File No: NA/471

Date: February 1997

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

GST

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

GST

1. APPLICANT

Mitsui & Co. (Australia) Ltd. of Level 24 Bourke Place 600 Bourke Street MELBOURNE VIC 3000, has submitted a standard notification statement with their application for an assessment certificate for GST.

2. IDENTITY OF THE CHEMICAL

GST is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the chemical composition and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

Other Names:	thia alkanethiol
Trade Name:	GST
Molecular Weight:	> 200
Method of Detection and Determination:	identified by Fourier Transmission infrared (FT-IR) spectroscopy and detected by high performance liquid chromatography (HPLC)

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	clear colourless liquid with a sulfur odour
Boiling Point:	not determined, decomposition occurs prior to boiling
Relative Density:	1.258 at 20°C (oscillating density meter)

Vapour Pressure:	56.2 Pa at 20°C (static method)
Water Solubility:	12.1 mg/L at 20°C, pH 7; 11.5 mg/L at 20°C, pH 4 and 9 (flask method)
Partition Co-efficient (n-octanol/water):	log P_{ow} = 3.16 at 25°C
Hydrolysis as a Function of pH:	not provided, the chemical does not have a hydrolysable functional group
Adsorption/Desorption:	not provided
Dissociation Constant:	PK_a of 10.61 (estimated using data for ethanethiol)
Flash Point:	243°C (Cleveland Open); 241°C (Pensky-Martens method)
Flammability Limits:	not flammable
Autoignition Temperature:	325°C
Explosive Properties:	not provided
Reactivity/Stability:	not highly reactive, it is expected to undergo typical thiol reactions

Comments on Physico-Chemical Properties

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

The determined vapour pressure indicates the notified chemical is relatively volatile, as suggested by the sulfurous odour. Hydrolysis testing was not conducted. The chemical does not contain any functionalities which would be expected to hydrolyse in the normal environmental pH range.

Adsorption/desorption data were not provided. The relatively high partition co-efficient, and low to moderate water solubility suggest the notified chemical will adsorb to organic matter in soils and sediments.

No dissociation constant was provided for the chemical. A reference citing the dissociation constant for ethanethiol as pKa=10.61 at 25°C was provided in the submission (1). The notifier expects the notified chemical to exhibit a similar dissociation constant.

4. PURITY OF THE CHEMICAL

Degree of Purity:	high
Toxic or Hazardous Impurities:	none
Non-hazardous Impurities (> 1% by weight):	low

5. USE, VOLUME AND FORMULATION

GST will be imported as a clear colourless liquid for use in the manufacture of ophthalmic lenses. GST will be formulated with other liquid resins and additives and will be present in the final product at a concentration of 20-55%.

The anticipated import volumes may reach up to 1 000 tonnes per annum by the fifth year.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported as a liquid for use in the manufacture of ophthalmic lenses. Wharf and transport workers will only be exposed to the notified polymer in the unlikely event of an accident, during unloading/loading at the dock and transportation to the manufacturing site.

The plastic ophthalmic lenses will be manufactured by a four stage process. The first stage is formulation of the notified chemical with other liquid resins and additives. Metal drums (200 L), containing the notified chemical, are transferred from the storage area to an industrial load cell by means of a special lifting/transport device. GST is introduced into a 500 L sealed mixing vessel by an electrical or air driven pump. The formulation will be mechanically stirred by a slowly rotating paddle. No heating is required at this stage.

In stage 2, the formulated liquid resin is held in 1 000 or 2 500 L stainless steel holding vessels. The resin is transferred from the holding vessel to filling pots by pressure through an in-line depth filter. The filling pot is then pressurised to transfer the liquid resin into mould assemblies via semi-automatic filling machines. The liquid resin is directly injected into the mould cavity through a point of use filter and filling port on the assembly. The operator loads and unloads the mould assemblies from the filling machine. Waste resin is produced at this stage.

At the third stage, the mould assemblies are loaded into hot air ovens. The time and temperature varies depending on the product. Typically curing starts at ambient temperatures and finishes at 100 to 150°C. Finally the cured assemblies are cleaned and disassembled to remove the plastic lens. The notified chemical is at room temperature until the start of the third stage and it will be in liquid form

until part way through this stage. At the end of the final stage, once cured GST forms part of a polymer in solid form and is inert.

There is the potential for dermal exposure during transfer of the notified chemical to the industrial load cell, in fitting pumps etc to the mixing vessels, filling of vessels and storage containers, in loading and unloading of the moulds. Eye contact would only be likely to occur in the event of accidental splashing. Dermal contact is also likely during the cleaning and maintenance of equipment. Potential exposure during the first three stages is not expected to exceed seven hours per person per day. The maximum total exposure is not expected to exceed 260 days per person per year. To minimise the potential for inhalational exposure to GST and other components, formulation and filling is carried out in an area with local exhaust ventilation. Mould assemblies are cured in ovens which are isolated from the work area, as is the storage area. Once the lens containing the notified chemical has been cured, it will be in an inert form and the potential for exposure is negligible. Mixing vessels, holding vessels and filling pots are cleaned annually, filing lines are cleaned weekly. GST will be removed whenever maintenance or modifications are carried out to reduce potential occupational exposure.

If accidental spillage occurs it will be contained with an absorbent material such as sand or vermiculite, which is stored in strategic locations.

7. PUBLIC EXPOSURE

GST will be incorporated into ophthalmic lenses at a concentration of 20-55%. The lenses will be fitted into spectacle frames and will be available to the general public. The notified chemical, will be bound in the lens matrix, and therefore exposure to the public will be negligible.

The potential for minor public exposure exists during transport, disposal of the chemical if accidentally spilt, and during formulation. This is minimised by the recommended practices, provided in the Material Safety Data Sheet (MSDS), during storage, transportation and formulation.

8. ENVIRONMENTAL EXPOSURE

Release

The chemicals (GST and other monomers and additives) are introduced into a 500 L sealed mixing vessel. These are then held in 1 000 or 2 500 L stainless steel holding vessels, from where they are transferred to filling pots by pressure through a filter.

The filling pots are then pressurised to transfer liquid resin into mould

assemblies. The liquid resin is directly injected into the mould cavity. Mould assemblies are loaded into an oven to cure, after which the chemical will be in solid (polymer) form.

Mixing vessels, holding vessels and filling pots are cleaned once a year using acetone. Filling lines are cleaned weekly using acetone. Acetone dissolves the GST. The notifier estimates around 0.003% of the chemical is lost through these mechanisms, which accounts for 30 kg per annum, based on the maximum anticipated import volume.

The notifier estimates the quantity of waste acetone used for cleaning purposes (including acetone used to clean process containers), at around 1 200 kg per annum. This is disposed of by incineration. Waste liquid monomer is anticipated to account for 1 200 kg per annum, which would contain the notified chemical at concentrations of 20 to 55%. This is disposed of through polymerisation followed by landfill.

Emissions from curing ovens and working environments are controlled by odour absorbing chemicals.

All clean up of spills and disposal of empty packaging should be carried out according to the Material Safety Data Sheet.

Fate

The ultimate fate of the notified chemical will be associated with the lenses it is used to make. This will be to landfill, in a very diffuse manner, and in locations countrywide. Here, the chemical will be immobile as it is in a solid, polymeric form.

Waste chemical will either be landfilled after being polymerised, or incinerated with acetone which is used to clean processing equipment or containers. Again, in landfill, the chemical will be immobilised through being in solid polymeric form. Any notified chemical disposed of through incineration will form oxides of carbon and sulphur.

A degradation test was conducted following OECD TG 301C. While stated as a ready biodegradation test, biodegradation was determined using biochemical oxygen demand (BOD), with sewage sludge. Around 1% degradation after 28 days was determined, indicating the substance is not biodegradable. This appears to more a measure of inherent biodegradability than ready biodegradability. It was thought from HPLC analysis and IR spectrum that the polymerisation of the test substance was promoted in sludge.

Tests were also supplied for the stability of GST in water. From these it was

concluded that GST easily oxidises to form oligomer compounds, with only 28% residual GST remaining after 2 weeks, and 14% residual GST remaining after 4 weeks. The rate of polymerisation of GST in the biodegradation test was faster than the stability test, and this was attributed to the presence of Fe^{+3} ions in the biodegradation culture medium. A further study concerning the abiotic degradation of GST in water has shown the half-life time of GST to be less than one day in water at 25°C (2).

Although release to the aquatic system is likely to be negligible, a bioaccumulation study of the notified chemical was conducted on Carp (*Cyprinum carpio*) following OECD TG 305C. Feed solution for high exposure contained GST at a concentration of 200 µg/ml (ppm), while the feed solution for low exposure contained GST at a concentration of 20 ppm. The concentrations of GST in test fish ranged from 82.9 to 233 ng/g and 5.6 to 42.8 ng/g in high and low exposure levels respectively. Bioconcentration Factors (BCF's) ranged from 9 to 24 times and 6 to 49 times in high and low exposure levels respectively. The values of BCF's appeared to be low and these results indicate that GST is not bioaccumulative.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of GST

Test	*Species*	*Outcome*	*Reference*
acute oral	rat	LD_{50} = 3 577 mg/kg	3
acute dermal	rat	LD_{50} > 2 000 mg/kg	4
acute inhalation	rat	LD_{50} > 4.8 mg/L	5
skin irritation	rabbit	slight irritant	6
eye irritation	rabbit	slight irritant	7
skin sensitisation	guinea pig	not a sensitiser	8

9.1.1 Oral Toxicity (3)

Species/strain:	rats/Sprague -Dawley CD
Number/sex of animals:	5/sex/dose level
Observation period:	14 days
Method of administration:	via intubation at dose levels of 1 200, 2 500 and 5 000 mg/kg

Clinical observations:	general signs of systemic toxicity were seen in animals that survived to the end of the study at the highest dose level; after an initial weight loss surviving animals gained weight between day 7 and the end of the study; significant signs of toxicity were reported in animals in the 2 500 mg/kg group and included, ataxia, convulsions, tremors, hypopnoea, irregular breathing and abdominal gripping; the surviving animals in this group and those at the lowest dose level gained weight on day 7 and on day 14.
Mortality:	none of the animals died following a dose of 1 200 mg/kg; on day 1, following administration of 2 500 mg/kg, 2/5 males and 1/5 females died; in the top dose group, 3/5 males and 4/5 females died within 21 hours of dosing
Morphological findings:	a variety of changes, primarily in the lung and gastrointestinal tract were reported on examination of animals that were found dead; some animals exhibited changes in the stomach and intestine which were suggestive of irritant/corrosive effects; in the low dose group observations were similar to controls
Test method:	similar to OECD Guidelines for Testing of Chemicals (9)
LD_{50}:	= 3 577 mg/kg
Result:	GST exhibited low acute oral toxicity in rats

9.1.2 Dermal Toxicity (4)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	neat test substance was applied to the shaved dorsal area of the rabbit under a semi- occluded dressing; the test substance was removed after 24 hours

Clinical observations:	no significant dermal or systemic toxicity was seen throughout the study, the majority of animals gained weight by the end of the study
Mortality:	nil
Morphological findings:	no abnormalities detected
Test method:	similar to OECD Guidelines for Testing of Chemicals (9)
Result:	GST exhibited low acute dermal toxicity in rabbits

9.1.3 Inhalation Toxicity (5)

Species/strain:	rat/Sprague-Dawley CD
Number/sex of animals:	5/sex
Observation period:	4 hours
Method of administration:	inhalation as an aerosol in the breathing zone
Clinical observations:	laboured breathing, nasal discharge and red/flaky skin following exposure; full recovery was not seen in all animals by the end of the study
Mortality:	none
Morphological findings:	no abnormalities detected
Test method:	similar to OECD Guidelines for Testing of Chemicals (9)
LC_{50}:	> 4.8 mg/L (mean concentration)
Result:	low inhalational toxicity in rats

9.1.4 Skin Irritation (6)

Species/strain:	rabbit/New Zealand white
Number/sex of animals:	6/males

Observation period: 3 days

Method of administration: 0.5 mL of neat test material applied to the shaved flank under a semi-occluded dressing for 4 hours

Draize scores (10):

Time after treatment (days)	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
1	2[a]	1	1	1	1	2
2	2	2	3	2	1	3
3	2	1	2	1	1	3
7	1	1	1	0	1	1
14	0	1	0	0	0	0
Oedema						
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	2	0	0	0	0
7	0	1	0	0	0	0
14	0	0	0	0	0	0

s
ee Attachment 1 for Draize scales

Test method: similar to OECD Guidelines for Testing of Chemicals (9)

Result: GST was a slight skin irritant in rabbits

9.1.5 Eye Irritation (7)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 6/males

Observation period: 21 days

Method of administration: 0.1 mL of undiluted test substance into conjunctival sac of the left eye of each rabbit

Draize scores (10) of irrigated eyes: no conjunctival or iridial effects were observed throughout the study; scores for conjunctival effects are given in the following table:

	Time after instillation														
Animal	**1 day**			**2 days**			**3 days**			**4 days**			**7 days**		
Conjunctiva	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**
1	3	0	0	1	0	0	2	0	0	1	0	0	0	0	0
2	2	0	2	1	0	0	2	0	0	1	0	0	0	0	0
3	3	0	0	1	0	0	0	0	0	1	0	0	0	0	0
4	1	0	0	1	0	0	1	0	0	0	0	0	0	0	0
5	2	0	0	1	0	0	1	0	0	1	0	0	0	0	0
6	2	0	0	2	0	0	1	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
[a] opacity [b] area [c] redness [d] chemosis [e] discharge

Irrigated eyes: after 24 hours

Test method: similar to OECD Guidelines for Testing of Chemicals (7)

Result: GST was a slight eye irritant in rabbits

9.1.6 Skin Sensitisation (8)

Species/strain: guinea pigs/Dunkin Hartley Pirbright White

Number of animals: 22 test and 22 controls

Induction procedure: 0.2% v/v of test chemical in liquid paraffin oil on day 0, intradermally; 1.0% w/w of test chemical in vaseline topically on day 7, for 48 hours

Challenge procedure: 0.005% w/w of test chemical in vaseline on day 21, topically for 24 hours; this is a very low challenge concentration, selected on the basis of the concentration in the sighting study, that did not cause skin irritation and solubility in the preferred vehicle

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	24 hours*	48 hours*	24 hours	48 hours
0.005%	0/22**	0/22	0/22	0/22

* time after patch removal
** number of animals exhibiting positive response

Test method: in accordance with OECD Guidelines for Testing of Chemicals (9)

Result: the GST was not a skin sensitiser in guinea pigs at the dose levels tested

9.2 Repeated Dose Toxicity (11)

Species/strain: rat/Sprague Dawley CD

Number/sex of animals: 5/sex/group including a recovery group

Method of administration: gavage

Dose/Study duration: 10, 50 and 200 mg/kg/day for a 4 week duration; an additional five rats of each sex were treated with 0 or 200 mg/kg/day for the same period followed by a 14 day recovery period prior to necropsy

Clinical observations: salivation, staining of the fur, hair loss and lack of grooming were observed in animals in the highest dose group; food consumption was lower for the males, in the first two weeks, in this group and higher in the females in the second and third week; with the exception of hair loss all other effects had reversed by the end of the recovery period

Clinical chemistry/Haematology blood chemistry investigations after 29 days showed the following changes in animals in the high dose group: low alkaline phosphatase, high erythrocyte acetylcholinesterase activities and low total cholesterol concentration in males and

	females; alkaline phosphatase was also low in males receiving 50 mg/kg/day; at the end of the recovery period high erythrocyte acetylcholinesterase and alkaline phosphatase activities were evident in males which had received 200 mg/kg/day; other altered parameters were not evident at the end of the reversibility period urinary volumes of females, treated at 200 mg/kg/day, were slightly higher than those of the controls, before termination of the treatment period haematological changes were noted in animals at 200 mg/kg/day and included: slightly high erythrocyte count, low mean cell volume and mean cell haemoglobin in males; high platelet count and longer prothrombin time in both sexes; there were some abnormalities of the blood film in males in the 50 mg/kg/day group; by the end of the study, high erythrocyte count, low mean cell volume, mean cell haemoglobin and abnormalities were still evident in males in the highest dose group at the end of the treatment period absolute and bodyweight relative liver weights were higher in females which received 200 mg/kg/day, than in the controls
Histopathology:	slight centriacinar hepatocytic fatty vacuolation was recorded in thee females from the high dose group
Test method:	similar to the OECD Guidelines for Testing of Chemicals (9)
Result:	treatment of GST at 200 mg/kg/day was associated with non specific toxicity and minor changes in the blood and liver; the changes in the liver were reversed over a 14 day period without treatment, the haematological changes were not; the changes seen at 50 mg/kg/day were considered to be minimal and this was considered to be level at which no toxicity was observed

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (12)

Strains:	*S. typhimurium* TA 98, TA 100, TA 1535 and TA 1537 *E. coli* WP2, WP2*uvrA*
Concentration range:	50-5 000 μg of notified chemical/plate, all strains with or without metabolic activation (rat liver S9)
Test method:	similar to the OECD Guidelines for Testing of Chemicals (9)
Result:	GST was found not to be mutagenic in this system

9.3.2 Chromosomal Aberrations in Chinese Hamster Lung Cells (13)

Concentration range:	10-40 μg of the notified chemical/mL for continuous treatment, 20-80 μg of the notified chemical/mL for pulse treatment; with or without metabolic activation (rat liver S9) for both treatment regimes
Test method:	similar to the OECD Guidelines for Testing of Chemicals (9)
Result:	not clastogenic in this system

9.3.3 Chromosomal Aberrations in Human Lymphocyte Cells(14)

Concentration range:	10-40 μg of the notified chemical/mL, with or without metabolic activation (rat liver S9)
Test method:	similar to the OECD Guidelines for Testing chemicals (9)
Result:	not clastogenic in this system

9.4 Overall Assessment of Toxicological Data

GST was of low acute oral and inhalational toxicity in rats and of low dermal toxicity in rabbits. In the inhalation study the highest dose tested was 4.8 mg/L. Although this falls below the threshold for classification as harmful by inhalation (15), it is very close to the cut off and there was no evidence of significant systemic toxicity at this dose level. It is therefore, considered unnecessary, on the basis of these data, to classify the notified chemical as harmful by the inhalation route following acute exposure. In a 28-day oral repeat dose study in rats, effects were observed in the liver and blood following treatment at 200 mg/kg/day. The changes in the liver were reversible, those in the blood did not reverse during the 14 day recovery period. At 50 mg/kg/day, no significant signs of toxicity were observed. GST was a slight skin and eye irritant in rabbits, was not a skin sensitiser in guinea pigs and was not genotoxic as judged by the lack of mutagenicity in bacteria and clastogenicity in Chinese hamster lung cells and Human lymphocyte cells *in vitro*.

Based on the submitted toxicological data, GST would not be classified as hazardous according to Worksafe Australia's Approved Criteria for Classifying Hazardous Substances (Approved Criteria) (15).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out according to OECD Test Methods (9).

Ecotoxicity Test Results

Test	Species	Results (mg/L)
Acute Toxicity (F; N)	Rainbow trout (*Oncorhynchus mykiss*)	96 h LC_{50}=0.21
Immobilisation (SS; N)	Water Flea (*Daphnia magna*)	48 h EC_{50}=0.22
Growth Inhibition (S; N)	Algae (*Selenastrum capricornutum*)	72h E_uC_{50} = 1.5

F=Flow through; S=Static; SS=Semi-statc; N=Nominal Concentration.

From the test results, GST can be described as highly toxic to fish and water flea, and moderately toxic to algae.

While not recorded in the algae test, both tests on fish and water flea support the observation that GST is highly unstable in water. In the fish test, around 70% of the GST was recovered immediately after spiking of test water at concentrations of 1 to 10 ppm, with 50-70% recovered after 6 to12 hours. Stability tests showed that the lower the concentration of GST, the faster the transformation rate from GST to various oligomer forms. The fish test was conducted at concentrations of 0.02 to

0.32 ppm, and practically no GST was detected in the test water samples from the bioassay.

Testing on *Daphnia* was conducted at concentrations of 0.015 ppm to 4 ppm. At the highest tested level, recoveries were 34 and 25% at the beginning of the test. After renewal of the test solution 24 hours later, the recoveries were 6.3 and 0%. In all other concentration levels, whether freshly prepared or after an exposure period of 24 hours, GST was not detected.

The number of affected organisms increased throughout the test duration (eg, at 0.5 ppm, 55% *Daphnia* immobilised after 24 hours, and 90% after 48 hours; and in the fish test at 0.32 ppm, there were 60% dead fish after 48 hours and 100% dead after 96 hours). At these concentrations and after both time periods, no GST was detected in the water. GST readily polymerises to form dimers, trimers and other oligomers, and the toxicity to aquatic species may be a result of this process.

No microbial inhibition test was performed. However, a biodegradability test, measured by BOD and using sewage sludge, did not make any observations on inhibition of microbes.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will be processed at one site only. Here it will be used for the manufacture of ophthalmic plastic lenses.

Manufacturing operations described in the submission indicate no release to the aquatic system. Around 1 200 kg of waste liquid monomers, at which GST will be present up to 55% (660 kg GST) are expected to be produced each year. This liquid waste monomer is polymerised and disposed of to landfill, where it will be immobile, and unlikely to present an environmental hazard.

The notifier has estimated a further 1 200 kg per annum of waste acetone, containing dissolved notified chemical, will be generated. This will be disposed of by incineration, where the notified chemical will be destroyed emitting oxides of carbon and sulphur.

Emissions from curing ovens are controlled by odour absorbing chemicals inside the oven, with working environment emissions being controlled in the same manner.

The majority of the notified chemical will ultimately share the fate of the plastic lenses they are used in. Disposal will be in a highly diffuse manner to landfills around the country, either as waste shavings from lens laboratories, or as part of domestic waste. In this form, the notified chemical is unlikely to cause a hazard.

The notified chemical should not be allowed to enter aquatic systems. The MSDS contains adequate instructions for clean up and disposal of spills.

The notified chemical is not likely to present a hazard to the environment when it is stored, transported and used in the typical manner.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on the submitted toxicological data, GST would not be classified as hazardous according to the Approved Criteria (15). Therefore the health hazard to workers using GST in the manufacture of ophthalmic lenses is considered to be low.

GST will be imported in 200 L sealed drums from the wharf to the manufacturing site. Wharf and transport workers are only likely to be exposed to GST in the unlikely event of an accident. The risk of adverse effects to GST for these workers is considered to be negligible.

The notified chemical is used in the manufacture of ophthalmic lenses in a four stage process. These stages include: formulation of the notified chemical with other liquid resins and additives, transfer of the formulated resin into mould assemblies by pressure through an in-line filter, heating the resin to form the cured polymer lens and removal of the plastic lens from the assembly moulds. Dermal contact is expected to be the main route of exposure for all workers involved in lens production, cleaning and maintenance of the equipment. Formulation and filling of mould assemblies is carried out under local exhaust ventilation, transfer of the notified polymer and resin occurs in closed vessels/lines and therefore inhalational exposure is minimised. Ocular exposure would only occur in the unlikely event of an accident.

The occupational health risk posed by GST to workers involved in the manufacture of the ophthalmic lenses is minimal, due to the expected low toxicity of the notified polymer and the anticipated low exposures.

The general public will come into contact with the finished lenses once fitted into spectacle frames. The notified chemical will be bound in the lens matrix, exposure will therefore be negligible and risk of adverse health effects correspondingly negligible. Risks to the public in the event of accidental spillage during transport are also considered to be negligible.

13. RECOMMENDATIONS

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

- Safe practices for handling any chemical formulation, should be adhered to and include:

  - minimising spills and splashes:
  - practising good personal hygiene; and
  - practising good house keeping and maintenance including bunding of large spills which should be cleaned up promptly with absorbents and put into containers for disposal;

- It is expected that in the industrial environment, protective clothing conforming to and used in accordance with Australian Standard (AS)2919 (16) and protective footwear conforming to Australian/New Zealand Standard (AS/NZS) 2210 (17) should be worn as a matter of course. In addition it is advisable when handling the notified polymer and formulation to wear chemical-type goggles (selected and fitted) according to AS 1336 (18) and meeting requirements of AS/NZS 1337 (19), impermeable gloves AS 2161-1978 (20) to protect against any unforseen circumstances.

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (21).

This MSDS was provided by the applicant as part of the notification statement. The MSDS 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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2. Knacker, T., Weidenauer, M., Schallna, B. H., & Diehl, T., 1993. Study on the Freshwater Fish (Rainbow Trout) Acute Toxicity of GST. Final Report BE-EA-32-92-03-F1A-01. Batelle-Europe, D-6000 Frankfurt am Main.

3. Mitchell, J.M.1990, Acute oral toxicity to the rat, GST. Bio/Dynamics Project No.: 5637-89. Bio/Dynamics Inc., NewJersey USA. Data on file.

4. Mitchell, J.M. 1990, Acute dermal toxicity to the rabbit, GST. Bio/Dynamics Project No.: 5638-89. Bio/Dynamics Inc., New Jersey USA. Data on file.

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6. POβnecker, A. 1992, Acute dermal irritation/corrosion study of GST in rabbits. Battelle Europe Study No.: BE-MT32-92-01-DIK-01. Battelle Europe, D-6000 Frankfurt am Main. Data on file

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Attachment 1

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 definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

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 translucent 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.	Discharge 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	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe