chromosomal damage in bone marrow cells of mice *in vivo*.

9.3.3 Chromosome Aberration Assay in Chinese Hamster V79 Cells *in Vitro* (12)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 473*.

Cibacron Orange TZ 3538 was investigated for its potential to cause chromosomal aberrations in the V79 line of cells from the Chinese Hamster.

Preliminary experiments were performed in order to determine the toxicity of Cibacron Orange TZ 3538 to the cells. Cytotoxicity was observed in the absence of liver S9 mix at 300 µg/plate and higher, and in the presence of S9 at 1000 µg/ml and higher. The culture medium was used as the negative control; ethylmethanesulfonate (8mM final concentration) and cyclophosphamide (15 µM final concentration) dissolved in nutrient medium were the positive controls utilized.

Two experiments were performed using cultures in the absence and presence of S9 metabolic activation. A single cell suspension of V79 was prepared from 3 day old exponentially growing stock. Cells were subsequently treated with Cibacron Orange TZ 3538 and chromosomes prepared 18 hours or 28 hours after treatment. Cultures with the S9 mix were treated for 4 hours and cultures without the S9 mix were treated for the 18 or 28 hour period between the start of treatment and fixation. Low, medium and high concentrations of Cibacron Orange TZ 3538 were used for the 18 hour fixation interval and high concentrations only for the 28 hour fixation interval.

After 48 hours (28 hour preparation interval) and 55 hours (18 h preparation interval) the cell medium of the 4 hour treatment group only was replaced by serum free medium.

Cells fixed 18 hours after treatment in the absence of S9 mix showed no increase in the frequency of aberrations compared to controls. Cells treated in the presence of S9 mix showed slight but not statistically significant increases over the control value.

Cells fixed 28 hours after treatment in both the presence and absence of S9 mix showed statistically significant increases in the number of chromosome aberrations over controls. In experiment I in the absence of S9 mix the frequency was 7.5% and 13.5 % for treatment doses of 1000 µg/ml and 2500 µg/ml respectively. In experiment II a dose of 2000 µg/ml produced a frequency of 11% aberrations. When S9 was incorporated into the incubations aberration rates of 35.5 % and 13.0 % were produced after treatment with 4750 µg/ml in experiments I and II respectively.

The positive control substances both elicited a significant increase in chromosomal aberrations. No increases in the occurrence of polyploid metaphases was noted.

In conclusion, Cibacron Orange TZ 3538 was found to be a clastogen *in vitro* as it induced structural chromosomal aberrations in the V79 Chinese Hamster Cell line.

9.4 Overall Assessment of Toxicological Data

Cibacron Orange TZ 3538 is of low oral and dermal toxicity to rats (LD_{50} > 2000 mg/kg), is a slight irritant to the skin and a non irritant to the rabbit eye. Cibacron Orange TZ 3538 is a skin sensitizer. It was found to result in minor microscopic and macroscopic changes in the gastrointestinal tract when administered to rats at 1000 mg/kg for 28 days. It was not mutagenic toward *S.typhimurium* or *E.coli* in the reverse mutation assay, and does not cause chromosomal damage to mouse bone marrow cells *in vivo*. Cibacron Orange TZ 3538 was found to be a clastogen to V79 Chinese Hamster Cell line *in vitro*. Since an *in vivo* test failed to show clastogenic activity for Cibacron Orange TZ 3538 its potential to cause this effect remain equivocal.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicity tests were performed using technical grade (75%) Cibacron Orange TZ 3538 dye and the results (table 2) were provided by the notifier. No precipitates or other irregularities were noted in these tests and the concentrations were measured (HPLC) at regular intervals for the fish and daphnia studies. The activated sludge and the earthworm studies used the nominal concentrations. These tests were performed in accordance with standard OECD test methods and at facilities complying with OECD principles of GLP.

Table 2 Summary of the Environmental Toxicity of Cibacron Orange TZ 3538 (concentrations are actual).

Species	Test	Result	Ref
Carp *Cyprinus carpio*	96 hr acute TG 203	NOEC >1000 $mg.L^{-1}$	13
Daphnia *Daphnia magna*	48 hr immobilisation TG 202	NOEC >1000 $mg.L^{-1}$	14
Mixed bacterial culture (activated sludge)	3 hr respiration inhibitory TG 209	IC_{50} > 100 $mg.L^{-1}$	15
Earthworms, *Eisenia foetida foetida*	7 and 14 days TG 207	NOEC >1000 $mg.L^{-1}$	16

The above results show that Cibacron Orange TZ 3538 is practically non-toxic to fish and daphnia. Based on these results, chronic effects would not be expected at the estimated environmental concentrations. The lack of daphnia reproduction tests results is acceptable.

Toxicity tests on algae were not performed because (as stated by the company) "interference of the dyestuff colouration of water with light quality is likely to effect growth so that direct toxicity may not be measured. It is recognised, of course that a concentration of dyestuff in the environment capable of causing this interference, would be a negative environmental effect." CEPA accepts this reasoning.

The dye is non-toxic to wastewater bacteria and does not affect bacterial respiration at 100 $mg.L^{-1}$.

A study on the toxic effects on earthworms was included with the notification but it is unlikely that any of the dye will be released into the soil.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As indicated above, 71% of the dye is fixed in the exhaust dyeing process, thus 29% of the dye used will be discharged into effluents of the dyehouses where it is used. The notifier has calculated the concentration of discharge for both rural and city locations. These calculations disagree with those made by CEPA. The calculated worst case is that for a rural based dyehouse, with the worst case scenario giving an estimated environmental concentration (EEC) of 50 ppb (CEPA) while the company's is 12 ppb. Both use the same assumptions and are for 'drought conditions' where the sewage effluent is 25% of the river flow. CEPA's result is based on the following:

Expected annual consumption in year 5 = 2, 000 kg of Cibacron Orange TZ 3538

Average quantity to be consumed per site = 220 kg per year

Days per year on which this dye used = 36 approx.

Use of Cibacron Orange TZ 3538 per day = 6.2 kg

Fixation rate of 71%, quantity passing to effluent = 1.82 kg

Total volume of dyehouse wash waters = 1,200,000 L

Influent concentration = 1.52 $mg.L^{-1}$

Dilution in sewage treatment plants for

City based 250 ML per day = 3.0 ppb at 50% removal (company's: 4.8 ppb)

Rural 5 ML per day = 152 ppb at 50% removal (company's: 48 ppb)

Dilution in receiving waters:
City based dyehouse @ 10:1 = 0.3 ppb
Rural dyehouse @ 3:1 = 50 ppb

These calculations are based on the international assumption of 50% removal of the dye in the sewa ge treatment plant. However, Cibacron Orange TZ 3538 is expected to have low affinity for soil and sediment because of its high water solubility (>700 $g.L^{-1}$) and low partition coefficient (log P_{ow} =<-5), thus is not expected to be retained in the sludge. Assuming that no dye is removed in the sewage treatment works then for the worst case from above is 100 ppb. This is significantly below the NOEL for the species tested (>1000 $mg.L^{-1}$) and unlikely to significantly affect algae. At a concentration of approximately 1 ppm, the dye is likely to be visible, which is of concern as algal growth will be inhibited in coloured water due to the reduced light intensity. At this concentration the dye will be very visible and thus be a negative environmental impact.

It should be noted that this calculation is for the worst case where 5 batches of textiles per day are dyed. In practice it is normal to do one batch per day using 1.2 kg of Cibacron Orange TZ 3538.

The dye is not expected to accumulate in the sediment nor bioaccumulate.

· **Conclusion**

The notifier has indicated that the fixation of Cibacron Orange TZ 3538 on cellulosic fibres by the exhaust method has an expected fixation of 71%. This level of fixation is low compared with cold pad batch methods of dyeing and will result in the concentration of dye in receiving water being relatively high. However, this concentration is claimed to be lower than those for older, non-reactive dyes and is thus environmentally better than the older type dyes.

Assuming that no dye is retained in the sludge during sewage treatment, then the worst case EEC is calculated at 100 ppb in the receiving waters an inland river. This is an extreme scenario, during drought and with all waste dye reaching the river. This concentration is significantly below the NOEC for the most sensitive species tested, of >1000 ppm. There is therefore a large margin of safety.

The chemical's high water solubility and low P_{ow} suggests that there is a possibility of effluent being coloured by the dye. At a concentration of approximately 1 ppm, the dye is likely to be visible, which

is of concern and at odds with the current standards adopted by the Ecological and Toxicological Association of the Dyestuffs (ETAD).

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified substance is a powder with 1 % of its particles being in the respirable range of < 10 µm. Exposure to Cibacron Orange TZ 3538 in this powder form may occur via skin contact or inhalation. Ciba Geigy has estimated that workers using the powder product will be exposed to 2.53 mg Cibacron Orange TZ 3538 on the days of weighing which will equate to 91 mg of the substance each year. After the substance has been dissolved and diluted in the dyeing vat skin contact is the most likely route of entry to the body.

Toxicological studies suggest that the risks associated with Cibacron Orange TZ 3538 pertain to its sensitizing properties and slight skin irritation potential. An in vitro mutagenicity test indicated that it may be clastogenic but this was not supported by *in vivo* tests and so its ability to cause chromosomal damage remains equivocal.

These properties indicate Cibacron Orange TZ 3538 poses a significant potential hazard to human health. However, as the exposure will be strictly controlled the risk of health effects would be limited.

There is low potential for public exposure to the notified chemical. Therefore, there should be negligible risk to public safety.

13. RECOMMENDATIONS

To minimise occupational to Cibacron Orange TZ 3538 the following guidelines and precautions should be observed:

- If engineering controls and work practices are insufficient to reduce exposure to a safe level, the following personal protective equipment should be used:
  - respiratory protection conforming to AS 1715 (17) and AS 1716 (18);
  - chemical-type goggles conforming to Australian Standards 1336 (19) and 1337 (20);
  - impervious gloves conforming to Australian Standard 2161 (21); and
  - protective clothing conforming to Australian Standards 3765.1 (22) or 3765.2 (23).
- Good work practices should be implemented to avoid generation of dust/splashing and spillages.
- Spills should be cleaned up promptly.
- Good personal hygiene practices, such as washing of hands prior to eating food, should be observed.
- A copy of the MSDS for products containing the notified chemical should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Cibacron Orange TZ 3538 (Attachment 1) was provided in Worksafe Australia format (24). The MSDS was provided by Ciba-Geigy Australia Ltd as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Ciba-Geigy Australia Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Cibacron Orange TZ 3538 shall 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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21. Australian Standard 2161-1978 Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves), Standards Association of Australia Publ, Sydney, 1978.

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