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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

3,4,5,6-TETRAHYDRO-2-METHYL-2H-CYCLOPENTA[D]-1,2-THIAZOL-3-ONE (MTI)

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989,* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Human Services and Health.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

3,4,5,6-TETRAHYDRO-2-METHYL-2H-CYCLOPENTA[D]-1,2-THIAZOL-3-ONE (MTI)

1. APPLICANTS

ICI Australia (Operations) Pty of 1 Nicholson Street, MELBOURNE, Victoria 3000 and BAYER Australia Ltd of 875 Pacific Highway Pymble, NSW 2073 have submitted a standard notification statement for an assessment certificate for MTI.

2. IDENTITY OF THE CHEMICAL

Chemical name:	3,4,5,6-tetrahydro-2-methyl-2H-cyclopenta[d]-1,2-thiazol-3-one
Chemical Abstracts Service (CAS) Registry No.:	82633-79-2
Other name:	MTI
	2-methyl-4,5-trimethylene-4-isothiazolin-3-one
Trade name:	Promexal X50 (5% aqueous solution of active)
Molecular formula:	C_7H_9NOS
Structural formula:	
Molecular weight:	155

Method of detection and determination:

The notified substance can be isolated by HPLC and identified by UV/Vis, infra red and NMR spectral analysis.

Spectral data:

UV/visible spectrum

Solvent:	methanol
Range:	500-200 nm
Position (and epsilon value) of main peaks:	269 nm
Effect of acid:	268 nm
Effect of alkali:	269 nm

IR Spectrum

Medium:	Kbr disc
Range:	4000-600 cm^{-1}
Result:	2964, 1373 N-methyl group
	2962, 2928, 1445 aliphatic -CH_2-
	1621 carbonyl group

NMR Spectrum

A proton NMR spectrum was provided and was consistent with the expected structure of MTI component.

3. PHYSICAL AND CHEMICAL PROPERTIES

All physico-chemical properties of MTI were determined according to the relevant section of EEC Directive 84/449/EEC (1).

Appearance at 20°C and 101.3 kPa:	fawn powder at 20°C and 101.3 kPa; the product to be imported is a colourless to pale brown liquid
Odour:	none
Melting Point:	121-123°C
Relative Density:	1.51 at 20°C
Vapour Pressure:	3 x 10^{-6} kPa at 25°C
Water Solubility:	> 20% w/w
Fat Solubility:	1335 mg/100g of fat; the result is given as a mean of 8 tests, performed at 30 and 50°C
Partition Co-efficient (n-octanol/water) log P_{OW}:	0.6
Hydrolysis as a function of pH:	< 10% at pH 4.7 and 9 at 50°C
Adsorption/Desorption:	test not performed; the applicants indicate claim that it is likely to desorb from soil due to its high solubility; as a result of the low Pow, weak adsorption to soil is also expected
Dissociation Constant pKa**:**	test not performed; the substance does not contain ionisable groups
Flash Point:	not applicable for a soild.

Flammability Limits:	not flammable
Combustion Products:	not provided
Decomposition Temperature:	not provided
Decomposition Products:	not provided
Autoignition Temperature:	not provided
Explosive Properties:	not explosive under the influence of a flame
Reactivity:	not oxidising
Particle size distribution:	not applicable as the chemical will only be imported as a 5% aqueous solution
Surface Tension:	61.9 mN/m; shows weak surface activity.

4. PURITY OF THE CHEMICAL

Degree of purity:	typically 94.8%, (range 90-96%); determined by HPLC
Toxic or hazardous impurities:	none known

Other impurities: (> 1% by weight)

Name	%w/w
1-benzylthio-x-hydroxy-2-methylcarbamoylcyclopentene	1.0
n-methyl-2-benzylsulphinyl-1-cyclopent-1-enyl-1-carboxamide	1.8
bis-(2-methylcarbamoylcyclopent-1-enyl) disulphide	1.0
benzyl alcohol	0.1
sodium propionate	0.2
dichloromethane	0.03
n-methyl-2-benzylthio-1-cyclopentene-1-carboxamide	0.4
unknown component	0.7

Additives/Adjuvants: none

5. INDUSTRIAL USE

MTI is an industrial biocide used as an in-can preservative in the paint, synthetic polymer emulsions and adhesives. The major uses have been estimated by the applicants as paints 50% and emulsion and adhesives 20% each. It will be used by industries in the formulation of the listed products. MTI is imported as a 5% aqueous solution (Promexal X50) will typically be used at 0.1% w/w in these applications, corresponding to 0.005% of the notified chemical.

The MTI is imported into Australia. It is estimated that the following quantities will be imported over the next five years:

Year	Quantity
1	1 tonne
2-5	1-10 tonnes

6. OCCUPATIONAL EXPOSURE

MTI is used in the coatings industries.

Categories of workers potentially exposed to the notified chemical in the coating industry include people involved in the manufacturing process (high speed dispersing, make up, quality control (QC) testing, filling into containers), application by professional tradespersons and application by home handypersons.

There is potential for spillage of chemical to occur at any of the above mentioned points. Transport and storage workers will only be exposed in the event of accidental spillage.

The nature and possible duration of exposure of the workers to the notified chemical are as follows:

Coating Industry: paint, adhesives, polymer emulsions and thickeners

Nature of work	**Number of workers**	**Maximum duration of exposure hours/day/days per year**
(I)Manufacture		
High speed dispersing	30	8 hrs / 20 days
Make up	30	8 hrs / 20 days
QC testing	6	2 hrs /20 days
Filling into containers	30	8 hrs / 20 days
(II) Application by professional tradesperson	Unable to estimate but will involve large numbers as products readily available through retail stores and trade outlets	6 hrs / 200 days
(III) Application by home handyperson	Unable to estimate but will involve large numbers as products readily available through retail stores and trade outlets	2 hrs / 3 days

Operators will be wearing as a minimum, impervious gloves, overalls and safety glasses.

7. PUBLIC EXPOSURE

During the manufacture of coatings, there will be no emission to the atmosphere as the notified chemical is involatile.

Equipment for using the water-based coatings used by home handymen is likely to be cleaned by rinsing with copious quantities of water.

8. ENVIRONMENTAL EXPOSURE

. Release

Releases to the environment will occur when paints, and polymer emulsions containing MTI are formulated and when these products are used. During formulation of paints etc. releases to the environment should be minimal and should only occur when equipment and the residues in mixing tanks etc. are cleaned. The applicant has estimated that the amount of chemical released during these operations is approximately 30 kg per annum.

When MTI is used in paints, adhesive and polymer emulsions most of the chemical will be embedded in the polymer matrix and bonded to the coated surfaces. Release to the environment should only occur when the equipment (brushes, rollers etc.) used is cleaned and for water based products most of the washings would be disposed of via the sewer. It is estimated by the applicant that approximately 50 kg of the chemical will be released by tradespeople and home handypeople cleaning up painting equipment. Empty containers of paint, adhesives etc. are expected to be disposed of with the domestic garbage to landfill or as trade waste, again to landfill. The applicant has not estimated the quantity released from use of the chemical in adhesive and polymer emulsions; however, as most of these users are expected to be industrial, releases will be confined to when equipment is cleaned, ie <5% of that used.

The only other possible releases could occur are in the event of an accidental spills either during transport or in the formulation of products. Spills during transport will be treated according to the Material Safety Data Sheet (MSDS) and spills that occur in the formulation process will be confined to the plant by bunding and other environmental controls and then treated according to the MSDS.

. Fate

The fate of most of the notified chemical is identical to that of the products to which it is incorporated. The paints, adhesives and polymer emulsions are expected to be used as coatings for surfaces and remain with the surfaces until it is removed or disposed of with the article which it coats. Therefore most of MTI imported will be trapped in a polymer matrix, some of which will be disposed of by landfill.

The MTI from washings from cleaning equipment from the coatings uses will enter the sewer. When tested for biodegradability, (modified Sturm test, OECD Test Guidelines 310C), MTI showed biocidal effects at high concentrations but was degraded at lower concentration,—54%, 82% and 100% degradation at 10, 5.6 and 1 mg/L, respectively (nominal concentration) after 28 days. Therefore some

degradation of MTI can be expected during sewage treatment but the extent of this is unclear. The notified chemical is unlikely to be adsorbed to the sludge or bioaccumulate due to the high solubility and low log P.

Additional data on the degradation of MTI was provided by the applicants. This additional data was presented as summaries of studies performed. (The studies were not carried out according to regulatory guidelines.) These studies indicate that MTI is susceptible to aquatic photodegradation in fresh water and seawater, with complete primary degradation occurring in both artificial (Xenon light) after 16 hours and in natural sunlight after 7-10 days (September light levels, UK). Further, the very polar metabolites formed (from irradiating a 10 mg/L MTI solution) were non-toxic to fresh water daphnia and *Tisbe battaghai,* a marine species. Therefore any MTI that enter natural water systems is likely to photolyse to non-toxic metabolites, provided the water is relatively clear.

A study was provided by the applicants on the degradation of MTI in soil. Again this study is reported as a brief summary and was not performed according to standard regulatory guidelines. The study indicated that soil mineralisation of MTI was occurring, with a half life of approximately 80 days. The information presented by the applicants was not sufficient to draw a firm conclusion but the study does show that MTI is likely to be ultimately degraded and is expected to be rated as slightly to moderately persistent in soil (2).

The waste released during formulation of products will be treated (flocculated) and either discharged to the sewer with the supernatant or trapped with the solids in the sludge, which is normally landfilled or incinerated. It is unclear whether flocculation will remove any of the MTI.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of 2-Methyl-4,5-trimethylene-4-isothiazolin-3-one (MTI)

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD_{50} (rat, male) 224 mg/kg (harmful) LD_{50} (rat, female) 168mg/kg (toxic)	(3)
acute dermal toxicity	rat	not determined	(4)
skin irritation	rat	*severe irritant	(4)
skin irritation	rabbit	slight irritant	(5)
eye irritation	rabbit	severe irritant	(6)
skin sensitisation	guinea-pig	strong sensitiser	(7)

* based on the results of acute toxicity test

9.1.1 Oral Toxicity (3)

Species/strain: (SPF) Wistar-derived albino rats

Number/sex of animals: 5/sex

Observation period: 4 days

*Method of administration (vehicle):*deionised water

Dose levels: 50, 100 and 500 mg/kg

Clinical observations: following a dose of 50 mg/kg, no signs of toxicity were observed in the males, however, signs of slight toxicity were observed in the females, with symptoms persisting up to day 4; following a dose of 100 mg/kg, extreme toxicity was noted in 1 female, however in the remaining animals signs of slight toxicity were observed up to day 4; following a dose of 500 mg/kg, signs of extreme toxicity were observed in all animals.

Mortality: none of the animals died following a dose of 50 mg/kg. Following a doseof 100 mg/kg, 1 female was found dead on day 2 but the remaining animals survived. Following a dose of 500 mg/kg, 1 male was killed in extremis and the rest of the animals were found dead within 3 hours of dosing.

Morphological findings: at post mortem examiniation, mottled liver, haemorrhagic stomach and intestines were seen in all animals dosed with 500 mg/kg.

Test Method: directive 92/69/EEC (1) Test B.1

LD_{50}: 224 mg/kg in males (estimated) and 168 mg/kg in females (estimated)

Result: toxic to female rat and harmful to male rat

9.1.2 Dermal Toxicity (4)

Species/strain: rat (Wistar - derived)

Number/sex of animals: 2 males, 5 males

Observation period: 9 days

*Method of administration (vehicle):*MTI in deionised water at dose levels of 50, 200 and 400 mg/kg

Clinical observations: there were no significant signs of systemic toxicity following a single dermal application of MTI at

dose levels of up to 400 mg/kg of the unformulated test sample and up to 1000 mg/kg of the test sample formulated in water.

the test sample caused severe irritation and necrosis both when tested, as supplied, at dose levels of 200 and 400 mg/kg, and also when formulated in water at dose levels of 400 and 1000 mg/kg.

Mortality: nil

Morphological findings: pathology was not performed

Test Method: the test methodology was designed to determine the dose levels for the main study. In view of the results obtained the main study was cancelled for animal welfare reasons.

LD_{50}: not determined

Result: not determined

9.1.4 Skin Irritation (5)

very slight or well defined erythema and slight oedema were seen in all animals at 30-60 minutes; very slight erythema and very slight oedema were seen in all animals for a further 2 days all signs of irritation had disappeared at 3 days; one animal had a scab on the edge of the application site at 3 and 4 days.

Species/strain: New Zealand White rabbits

Number/sex of animals: 3 males, and 3 females

Method of administration: the test sample (approximately 500mg) was moistened with a small amount (0.1ml) of deionised water and applied to the test site (approximate size 2.5cm x 2.5cm) on the left flank of each rabbit, using a metal spatula.

Test Method: directive 92/69/EEC (1) Test B.4

Result: slight irritant

Draize () Scores[i]:

Animal	Time after decontamination				
	30-60 min	1 day	2 days	3 days	4 days
ERYTHEMA					
1	2	1	1	0	0
2	2	1	1	0	
3	1	1	1	0	
OEDEMA					
1	2	1	1	0	0
2	2	1	1	0	
3	2	1	1	0	

9.1.5 Eye Irritation (6)

Species/strain: New Zealand White rabbits

Number of animals: one male

Observation period: 4 days

Method of administration: the test sample (approximately 100mg) was applied into the conjunctival sac of the left eye of the rabbit.

Applied eye: the application of the notified chemical into the eye of one of the rabbits caused a moderate initial pain reaction; approximately one hour after application, there were severe redness and chemosis of the conjunctiva, a slight discharge and moderate erythema of the eyelids; as a result the animal was killed 90 minutes after application; no further animals were dosed and the study was terminated

Test Method: directive 92/69/EEC (1) Test B.5

Result: MTI is considered to be an extremely severe irritant to the rabbit eye.

Draize () Scores[ii]

Animal	**Time after instillation 1 1 Hrs**
CORNEA:	opacity area
1 **IRIS**	**?**
1 **CONJUNCTIVA**	**?** r[a] c[b] d[c]
1	3 4 1

[a] redness [b] chemosis [c] discharge

9.1.6 Skin Sensitisation (7)

Species/strain: Guinea Pig (Dunkin Hartley)

Number of animals in test group: 20 (females)

Number of animals in control group:10 (females)

Concentration of test material at each stage of induction:
3% w/v in deionised water. (1st and 2nd exposure)
1% w/v in deionised water. (3rd exposure)

Concentration of test material used in challenge dose:
1% and 0.3% w/v in deionised water

Challenge outcome:

Challenge Concentration	24 hrs		48hrs	
	test	control	test	control
0.3%	18/20	0/10	9/20	0/10
1%	20/20	3/10	20/20	3/10

challenge with 1% (w/v) preparation of the test sample in deionised water elicited a strong sensitisation response in previously-induced guinea pigs; challenge with 0.3% (w/v) preparation of the test sample in deionised water elicited an extreme sensitisation response in previously-induced guinea pigs; all MTI can be considered as a strong sensitiser in albino guinea pigs under the conditions of the test

Test Method: directive 92/69/EEC (1) Test B6

Result: MTI is a strong sensitiser under the conditions of the test

9.2 Repeated Dose Toxicity (8)

Species/strain: rat (Alpk: APfSD, Wistar-derived)

Number/sex of animals: 5 males and 5 females at each dose level

Method of administration (vehicle):none

Dose/ Duration of administration: 0, 100, 400 or 1250 (reduced to 1000) ppm daily for 28 days

Toxicologically Significant Observations:

1. *Clinical:* treatment at a dietary level of 1250 ppm led to a hunched and thin appearance of half of the animals during the first week of treatment, which was accompanied by a body weight loss; it was considered that this dose level was not suitable for the duration of the study and was reduced to 1000 ppm; at 1000 ppm the clinical signs did not persist, and growth was resumed, but a reduced body weight gain continued throughout the remainder of the study

   the reduction in body weight gain in both sexes given 1000 ppm during the main study showed some recovery after the compound was withdrawn, though the body weight of the test groups remained below those of the concurrent at termination

   there was a slightly reduced body weight gain, during the first week, for animals given 400 ppm, but this subsequently recovered to control levels.

2. *Clinical Chemistry/Haematology*

   the statistically significant reduction, when compared to controls, in the plasma total protein of females that received 1000 ppm MTI during the main study reflected a high concurrent control value though a nutritional effect cannot be entirely eliminated.

   there was a statistically significant increase in potassium and an increase in phosphorus levels of females given 1000 ppm MTI after 28 days of treatment the levels of phosphorus and potassium were still increased after 2 weeks of the reversibility phase; the high value of plasma

triglycerides apparent in females given 100 ppm MTI was due entirely to one animal; the statistically significant increase in plasma alkaline phosphatase activity of the males given 1000ppm MTI after 2 weeks of the recovery period was a reflection of a low concurrent control value, and as this effect was not apparent during the main study it is considered to be of no toxicological significance

3. Necropsy Findings/ Histopathology

there were no macroscopic findings attributable to treatment with MTI; increase in absolute testes weights and testes:bodyweight ratios were observed in males receiving 1000 ppm MTI; histopathological examination was confined to the control and the 1000 ppm MTI groups terminated on day 29; there were no microscopic findings considered to be related to treatment with MTI, those few changes seen were confined to the kidney and were considered of a type and incidence commonly seen in rats of this age and strain

Test Method: directive 92/69/EEC (1) Test B.7

Result: target organg probably testis; no effect level at 400 ppm

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (9)

Strains: *Salmonella typhimurium* TA 98, TA 100, TA 1535, TA 1537, TA1538 and *Escherichia coli* WP2 uvrA pKM101

Concentration range: 200-0.32 μg/ plate - experiment 1
100-0.16 μg/ plate - experiment 2

Metobolic activation: rat liver S9

vehicle: dimethylsulphoxide

Test Method: directive 92/69/EEC (1) Test B.14

Result: under the conditions of this assay, MTI gave a negative, i.e. non-mutagenic, response with *S.typhimurium* strains TA 1535, TA 1538, TA 98,

	TA 100 and in *Escherichia coli* WP2 uvrA pKM101 in the presence and absence of an auxiliary metabolisng system (S9), when tested to toxic concentrations in each case.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (10)

Species/strain:	mouse (C57BL/6JfBL10/Alpk)
Number and sex:	5 males and 5 females
Doses:	the mice were injected with notified chemical at doses of 85 and 136 mg/kg - males 103 and 164 mg/kg - females
Sampling times:	24, 48 and 72 hours
Comments:	no statistically or biologically significant increase in the incidence of micronucleated polychromatic erythrocytes, compared to the vehicle control values, were seen when the data from both sexes were pooled prior to statistical analysis or when the female data were considered separately
Test Method:	directive 92/69/EEC (1) Test B.12
Results:	MTI is not clastogenic in the mouse bone marrow micronucleus test

9.3.3 Non-Bacteriological *in vitro* test - Cytogenetics (11)

Organism tested:	human lymphocytes (male and female donors)
Doses	2, 10 and 20 μg/ml - male ± S9, female + S9 1,5 and 10 μg/ml - female - S9
Vehicle:	dimethylsulphoxide
Fixation time:	72 hours
Test Method:	directive 92/69/EEC (1) Test B. 10
Results	MTI is considered to be clastogenic to human lymphocytes *in vitro.*

9.3.4 Assessment for the induction of unscheduled DNA synthesis in rat hepatocytes *in vivo* (12)

Species/strain:	rat (Alpk : APfSD)
Number and sex	5 males
Doses:	the rats were given a single oral dose of MTI by gavage at 76, 117 or 180 mg/kg body weight Sampling times 4 and 12 hours*:*

Comments:	*s*alivation, breathing difficulties and staining with fluid around the nose were noted immediately after dosing; generally these signs were less severe or had ceased prior to perfusion, 4 or 12 hours later hepatocytes from MTI-treated rats were assessed for the induction of UDS at two dose levels, 117 and 180 mg/kg; examination of the mean net nuclear grain count and percentage of cells in repair showed that MTI did not induce UDS at either dose level or time point
Test Method:	Ashby J et al., Mutat. Res., 1985, 156, 1-18
Results:	when tested up to a maximum tolerated dose, the test sample of MTI did not induce DNA repair in hepatocytes of rats exposed *in vivo.*

9.4 Overall Assessment of Toxicological Data

MTI is hazardous to animals via the oral route. The oral LD_{50} was 224 mg/kg (harmful) for male rats and 168 mg/kg (toxic) for female rats. There were no significant signs of toxicity at any dose level when rats were given a single dermal application, however, found to be a severe irritant to skin of rat. MTI is a slight skin irritant (rabbit) and a severe eye irritant (rabbit) and a strong skin sensitiser (guinea pig). MTI was found to be non-mutagenic *in vitro* to *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, TA 1538 and *E.coli* WP2 uvrA. MTI is considered to be clastogenic to human lymphcytes *in vitro. In vivo* Micronucleus test found no significant increase in the frequency of micronucleated polychromatic erythrocytes. Assessment for the induction of unscheduled DNA synthesis in rat hepatocytes *in vivo* showed that MTI did not induce DNA repair in hepatocytes of rats exposed *in vivo.* Twenty eight day repeated dose studies indicated that the target organ may be the testes, although no histological or biochemical evidence of cellular damage was evident. No effect level of MIT was found to be 400 ppm.

On the basis of submitted data, the notified chemical will be classified as hazardous in accordance with Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)] in relation to acute oral toxicity, sensitising effects (skin) and irritant effects (skin and eye).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been provided by the notifier. These studies were conducted according to standard EEC directives for static tests.

Test	Species	Result (nominal)
Acute toxicity	Rainbow trout	96h LC_{50} =1.2 mg/L and NOEC =0.56 mg/L
Acute toxicity	Daphnia magna	48h EC_{50} =1.3 mg/L and NOEC =0.56 mg/L

Growth inhibition	Algae, *Selenastrum capricornutum*	96h E_bC_{50} = 0.28 mg/L 96 hr NOEC (biomass) =0.1 mg/L 96h E_rC_{50} = 0.55 mg/L 96 hr NOEC (growth) =0.18 mg/L
OECD TG 209	Activated Sludge	Nitrifying IC_{50} = 20 mg/L, NOEC =10 mg/L Respiration IC_{50} = 18 mg/L, NOEC =3.2 mg/L

The ecotoxicity studies show that MTI is moderately toxic to fish and daphnia and highly toxic to algae. Significant effects on micro organisms have been noted by the applicants and they have indicated that levels released to sewage works should not exceed 1 mg./L

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority (approx. 90%) of the notified chemical, MTI, that is imported is expected to be used with polymers of one type or another, eg paints, adhesives and polymer emulsions. When these polymers dried and cured, the chemical MTI is expected to be incorporated into the polymer matrix and be inert. Residues that are in this form are likely to be disposed of into landfill, ie dried paint residues in paint cans etc., and are unlikely to leach. When equipment used in paints and other coating applications is cleaned up, some of the chemical is expected to be released to the sewer. The amount of chemical released has been estimated by the applicants to be 50 kg per annum. A similar quantity could be expected to be released from cleaning equipment used by adhesive and polymer emulsion users.

The amount of MTI to be disposed of from formulation has been stated by the applicants to be 30 kg per annum. Waste material from the formulators is expected to be flocculated with the solids landfilled and the liquids disposed of via the sewer. As a result of the high water solubility and low log P, it is likely that most of the waste chemical will be disposed of to the sewer.

In total it is estimated that 330 kg per annum of MTI will be released throughout Australia to the sewer. Assuming that all this is release from Melbourne (population 3 million, 720 ML of sewage per day, Werribee and South Eastern Purification Plant) then the concentration of MTI in the effluent is

Amount of chemical released per day : 330/365 kg per day

Concentration in effluent discharged 1.3 ppb

The estimated concentrations are at least 2 orders of magnitude below the NOEC for the most sensitive species tested, algae. These calculation assume that there was no removal of the notified chemical by the sewage treatment process and that all of the chemical is released via the waste water. As the concentration of MTI is below the biocidal concentration, degradation of the chemical should occur and therefore reduce the actual concentration that is discharged to the environment. Also there is further dilution upon discharge into the receiving waters and the chemical is expected to photolyse to non-toxic species. Significant environmental effects are not expected and MTI is unlikely to persist in the aquatic environment.

Articles coated with paints and other coatings containing the notified chemical could be eventually disposed of in the domestic garbage, which is incinerated or landfilled. Incineration of the notified chemical will generate oxides of carbon , sulphur and nitrogen as well as water. The chemical is not to leach from the cured paint. The environmental hazard from the disposal of articles painted with paints containing the notified chemical by landfill or incinerated is rated as negligible.

The only other sources of environmental contamination during normal usage is from accidental spills etc. Instructions in the MSDS are adequate to limit the environmental exposure from spills etc. and therefore the environmental hazard from possible accidentals should be low.

The overall environmental hazard can be rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is a strong skin sensitiser in humans and should be considered a potential respiratory sensitiser. In addition it is toxic (female rat) and harmful (male rat) via the oral route [LD_{50}(male, rat): 224 mg/kg; LD_{50} (female, rat): 168 mg/kg)] and is a severe skin and eye irritant.

The notified chemical will be imported as a 5% aqueous solution in 25kg and 200kg polylined pails and drums. Operators involved in coatings manufacturing should avoid skin and eye contact by wearing personal protective equipment including impervious gloves, overalls and safety goggles. As the chemical is not volatile inhalation exposure is unlikely, unless aerosol is formed in the manufacturing processes. Also fine sprays of mist containing the notified chemical could be airborne during mixing. However, the level of risk should be minimal if the mixing processes are in sealed containers or under specific engineering controls.

Although the notified chemical should be regarded as a potential respiratory sensitiser, the risk of respiratory sensitisation would appear to be low given that the chemical is not volatile. There is clearly a risk of skin sensitisation from the notified chemical and personal protective equipment as outlined below should be used.

In spite of very low levels of the notified chemical (0.005%) used in coating products, (eg paint and adhesives) professionals and home handy people handling these products are advised to wear impervious gloves, overalls and safety glasses.

13. RECOMMENDATIONS

To minimise occupational exposure to MTI the following guidelines and precautions should be observed:

. good general and local exhaust ventilation should be provided during manufacturing operations;

. particular care should be taken to avoid spillage or splashing of the notified chemical;

. production of mists in the workplace during mixing operations should be avoided;

. when handling the notified chemical personal protective equipment which conforms to and is used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS 1337) (13,14), impermeable gloves (AS 2161) (15) protective clothing (AS 3765.1, 3765.2) (16,17) and, if there is any possibility of aerosol generation, respiratory protection (AS 1715) (18), should be worn;

. if the concentration of the notified chemical exceeds 5% in a formulation then the Director should be advised in writing;

. good personal hygiene should be practiced to minimise the potential for ingestion; and

. a copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The attached MSDS for PROMEXAL X50 containing the noitified chemical was provided in a suitable format.

This MSDS was provided by ICI Australia Operations Pty 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 ICI Australia Operations Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of MTI shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise and if the notified chemical for detergent use exceeds 10 tonnes or additional uses are applied.

16. REFERENCES

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[ii] The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	rating	Oedema Formation	rating
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by by definite raising)	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

[ii]

The Draize scale for evaluation of eye reactions is as follows:

CORNEA			
Opacity	**rating**	**Area of Cornea involved**	**rating**
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translu cent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE					
Redness	**rating**	**Chemosis**	**rating**	**Discharge**	**rating**
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Disharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS	
Values	**rating**
Normal none	0
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe