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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Reactive Yellow TZ 4165

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Reactive Yellow TZ 4165

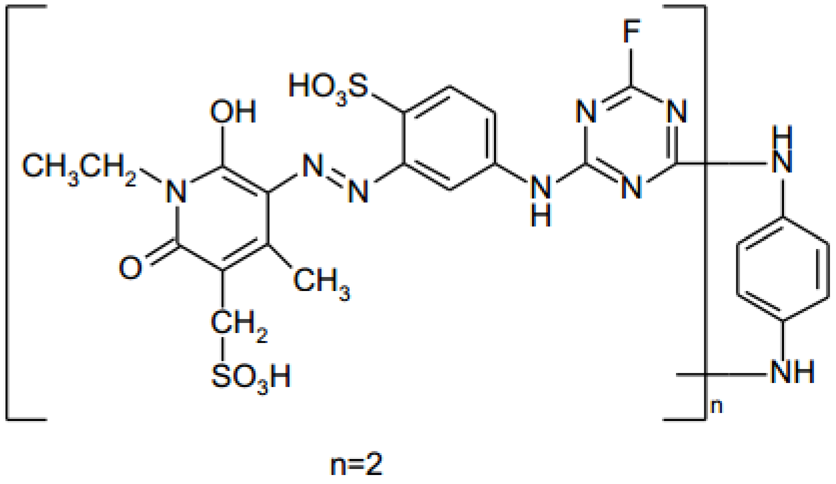
1. APPLICANT

Ciba Specialty Chemicals of 235 Settlement Road THOMASTOWN VIC 3074 has submitted a limited notification statement in support of its application for an assessment certificate for Reactive Yellow TZ 4165.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	3-pyridinemethylsulfonic acid, 5,5'-[1,4-phenylenebis[imino(6-fluoro-1,3,5-triazine-4,2-diyl)imino(6-sulpho-3,1-phenylene)azo]]bis[1-ethyl-1,3-dihydro-6-hydroxy-4-methyl-2-oxo. sodium salt
Chemical Abstracts Service (CAS) Registry No.:	178198-11-3
Other Names:	FAT 40'560/A
Trade Name:	Reactive Yellow TZ 4165 Cibacron Yellow LS-4G (product name)
Molecular Formula:	$C_{42}H_{40}F_2N_{16}O_{16}S_4$. xNa

Structural Formula:



Molecular Weight: 1279

Method of Detection and Determination: reports with ^{1}H-NMR, UV/Visible absorption and IR (infrared) spectrometric data were submitted for the identification of the notified substance.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: violet to yellow-orange (ochre) powder with no odour

Melting Point: > 400°C

Specific Gravity: 1.59×10^3 kg/m^3 at 21°C

Vapour Pressure: $< 5 \times 10^{-12}$ kPa at 20°C (extrapolated)

Water Solubility: 291 g/L at 20°C (mass saturation)

Partition Co-efficient (n-octanol/water): $\log P_{ow} < -10.0$ at pH 6.43 and 25°C

Hydrolysis as a Function of pH:
$T_{1/2}$ at pH 4.0 and 25°C = 383.6 hours
$T_{1/2}$ at pH 9.0 and 25°C = 253 days

Adsorption/Desorption:
Loamy sand $K_{oc} = 710$ mL/g
Sandy loam $K_{oc} = 744$ mL/g
Silt loam $K_{oc} = 867$ mL/g

Dissociation Constant: estimated dissociation constants are:
aromatic sulfonic acid $-2.5 > pK_a > -3.0$;
aliphatic sulfonic acid $-1.9 > pK_a > -2.1$;
phenylamino triazine $pK_a \approx 0.8$;
2,6,-hydroxy-oxy-pyridine
basic $pK_a \approx 1.8$
acidic $pK_a > 11$

Particle Size: 7.7 µm (median diameter of mass distribution); 45% has diameter less than 7 µm; particle size for the imported product was not provided.

Flash Point: not determined

Flammability Limits: not highly flammable-brief ignition, flame would not spread

Autoignition Temperature: 270°C

Explosive Properties: not explosive, neither by thermal nor mechanical stress

Reactivity/Stability: not an oxidising substance

Surface Tension: 71.8 mN/m at 1 g/L, 20°C

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice. Full test report were provided.

Adsorption/desorption data were provided. High water solubility and a low partition coefficient would normally indicate low affinity for soil or sediment. The notifier has indicated the notified chemical is unlikely to bind/adsorb strongly to soil and to move with the ground water.

The notified chemical contains both aliphatic and aromatic sulfonic acid groups that will be expected to completely dissociate under environmental conditions. The strongly acidic sulfonic acid groups will render the molecule negatively charged over the whole environmentally relevant pH range (pH 4-9). The possible protonation of the weakly basic amino groups will have negligible effect in the lowest pH region (below pH≈2).

The notified chemical is not surface active at a concentration of 1 g/L. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (EEC, 1992).

4. PURITY OF THE CHEMICAL

Degree of Purity: 52.7% (45-60%)

Toxic or Hazardous Impurities: unspecified

Composition and Impurities of Notified Substance, including isomers and by-products:

Name	*CAS Number*	*% Weight*
notified chemical	178198-11-3	52.7
known coloured by-products	–	28.5
unknown coloured by-products	–	4.4
unknown uncoloured by-products	-	0.1
sodium chloride	7647-14-5	0.2
sodium phosphate		3.8
sodium sulfate	7757-82-6	0.4
sodium fluoride	7681-49-4	0.7
water	7732-18-5	10.3

Additives/Adjuvants: none in the notified substance. Additives and adjuvants are included only in the commercial version of the dyestuff, not in the notified chemical itself.

Composition of Cibacron Yellow LS-4G (the product containing the notified chemical):

Name	*CAS Number*	*% Weight*
Reactive Yellow TZ 4165	178198-11-3	73
sodium tripolyphosphate	7758-29-4	3
sodium sulfate	7757-82-6	15
anti-dust preparation	8012-95-1	1
water	7732-18-5	8

5. USE, VOLUME AND FORMULATION

The dyestuff is an azo dye used for colouring cellulose textiles by the exhaust dyeing method. The dye has a fixation performance of 75%.

The notified chemical will not be manufactured in Australia. It will be imported into Australia in a granular form as a component of the product Cibacron Yellow LS-4G at a concentration of 70-75%. It will be imported in polythene lined fibre kegs of 25 kg capacity. Import volumes for the notified chemical are less than 1 tonne per year for the first five years.

The notifier anticipates that the dyestuff will be sold to approximately six dyehouses in city and country locations. Some minimal re-packing will occur for the purpose of supplying samples or material for mill trials. Repacking will be carried out at the notifier's warehouse.

6. OCCUPATIONAL EXPOSURE

The vapour pressure of the notified chemical is low, so exposure to airborne vapours is not anticipated. Respiratory exposure to the notified chemical powder could occur as 45% is in the respirable range. This level of exposure is not anticipated for the commercial product since it is provided in granular form and an anti-dusting substance is added. Dermal contamination would be the main route of occupational exposure. Workers who will handle the notified chemical include transport workers, dyehouse workers and storemen.

Transport and storage

Transport workers and storemen are unlikely to be exposed to the notified chemical unless the package is breached.

Repacking

Most customers will receive full 25 kg containers of the notified chemical. If packs need to be broken, then repacking will occur at the notifier's warehouse which has facilities for the handling of hazardous substances. In the down-flow booth in which dyes are repacked, the air flow is away from operators and the capture velocity for particulates is exceeded to minimise the exposure. The repack operators are trained in the handling of hazardous substances. There will be 2 repack operators. It is estimated that less than 100 kg will need to be repacked, this operation would take 15-20 minutes per day and up to 10 days annually. During these operations, workers wear elbow-length PVC gloves, safety glasses, face shield and overalls.

End use

Briefly, the incorporation of the dyestuff in a dye-bath solution can be represented:

Weighing → Adding to blending vessel → Transfer to dyeing apparatus

It is expected that up to 40-50 workers will handle the notified chemical in dyehouses. This would include 5 weighing-operators, 20 wash-off operators, 12 drier operators and 2 laboratory technicians. Estimated total number of employees potentially exposed in Australia is 240. The notified chemical will be handled on 25 days per year for a maximum of 30 minutes per operator, on those days.

Occupational exposure during weighing and mixing procedures is possible. The product containing the notified chemical will be weighed in a dispensary equipped with local exhaust ventilation. The weighed powder is added to the blending vessel also under local exhaust ventilation. It has been observed that the personal protective equipment worn by weighing operators includes half-face piece particulate filter respirator, long impervious neoprene or rubber gloves, overall, industrial footwear and safety spectacles with side shields.

Padding of the dye and fixation are carried out in a closed system so there is no occupational exposure during this process.

During wash-off and dry processes after fixation, workers will handle the dyed cloth for a short time only. The dyestuff has a high fastness (75%) and becomes chemically bonded to the cellulose fibres. There is no evidence of loss of dye fixed to fibre subsequent to wash-off or during drying. Dyed cloth is taken up on beams or trucks so that little manual handling of the cloth will be involved. During these operations, workers will wear protective gloves.

Laboratory technicians will take and analysis samples containing the notified chemical. The exposure to the notified chemical for laboratory technicians is expected to be low.

Worker exposure to the notified chemical during weighing was calculated by the notifier. A US EPA survey of dye dust in plants that use powder dyes revealed that the mean concentration of commercial dye dust was 0.18 mg/m^3 for the target population. Assuming a total volume of 10 m^3 inhaled air per person per shift, a maximum of 1.8 mg commercial dye per person would be inhaled by a worker from the beginning to the end of the shift. That represents a maximum dose of 25.7 μg/kg bodyweight/day, for an average 70 kg worker.

7. PUBLIC EXPOSURE

Minimal public exposure to the notified chemical is expected through manufacturing, repackaging, transport or disposal.

Public exposure will occur mainly through dermal contact with dyed fabrics. The notified chemical will be fixed to cellulose fibres prior to reaching the market place.

8. ENVIRONMENTAL EXPOSURE

Release

The bulk of the dye will become chemically fixed to the cellulose textiles, and in this state is not expected to impact on the environment. The result of fastness performance tests shows that a high order of fastness rating is achieved in all cases. After application to fabrics, the dye undergoes a chemical change involving chemical bonding with hydroxy groups on the cellulose fibres.

The major environmental exposure to dye will come from effluent discharge from dyehouses and waste water treatment systems. Other releases will be limited to traces remaining from repacking operations and clean-up of any spills, and from trace residues in empty packaging (estimated at a maximum of 0.1% based on previous similar notifications by the notifier).

All clean up of spills and disposal of empty packaging should be carried out according to the instruction in the material safety data sheet (MSDS).

Fate

The dye normally released in water as effluent from the dyehouse is expected to be the major environmental exposure. The dye may either partition to sediment or stay in the aqueous compartment. Hobbs (1988) reports that reactive dyes have been found not to adsorb to sludge in model systems. Any dye that binds to the sludge during the waste treatment process would be disposed of through incineration or landfill. Incineration is the preferred option because of the high water solubility and potential mobility of the material. Incineration of the dye will produce oxides of carbon, nitrogen and sulfur, together with sodium salts in the ash and a small amount of hydrogen chloride. Disposal by landfill will be at a secured site, so the risk of leaching to the water table is significantly reduced.

The dye was found to be not readily biodegradable (measured as dissolved organic carbon (DOC) and expressed as percentage elimination, biodegradation ranged from 1-11% over the 28-day exposure to micro-organisms from a domestic sewage treatment plant). The dye's inherent biodegradability was a mean of 8% after 28 days according to the test procedure that followed OECD 302B guidelines (Zahn-Wellens/ EMPA Test).

Although the dye is not readily biodegradable, the potential for bioaccumulation is low due to the low partition coefficient (log $P_{OW} < -10.0$) and very high water solubility of the substance. Hydrophilic dyes with log $P_{OW} < 3$ have been shown not to bioaccumulate (Yen et al, 1991). Also, biological membranes are not permeable to chemicals of very large molecular size so bioaccumulation of the notified polymer is not expected (Gobas et al, 1986; Auliker et al, 1988).

Residues that persist after sewage treatment will enter marine or freshwater environments in solution (from city and country waste water treatment systems, respectively). A possible route of entry of the dye to the sediment is by the precipitation of its calcium salts, as several calcium salts of sulfonic dyes are known to be insoluble at modest concentrations (Weber, 1991). Degradation of such dyes in sediment water systems proceeded with a half-life of 2-16 days. Accordingly, no significant increase in dissolved concentrations over time is predicted, while residues bound to sediment are expected to undergo reductive degradation.

9. EVALUATION OF TOXICOLOGICAL DATA

The notifier provided a summary of the notification statement to the European Union (EU) (French language). This included a summary of toxicity information for the notified chemical. Some of those studies were summarised in the Australian notification statement.

The acute oral and dermal LD_{50} found in rats were both > 2 000 mg/kg. There were no animal deaths or organ effects in the treated animals in either tests. The notified chemical was not a skin or eye irritant in rabbits. However, slight eye colouration was observed at the end of the observation period (72 hours) in the eye irritation study. At test concentration of 25%, the notified chemical was a sensitising agent in the Magnusson and Kligman maximisation test on guinea pigs. A 28 day repeat dose oral study was reported in the EU notification. The NOEL was 50 mg/kg/day, based on kidney pigmentation (mid dose and high dose) and stomach effects (high dose). In the *Salmonella typhimurium* and *Escherichia coli* reverse mutation assays, no mutagenic potential was observed for the notified chemical. The EU notification contains a summary of the *in vitro* Chinese hamster V 79 assay. Genotoxic responses were not observed, however, precipitation of the test substance was observed at low concentrations (30 µg/mL). Therefore, the concentration of the chemical in the tests was unknown.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were performed in compliance with OECD/EEC Test Methods and according to OECD Principles of Good Laboratory Practices.

Ecotoxicity Test Results

Test	*Species*	*Test concentrations (nominal) mg/L*	*Results (Nominal) mg/L*
Acute Toxicity (Static Test) (OECD TG 203)	Zebra fish *Brachydanio rerio*	21, 45 & 100	96 h $LC_{50} > 100^a$ 96 h $LC_0 > 100^{b,c}$
Acute Toxicity - Immobilisation (Static Test) (OECD TG 202)	Water Flea (*Daphnia magna*)	21, 45 & 100	48 h $EC_{50} > 100^{b,d}$ 48 h NOEC $> 100^{b,d}$
Growth Inhibition -Growth (μ) & Biomass (b) (Static Test) (OECD TG 201)[†]	Green Algae (*Scenedesmus subspicatus*)	4.6, 10, 21,46 & 100	$E_{\mu}C_{50} > 100^e$ $E_bC_{50} = 371^e$ LOEC = 21^e
Respiration Inhibition (OECD TG 209)	Activated Sludge - Aerobic Waste Water Bacteria	3.2, 10, 32, 50 & 100	30 min $IC_{50} > 100$

a Limit test.
b Definitive study.
c The analytically determined test substance concentrations in the test media varied in the range of 92% to 100% of the nominal value at the start of the test period.
d The analytically determined test substance concentrations in the test media varied in the range of 89% to 95% of the nominal value at the start of the test period.
e The analytically determined concentrations in the test media varied in the range from 89% to 97% of the nominal values.

Fish

Toxicity tests, performed in accordance with the test guidelines, demonstrated that the notified substance had no toxic effects on the test fish up to concentration of nominal 100 mg/L. The report notes that the test medium was coloured by the test substance.

Aquatic Invertebrates

The 24 h and 48 h LC_{50} and NOEC were determined to be >100 mg/L as no daphnids were noted to be immobilised at the highest concentration tested. One daphnid in the 46 mg/L treatment was observed to be immobile at the 48 hour observation. This appears to have been an occurrence unrelated to the chemical concentration.

A *Daphnia sp.* reproduction test was not supplied. However, based on the negligible acute toxicity to both fish and daphnids, reproduction effects on daphnids are not expected.

Algae
A statistically significant inhibitory effect on the growth of algae occurred after 72 hours at concentrations above 21 mg/L. As such, the 72 h NOEC was determined to be 21 mg/L. The EC-values (indicated in the above table) were calculated for the algal biomass (b) and the growth rate (μ) after 72 hours. There was no observed difference in the shape of algal cells when compared to those growing in the control medium. The notified chemical can be considered as practically non toxic to algae.

Microorganisms
The inhibitory effect of the notified substance on aerobic waste water bacteria (activated sludge from a domestic waste water treatment plant) was investigated in a respiration test. The notified substance showed practically no toxic effects. The respiration rate was not inhibited by test concentrations over an exposure period of 30 minutes, and the final 3 hour IC_{50} was greater than 100 mg/L.

Conclusion
The ecotoxicity data for the notified substance indicates that it is practically non-toxic to fish, aquatic invertebrates, algae and microorganisms. Reproductive effects on aquatic invertebrates are not expected.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the dye, when fixed to the cellulose fibre, is rated as negligible.

The notifier has specified that a limited number of dyehouses (approx. 6) in city and possibly country areas will be using the notified dye. The environmental hazard has been determined for two dyehouses located in two general locations, one metropolitan based dyehouse and the other country based. The Predicted Environmental Concentration (PEC) is estimated below.

Predicted Environmental Concentration (PEC)

Calculation Factor	Country Dyehouse high use	City Dyehouse
Typical use of product expected per day (700 kg cloth)	60 kg	30 kg
Amount of notified chemical (at 73%)	43.8 kg	21.9 kg
Concentration in wastewater (fixation rate 75%)	11 kg	5.5 kg
Quantity of water used incl. wash-off water	60 000 L/day	35 000 L/day
Effluent concentration in product-specific wash-water	183 mg/L	157 mg/L
Dilution factor in dyehouse by other wash-waters	1:70	1:100
Influent concentration	2.6 mg/L	1.57 mg/L
Dilution factor in sewage treatment plant[1]	1:10	1:100
Concentration balance in effluent from sewage treatment plant	0.26 mg/L	0.016 mg/L
Dilution factor in receiving waters	1:2 (river)	1:10 (ocean)
PEC in receiving waters	0.13 mg/L (0.13 ppm)	1.6 µg/L (1.6 ppb)
Safety factor (EC_{50}/PEC) for exposure to most sensitive aquatic organism, Algae[2] (72 h $E_{\mu}C_{50} > 100$ mg/L)	770	62 500

[1] The dilution at a rural town could reasonably be expected to be about 5-6 ML/day, while for a major city, say Sydney, it would be between 150-500 ML/day.

[2] The growth of Green algae was inhibited by 50% after 72 hr at a test concentration of >100 mg/L.

These calculations assume that no dye is removed in treatment of the different waste effluents and represent the worst case scenario for dyehouses. The “typical use of dye expected per day” is an estimation of typical throughput for day batches, not a representation of yearly use.

The calculations show that the exposure to fish, daphnia, algae and waste water treatment bacteria is at levels unlikely to cause any significant effect. At higher release rates, there is still unlikely to be any significant effect on these species. Once in the aquatic environment, the chemical is expected to swiftly dilute to undetectable concentrations, and undergo biotic and abiotic degradation. An adequate safety margin exists for use in country locations.

The only other source of environmental contamination is from accidental spills and disposal of packaging. The information provided in the MSDS is adequate to enable workers to limit the environmental exposure and therefore limit the environmental effects.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notifier provided summary data indicating that Reactive Yellow TZ 4165 had very low acute oral toxicity (LD_{50}>2 000 mg/kg) and low dermal toxicity (LD_{50}>2 000 mg/kg) in rats. Reactive Yellow TZ 4165 was not an eye or skin irritant in the rabbit, but was a sensitiser in a guinea pig maximisation test. The notified chemical was not a mutagen in the Ames test or in the *in vitro* Chinese hamster V79 assay. The NOEL for the notified chemical was determined to be 50 mg/kg/day in a 28 day oral repeat dose study in rats. The notified chemical is determined to be a hazardous substance based on the its skin sensitising effects according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a). It will warrant the risk phrase R43 (May cause sensitisation by skin contact), with a cut off concentration of ≥1%.

A large proportion (45%) of the particles in the notified chemical is within the respirable range. However, the chemical will be imported in granular form and, although the particle size distribution of the product was not provided, it is expected that the respirable portion will be small. In addition, the imported product will contain an anti-dusting additive.

Transport and storage
The health risk for transport workers and storemen is expected to be negligible unless the package is breached.

Repacking
Exposure to the notified chemical during repacking is estimated to be infrequent and of short duration. It is essential that the exposure control measures identified by the notifier are in place, namely exhaust ventilation, plus the wearing of personal protective equipment, because the chemical is a skin sensitiser.

End use
The notified chemical is a skin sensitiser and exposure to small amounts may be harmful, so it is very important that a high level of exposure control is implemented.

The weighing operators have potentially the highest exposure to the notified chemical. Local exhaust ventilation is provided in the dispensary and blending vessel areas, and as the operators wear respirator, overalls and gloves to minimise exposure, the risk of adverse systemic health effects during this operation is likely to be low.

Based on data reported to be from a US air monitoring study, the notifier estimated that the average daily exposure of a worker during weighing would be 0.0275 mg/kg/day. Based on the NOEL of 50 mg/kg/day from a 28-day oral repeat dose study in rats, a margin of exposure (MOE) for this estimate is 1818, which indicates that the risk of adverse health effects resulting from inhalation exposure is of low concern. However, this conclusion is qualified because the estimation of exposure excludes any contamination via the dermal route. In addition, the study methodology or parameters/assumptions used in calculating exposure were not provided.

Operators in charge of padding and fixing processes will have low exposure to the unfixed notified chemical as these stages are enclosed. Workers in charge of wash off and drying processes may need to handle waste chemical as well as the cloth containing the chemical bound to the cellulose cloth fibres. Workers involved in handling the dried cloth will wear protective gloves. If these conditions are maintained, exposure and subsequent health risk to these workers will be low.

As the notified chemical is a skin sensitiser, workers who maintain the dye solutions or handle the wash-off solutions should wear overalls, goggles and gloves. Any workers who have become sensitised to the notified chemical should not continue to work with it.

Public Health

Minimal public exposure to the notified chemical is expected through the distribution, application or disposal of the dyestuff. In the event of an accident or spill the notified chemical will be cleaned up and disposed of as outlined in the MSDS.

Extensive public exposure to the notified chemical is expected through contact with dyed fabrics, however the chemical forms a bond with cellulose fibres of fabrics and little is removed by washing or drying processes. In addition, the high molecular weight and low octanol/water partition coefficient are indicative of poor absorption across the skin, therefore the notified chemical is expected to be poorly bioavailable. The primary hazard to exposed persons will be skin sensitisation, however as the notified chemical is covalently bonded to fabric, the risk of sensitisation is considered to be low.

Therefore based on the use pattern and physico-chemical characteristics of the notified chemical, it is considered that Reactive Yellow TZ 4165 will not pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical in Reactive Yellow TZ 4165, the following guidelines and precautions should be observed:

- Respirator should be selected and fitted in accordance with Australian/New Zealand Standard (AS/NZS) 1715 (Standards Australia/Standards New Zealand, 1994a);

- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990);

- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998);

- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994b);

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;

- A copy of the MSDS should be easily accessible to employees.

- Workers who become sensitised to the notified chemical should not continue to handle it in the workplace.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994b).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical 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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