

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**TETRASODIUM, 4-AMINO-5-HYDROXY-6-(3-(2-(2-SULPHOXYETHYLSULPHONYL)ETHYL)-AMINOCARBONYLPHENYLAZO)-3-(4-(2-SULPHOXYETHYLSULPHONYL)PHENYLAZO)NAPHTHALENE-2,7-DISULPHONATE AND ITS HOMOLOGUES, SYNTHESIS BY-PRODUCTS AND ADDITIVES (ALSO KNOWN AS DISAZO NAVY TZ 2646)**

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For Enquiries please contact Ms Karen Bell at:

*Street Address:* 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA

*Postal Address:* GPO Box 58, Sydney 2001, AUSTRALIA

*Telephone:* (61) (02) 565-9466 **FAX (61) (02) 565-9465**

Director

Chemicals Notification and Assessment

Date: 28 May 1991

## Full Public Report

**TETRASODIUM, 4-AMINO-5-HYDROXY-6-(3-(2-(2-SULPHOXYETHYLSULPHONYL)ETHYL)-AMINOCARBONYLPHENYLAZO)-3-(4-(2-SULPHOXYETHYLSULPHONYL)PHENYLAZO)NAPHTHALENE-2,7-DISULPHONATE AND ITS HOMOLOGUES, SYNTHESIS BY-PRODUCTS AND ADDITIVES (ALSO KNOWN AS DISAZO NAVY TZ 2646)**

**1. IMPORTER**

CIBA-GEIGY Australia Ltd., 140 Bungaree Road, Pendle Hill, NSW 2145.

**2. IDENTITY OF THE CHEMICAL**

**Chemical name:** Tetrasodium, 4-amino-5-hydroxy-6-(3-(2-(2-sulphoxyethylsulphonyl)ethyl)-aminocarbonylphenylazo)-3-(4-(2-sulphoxyethylsulphonyl)phenylazo)naphthalene-2,7-disulphonate

**Chemical Abstract Service Registry Number**

(CAS No): 116889-78-2

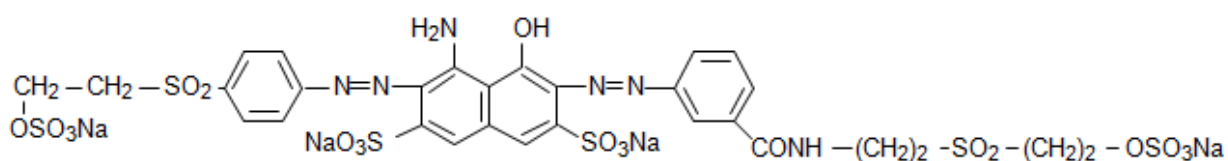
**Trade name:** CIBACRON Navy C-B (containing 35% of Disazo Navy TZ 2646)

**Other names:** Disazo Navy TZ 2646  
C.I. Reactive Blue 238  
FAT 40'362/A,B

**Empirical formula:**  $C_{29}H_{30}N_6O_{20}S_6 \cdot 4Na$

**Molecular weight:** 1062.89

**Structural formula:**



**Spectral Data:** Infrared spectra (major absorption bands at 1160-1350  $\text{cm}^{-1}$ ; 1500-1550  $\text{cm}^{-1}$ ; 1640-1690  $\text{cm}^{-1}$ ; 3200-3600  $\text{cm}^{-1}$ ; 3300-3500  $\text{cm}^{-1}$ ).

### 3. PHYSICAL AND CHEMICAL PROPERTIES

At room temperature and atmospheric pressure, Disazo Navy TZ 2646 is a dark blue powder of low volatility. Its physical and chemical properties include:

<b>Melting point:</b>	below 300°C no melting point was detected; the chemical will decompose and autoignite before it melts.
<b>Density:</b>	$1.51 \times 10^3 \text{ kg/m}^3$ (at 23°C)
<b>Flammability:</b>	flammable
<b>Autoignition temperature:</b>	280°C
<b>Explosion potential:</b>	non-explosive
<b>Thermal decomposition potential:</b>	stable at room temperature to 150°C in the absence and presence of air
<b>Reactivity:</b>	not an oxidising agent
<b>Water solubility:</b>	>300 g/L (at 20°C)
<b>Fat solubility:</b>	<0.05 mg/100 g fat (at 37°C)
<b>Hydrolytic potential:</b>	half-life < 1 day at 50°C and pH = 7 and 9;  half-life > 1 year at 50°C and pH = 4
<b>Partition coefficient log P (o/w):</b>	-12.4

**Particle size** 28.0 µm  
**(median of mass distribution)**

**Comments on Physico-Chemical Properties** The lack of a result for vapour pressure is acceptable as the notified substance is a high molecular weight tetrasodium salt and the vapour pressure is likely to be negligible.

The lack of a result for adsorption\ desorption is acceptable as the high water solubility and low partition coefficient of the notified substance suggests that adsorption will be low.  
The lack of a result for dissociation constant is acceptable on the grounds that the substance contains four sulphonic acid moieties which are known to be strongly acidic.

#### **4. METHODS OF DETECTION AND DETERMINATION**

High Pressure Liquid Chromatography; Thin Layer Chromatography; Gas Chromatography; Atomic Absorption Spectroscopy; Volumetry.

#### **5. PURITY OF THE CHEMICAL**

**Degree of purity:** 10-60% w/w

**Homologues and synthesis by-products:** 10-60% w/w

**Additives/Adjuvants:**

sodium sulphate (CAS No: 7757-82-6) <10% w/w

sodium acetate (CAS No: 127-09-3) <10% w/w

water (CAS No: 7732-18-5) <10% w/w

#### **6. INDUSTRIAL USES**

Disazo Navy TZ 2646 is intended to be used solely as a reactive dye for the colouration of cellulosic textiles by the cold padbatch or thermofix method. It is expected that 1 to 10 tonne of Disazo Navy TZ 2646 will be imported per year in the first 2 years after which 10 to 100 tonne will be imported annually in the next 3 years.

## **7. PUBLIC AND OCCUPATIONAL EXPOSURE**

The notified substance, Disazo Navy TZ 2646, will be imported as a constituent of the formulated commercial product, CIBACRON Navy C-B. CIBACRON Navy C-B will contain 35% of Disazo Navy TZ 2646. This product will be imported in sealed robust containers and will be transported to users in similar 20 kg containers, therefore, significant risk is not anticipated from accidental spillage during transport. From time to time, the product will be repackaged locally into smaller receptacles before distribution, and before use in the dyeing process, the product will be weighed and dissolved. If control and personal protection measures and safety work practices are not implemented in areas where the powder dye will be handled, the potential occupational exposure to the dye during repackaging and use can be high. Once a solution of the dye has been formed, the potential for exposure will be significantly reduced. After dyeing has occurred, the dye is permanently fixed to cellulosic textiles, presenting no public or occupational risk. The fixation level of the dye is 98% which implies that 2% will be discharged in process effluent water and into the municipal water treatment system. Should effluent discharges exceed 2%, public risk is not anticipated as the chemical has low stability and is unlikely to accumulate in the environment. Thus under correct handling and dyeing procedures, the potential for public and occupational exposure is minimal.

## **8. ENVIRONMENTAL EXPOSURE**

The dyestuff will be used in the textile industry in NSW, Victoria, South Australia and Tasmania.

### **. Environmental Exposure**

#### **- Release**

The major environmental exposure of the dyestuff will occur through release of unfixed dye in the effluent from the dye factories. The notifier indicates the dyestuff has a fixation degree of 98% (colourimetric analysis of the liquors from the dyeing process indicates this level of fixation of the notified substance) resulting in 30% less unfixed dye passing to the effluent in a washing-off operation than currently used dyes. The company states that no more than 14 kg/yr of the notified substance will be lost to each user's treatment plant from the dyeing operations. This is based on 700 kg notified substance per

customer (10 tonne commercial product sold suggests product used at about 14 different sites) and 98% fixation. However, factories are unlikely to all use an equal quantity and given the level to be imported a maximum of about 50 kg/yr may be expected to be lost at the site of highest use. The company states that discharge in all sites contemplated for use of the notified substance will be to municipal sewage works where municipal streams' volumes vary from several megalitres to over 500 ML (MMBW - Werribee). The notifier predicts the concentration in receiving waters to be 1.4 ppb under low flow conditions and 0.4 ppb under normal flow conditions (Appendix 1). The dye factories using the notified substance that have their waste treated by sewage treatment plants that dispose of effluent into the oceans will result in a large dilution of the notified substance. 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 and could be very low in dry or drought conditions. For example, it is known that one of the dye factories that will be using this product is situated inland. The company calculates the expected concentration at the treatment works to be 5.8 ppb based on 23 g/day notified substance released to the environment and an average volume of 4 ML per day. Further dilution will give receiving water concentration as follows:

1:3	1.9 ppb	1:10	0.58 ppb.
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In the extreme "worst case", assuming no loss in the treatment works and a maximum of 50 kg/yr (161 g/day) released at any one site, the expected concentration at the treatment works (based on a average volume of 4 ML) is calculated to be 40 ppb. Further dilution will give receiving water concentrations of 13 ppb (1:3 dilution) and 4 ppb (1:10 dilution). The company states that current levels of unfixed dyestuff discharge are more than ten times higher than that will be achieved with the notified substance.

#### **- Fate**

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 (1). Normally, a significant proportion of the dyestuff may be eliminated by adsorption onto the sludge. However, a study which mimicked the mixing of dyewastes with the biomass in an activated sludge plant showed that reactive dyes do

not adsorb to sludge (2). On this basis, the remaining dyestuff that reaches the receiving waters will remain with the water phase and is unlikely to bind onto suspended sediment. This is not unexpected in view of the substance's high water solubility and low partition coefficient. Also, a recent study by the US Environment Protection Authority (EPA) to determine the partitioning of water soluble azo dyes in the activated sludge process indicates little or no adsorption of azo dyes with high sulphonic acid substitution (as this is) by the sludge occurs (3). It should be noted however, that in Appendix 1 the company assumes that 50% of the notified substance is removed during the sewage treatment process, suggesting that it expects the notified substance is likely to degrade by abiotic hydrolysis due to the wastewater from dyeworks predominately being alkaline, which is typical of effluent from sewage works (4). As noted below the notified substance is unstable in alkaline conditions (half-life of < 24 hours). Some of the notified substance may also be removed by binding to sludge but hydrolysis to polar, water soluble substances is likely to predominate. 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 4.2 ppb (Appendix 1). Should some adsorption occur the notified substance could also enter the soil compartment when sewage sludge containing dyes are disposed of onto agricultural lands. The remaining dyestuff that reaches the receiving waters is also likely to bind onto suspended sediment and eventually find its way to the bottom sediment.

### **-Hydrolysis**

The notified substance is hydrolytically stable under acidic conditions, but readily degrades under neutral to alkaline conditions with a half-life of < 2.4 hours at 50°C at pH 7 or above. The company did not indicate what degradation products were formed. Assuming a 25°C change in temperature causes a factor of 10 change in the rate of hydrolysis (5) the half-life of the notified substance at 25°C is likely to be < 24 hours at pH 7 or higher. As noted above effluent from sewage treatment works is alkaline, therefore, the notified substance is likely to be degraded as it passes through the sewage treatment works.

### **-Bioaccumulation**

The notified substance's high water solubility, very low partition coefficient and low fat solubility indicate that it is unlikely to bioaccumulate..

### **-Biodegradation**

The notifier has provided information on biodegradation studies for the notified substance (Table 1). The dissolved organic carbon study (6) and biological oxygen demand study (7) show that Disazo Navy TZ 2646 is not readily biodegradable. The activated sludge, respiration inhibition test (8) shows that Disazo Navy TZ 2646 does not inhibit respiration of micro-organisms.

**Table 1: Biodegradation studies on Disazo Navy TZ 2646**

<b>Test</b>	<b>Result</b>	<b>Ref.</b>
Dissolved organic carbon	0%	6
Biological oxygen demand	0 mg/g O <sub>2</sub>	7
Respiration inhibition	IC50 (3h) >100 mg/L	8

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 (9). 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 (9). Biodegradation under anaerobic conditions is therefore an important environmental fate mechanism for azo dyes. However, given the expected fate of the notified substance, anaerobic biodegradation is expected only to be a minor pathway. This may only occur when contaminated effluent is used for irrigation purposes since the notified substance is unlikely to adsorb significantly to sewage sludge and will not therefore be subjected to anaerobic sludge digestion processes at sewage treatment works.



## 9. EVALUATION OF TOXICOLOGY DATA

### 9.1 Acute Toxicity Studies

**Table 2. Summary of acute toxicity of Disazo Navy  
TZ 2646 (also known as FAT 40'362/A,B)**

Test	Species	Outcome	Reference
Oral	Rat	LD <sub>50</sub> : >2000mg/kg	10
Dermal	Rat	LD <sub>50</sub> : >2000mg/kg	11
Skin irritation	Rabbit	non-irritant	12
Eye irritation	Rabbit	slight irritant	14
Skin sensitisation	Guinea pig	sensitising	16

#### 9.1.1 Oral Toxicity (10)

FAT 40'362/A,B in water was administered by gavage to rats (KFM-Han. Wistar - outbred SPF-Quality) of both sexes at a dose of 2000 mg/kg. Five rats of each sex were used. Clinical observations were made over a 15-day period. No deaths occurred during the study. No clinical signs of toxicity were observed. Gain in bodyweight was unaffected by treatment. Necropsy revealed no treatment-related organ toxicity. The results from this study indicate that the acute oral LD<sub>50</sub> for FAT 40'362/A,B is >2000 mg/kg in male and female rats.

#### 9.1.2 Dermal Toxicity (11)

A single dose of 2000 mg/kg of FAT 40'362/A,B moistened with water was applied to the shaved backs of five male and five female rats (KFM-Han. Wistar - outbred, SPF-Quality). Clinical

observations were made over a 15-day period. No deaths occurred during the study. No clinical signs of toxicity were observed. Gain in bodyweight by the test animals was unaffected by treatment. Necropsy revealed no treatment-related organ toxicity. The results from this study indicate that the acute dermal LD<sub>50</sub> for FAT 40'362/A,B is >2000 mg/kg in male and female rats.

#### **9.1.3 Skin irritation (12)**

A single dose of 0.5 g of FAT 40'362/A,B moistened with water was applied to the intact skin of the shaved area of one male and two female rabbits [New Zealand White, KFM (SPF-Quality)]. The duration of treatment was four hours. Skin reaction was scored according to the numerical scoring system described in OECD Guideline 404 (13) at 1, 24, 48 and 72 hours post-treatment. No deaths occurred during the study. No signs of erythema or oedema were observed. However, at the area of application, a blue discolouration of the treated skin was observed which may have hindered the observation of erythema but the effect would have been very slight for it to be masked. The results of this study indicate that FAT 40'362/A,B is not a skin irritant.

#### **9.1.4 Eye irritation (14)**

A single dose of 0.1 g of FAT 40'362/A,B was instilled in the conjunctival sac of one eye of each of three rabbits [New Zealand White, KFM (SPF-Quality)] with the other untreated eyes acting as controls. The eyes were examined at 1, 24, 48 and 72 hours post-treatment. Irritation was scored according to the numerical scoring system described in OECD Guideline 405 (15). One hour after treatment, slightly visible oedema of the conjunctivae was observed in all three treated eyes. Blue discolouration of the nictitating membrane, conjunctivae, eyelashes and whole eye area was also observed in the three treated eyes. In two of the treated eyes, the discolouration decreased after 48 hours. At 48 hours the oedema had totally subsided in all three treated eyes. No corrosion was observed. No deaths occurred during the study and systemic toxicity was not evident. The results from this study indicate that FAT 40'362/A,B is a slight eye irritant in rabbits.

#### **9.1.5 Skin sensitisation (16)**

The Magnusson and Kligman Maximisation Test (17) was used. Skin reactions were scored according to the scoring system described

in OECD Guideline 404 (13). The positive control used was formaldehyde. Petrolatum oil was used as the negative control. Positive erythema reactions were observed in 60% of the animals which were epidermally challenged with formaldehyde.

In the preliminary study, the test substance, FAT 40'362/A,B in petrolatum oil, was administered by intradermal injection and epidermal application to the clipped flanks of Dunkin-Hartley albino guinea pigs (DUHA KFM). A 1% solution was selected for induction via the intradermal route in the main study. The concentration selected for induction via the epidermal route was 25% and for the first challenge procedure, 10%.

In the induction and challenge study, 30 animals (15 males and 15 females) were used of which ten (five males and five females) served as controls. At the beginning of the induction period, the 20 animals receiving the test substance (the test group) were first induced by intradermal injection of 1% FAT 40'362/A,B in petrolatum oil. One week later, the same animals were induced epidermally with 25% of FAT 40'362/A,B in petrolatum oil. Slight oedema was observed in 4 of the 20 animals. Erythema was not observed but this could be due to masking by the blue discolouration of the skin caused by the test substance. Two weeks after the epidermal application, each animal (including controls) was challenged epidermally with 10 % FAT 40'362/A,B in petrolatum oil. After the first challenge, slight to well-defined erythema was observed in 13 of the 20 animals in the test group and in some cases was still evident 72 hours after application. One positive case was reported in the control group. Two weeks after the first challenge, a second challenge on the test animals alone using 5% test substance resulted in 13 of the 20 test animals responding positively and 11 still exhibited a positive response at 72 hours. An overall increase in the severity of erythema was observed in these animals. No deaths occurred during the study. Local reactions around the injection sites were observed but as these were also seen in controls they are not thought to be related to the test substance. No systemic toxic symptoms were noted. No necropsy was performed. According to Buehler's sensitisation ranking (18), the results of this study indicate that FAT 40'362/A, is a moderate to strong skin sensitiser in male and female albino guinea pigs.

## **9.2 Five-day oral toxicity (19)**

Groups of six rats (Wistar KFM-Han., outbred, SPF-Quality) each consisting of three males and three females were administered FAT 40'362/A,B at doses of 0, 200 and 1000 mg/kg/day by gavage for five days. Animals were sacrificed on the fifth day of treatment. No treatment related deaths were observed during the study. No clinical signs of toxicity were observed. Food consumption and gain in bodyweight were unaffected by treatment. No statistically significant differences in absolute and relative organ weights between the animals in the treated groups and those in the control group were observed. No macroscopical organ changes were observed in the control or 200 mg/kg group. However, in the 1000 mg/kg group, bluish discolouration of the mucosa of the stomach and intestines was seen in one male and one female, and similar discolouration of the kidneys was also seen in another male and female. From the results of this study, the dose levels for the 28-day study were set at 0, 50, 200 and 1000 mg/kg.

## **9.3 Short-term 28-day repeated dose oral toxicity (20)**

Groups of 10 rats (Wistar, KFM-Han., outbred, SPF-Quality) each consisting of five males and five females were gavaged with 0, 50, 200 and 1000 mg/kg/day of FAT 40'362/A,B for 28 days. In addition, satellite groups of 0 and 1000 mg/kg/day were observed for a period of 14 days post-treatment to determine the reversibility of any toxic effects. No deaths were recorded during the study. Food consumption and gain in bodyweight were unaffected by treatment. Corneal opacity was observed in one male from the 50 mg/kg dose group at four weeks but this effect is unlikely to be treatment related as it was not observed in higher dose groups. Blue discoloured faeces and urine were reported but these effects were reversible during the recovery period. Haematological, biochemical and urinalysis data revealed no changes of toxicological significance. Many high dose animals were reported to have blue discolouration of the gastrointestinal tract and dark discolouration of the kidneys but the discolouration was not apparent microscopically. Pathological findings also showed an increase in renal tubular eosinophilic inclusion bodies in all the treated males at all dose levels but a dose relationship was not apparent, and recovery had occurred after 14 days of abstinence from the test substance. Such an effect was not observed in females. The no-effect level was not established.

## 9.4 Genotoxicity

**Table 3. Summary of genotoxicity studies with Disazo Navy TZ 2646 (also known as FAT 40'362/A,B)**

Test type	Dose range	Outcome	Ref.
<i>Salmonella typhimurium</i> ReverseAssay	10 - 5000 ug/plate	negative	21
Chromosome AssayChinese HamsterCells	0.03 - 1 mg/ml	positive	22
<i>In vivo</i> mouse assay	4000 mg/kg	negative	23

### 9.4.1 Ames Salmonella typhymurium Reverse Mutation Assay (21)

FAT 40'362/A,B at concentrations of 10, 100, 333.3, 1000 and 5000 ug/plate was tested for gene mutations according to the direct plate incorporation method using *Salmonella typhimurium* strains TA 1537, TA 1538, TA 98, TA 1535 and TA 100 in both the presence and absence of metabolic activation. Positive, untreated and solvent controls were used. Positive controls used without metabolic activation were sodium azide and 4-nitro-o-phenylene-diamine, and 2-aminoanthracene was used in the presence of metabolic activation. No increase in revertant colony numbers of any significance was observed in any of the strains exposed to FAT 40'362/A,B both in the presence and absence of metabolic activation, in contrast the positive controls caused a significant increase in revertant colony numbers. Under the experimental conditions, FAT 40'362/A,B is considered to be non-mutagenic in the *Salmonella typhimurium* reverse mutation assay.

### 9.4.2 Chromosome Aberration Assay (22)

FAT 40'362/A,B was tested for its potential to induce structural chromosome aberrations in Chinese Hamster V79 cells *in vitro* at dose levels of 0.03, 0.6 and 1 mg/ml in the presence of metabolic

activation, and 0.05, 0.1 and 0.2 mg/ml in the absence of metabolic activation. Both positive and solvent controls were used. Positive controls used were ethylmethanesulphonate in the absence of metabolic activation and cyclophosphamide in the presence of metabolic activation. When compared with the solvent controls, in the presence of metabolic activation, significant increases in cells with structural chromosome aberrations of 18.25% and 11% (including gaps) were observed with test concentrations of 0.6 mg/ml (at 7 hours) and 1 mg/ml (at 28 hours) respectively. Significant increases were also observed with the positive controls both in the presence and absence of metabolic activation. Under the experimental conditions reported, FAT 40'362/A,B induced structural chromosome aberrations in V79 cells of the Chinese Hamster. Therefore, FAT 40'362/A,B is considered to be mutagenic in this chromosomal aberration test.

#### **9.4.3 In-vivo Mouse Micronucleus Assay (23)**

FAT 40'362/A,B in aqua dest., was administered orally in a single dose of 4000 mg/kg to NMRI mice. Both positive and solvent controls were used. Cyclophosphamide administered as a positive control showed a distinct increase of induced micronucleus frequency. When compared with the solvent controls, no significant increases in the number of micronucleated polychromatic erythrocytes were observed with the test substance 24, 48 and 72 hours post-treatment. Under the test conditions reported, FAT 40'362/A,B is considered to be non-mutagenic in the mouse micronucleus assay.

#### **9.5 Overall Assessment of Toxicological Data**

FAT 40'362/A,B has low acute oral toxicity (oral LD<sub>50</sub> in rats: >2000 mg/kg) and low acute dermal toxicity (dermal LD<sub>50</sub> in rats: >2000 mg/kg). Tests in rabbits reveal that it is a slight eye irritant but is non irritating to the skin. FAT 40'362/A,B has been found to be a skin sensitiser in guinea pigs. It is therefore anticipated that if inhaled, FAT 40'362/A,B may irritate or sensitise the upper respiratory tract. No acute inhalation toxicity data was presented. A short term repeated dose study shows an increase in renal tubular eosinophilic inclusion bodies in males at the lowest dose level of 50 mg/kg/day but this did not become more severe at higher doses and

recovery had occurred after 14 days of abstinence from the test substance. The toxicological significance of this is not known. The no-effect level was not established.

FAT 40'362/A,B was found to be non-genotoxic in both the *Salmonella typhimurium* reverse mutation test and the *in vivo* mouse micronucleus assay. However, FAT 40'362/A,B was found to induce structural chromosome aberrations *in-vitro* in V79 cells of the Chinese Hamster.

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

**Table 4 Summary of the acute oral toxicity and ecotoxicity of Disazo Navy TZ 2646**

Test	Species	Result	Ref.
Acute Oral	Rat	LD50 >2000 mg/kg	10
Acute toxicity	<i>Zebrafish</i>	96h LC50 >1000 ppm	24
Acute Immobilization	<i>Daphnia magna</i>	24h NOEL >1000 ppm	25

Reports were provided and these indicate the above tests were satisfactorily conducted according to OECD guidelines. The results demonstrate that the notified substance is practically non-toxic to the species tested.

The aquatic toxicity test for *daphnia magna* was modified (only the acute test was performed) because "fish toxicity and *daphnia* immobilisation effects are very low and hence reproductive effects are not expected to be observed". Assuming a safety factor of 1000 for the acute immobilization result, the predicted chronic toxicity for *daphnia magna* would be > 1 ppm, which is still two orders of magnitude higher than the worst case predicted environmental concentration in water. No data were provided for algae growth inhibition on the grounds that "...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 (9). Algae growth inhibition tests of 56 dyestuffs showed close parallels

with fish toxicity data (9). Based on the above information and the notified substance fish toxicity result, it is unlikely that the notified substance will be toxic to algae.

## **11. ASSESSMENT OF ENVIRONMENTAL HAZARD**

. Release from dyeworks 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. However, it is likely to degrade by abiotic hydrolysis under neutral or alkaline conditions. It is unlikely to undergo volatilisation given the 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 The company predicts that the environmental concentration of the notified substance in receiving waters to be in the range 0.42 - 1.4 ppb/day (Appendix 1). Using a named Dyeworks as a "worst case" inland situation, it calculated these predicted environmental concentrations in the receiving water to range from 0.58 ppb to 1.9 ppb. These predicted environmental concentrations of the notified substance are based on 50% removal of the dyestuff during the sewage treatment process and an even use per customer. Assuming that no notified substance is removed during the sewage treatment process and a higher use by the larger customers, the predicted environmental concentration of the notified substance will be 13 ppb, still a very low concentration. The level of unfixed notified substance in the wastewater being discharged from the dyeworks is stated to be ten times less than the current levels of unfixed dyes in wastewater. Therefore the environmental hazard posed by the notified substance is likely to be lower than those dyes currently in use, assuming similar toxicities..

Ecotoxicity hazard Ecotoxicity results indicate Disazo Navy TZ 2646 is unlikely to present either an acute or chronic hazard to aquatic invertebrates, freshwater fish and micro-organisms. Although no algal toxicity results were provided for Disazo Navy TZ 2646, the notified substance is also unlikely to present a hazard to algae. While Disazo Navy TZ 2646 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.. Hazard arising from use of effluent or sludgeIrrigation of agricultural or municipal (ie golf courses, racecourses) land with effluent containing the notified substance has the potential to cause groundwater pollution, as Disazo Navy TZ 2646 is unlikely to adsorb to sewage sludge and may not bind to soil. However, based on the predicted low quantity of notified substance present in the effluent (in the order of ppb, Appendix 1), effluent used for irrigation is unlikely to adversely affect groundwater quality or present a hazard to terrestrial organisms.The irrigation or fertilization of agricultural land with water or sludge containing dyestuff may have an effect on terrestrial plants. However, the limited number of plant growth studies on other dyes do not indicate adverse effects will arise from this use. Plant growth studies showed that only at a dye concentration of 1000 mg/kg soil were variable effects on plant growth noticed (9). The amount of notified substance lost to sewage sludge is likely to be low ("worst case" of ~20 g/day; based on 50% removal of 45 g/day notified substance released to sewage treatment plant) and the final concentration in the sludge is unlikely to present a hazard to the environment. [Note: a large dilution effect is likely to occur as 150 dry tonnes of sewage sludge is produced per day in NSW, (26)].

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

FAT 40'362/A,B is a slight eye irritant and a skin sensitiser, therefore, if inhaled it may irritate or sensitise the upper respiratory tract. Other reactive dyes have been linked with respiratory sensitisation. Inhalation and skin contact should be prevented as this may result in sensitisation. Due to low public and occupational exposure under normal use conditions, it is unlikely that the notified chemical will pose any serious health or safety hazard to the public and workers. Under these circumstances, the recommendations under Section 13 should be sufficient to minimise exposure.

### **13. RECOMMENDATIONS FOR SAFETY PROCEDURES TO CONTROL PUBLIC AND OCCUPATIONAL EXPOSURE**

To minimise public and occupational exposure to the formulated commercial product, the following guidelines and precautions should be observed:

- . Engineering control procedures such as local exhaust ventilation should be employed in areas where the powder dye will be handled.
- . Personal protection measures should be implemented such as the wearing of safety glasses, impervious elbow length gloves, protective clothing and disposable dust masks. When ventilation is insufficient, approved respiratory protection must be worn. Should splashing occur when handling the dye solution, a face shield should be worn in place of safety glasses.
- . As safe work practice the product should be handled with care to avoid spillage or the generation of a dust cloud. Containers of powder dye should only be opened during weighing. The handling of powder dye should be minimised for example by making a solution or paste from the powder after weighing.
- . Wet methods or vacuum cleaning which do not lead to dispersion of settled dust should be used for plant maintenance and sanitation. Spillages should be attended to immediately.
- . A copy of the MSDS for both the notified chemical and the formulated commercial product should be easily accessible to employees.

### **14. RECOMMENDATIONS FOR MATERIAL SAFETY DATA SHEET (MSDS)**

The MSDSs for Disazo Navy TZ 2646 and CIBACRON Navy C-B, were compiled according to Worksafe Australia format. A copy of these MSDSs are attached (Attachment 1 and 2).

## 15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act), secondary notification of Disazo Navy TZ 2646 shall be required by CIBA GEIGY Australia Ltd if any circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

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