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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

CGL 411 ISO CONC.

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT**CGL 411 ISO CONC.****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Ciba Specialty Chemicals (ABN 97 005 061 469)
235 Settlement Road, Thomatown VIC 3074

NOTIFICATION CATEGORY

Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical name,
Other names,
CAS number,
Molecular formula,
Structural formula,
Molecular formula,
Molecular weight,
Spectral data,
Composition,
Manufacturing process,
Import volume,
Identity of sites.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

The notifier seeks variation of data requirement for the physicochemical properties, where surrogate data has been provided.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Nil

NOTIFICATION IN OTHER COUNTRIES

Korea, Japan, China, Phillipines.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Tinuvin 411L (contains >50% notified chemical)

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Mass Spectrometry (MS), NMR Spectrometry, Infrared (IR) and UV-VIS Spectroscopy.
Remarks	Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

High

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified chemical will be imported in solution at >50% and will be reformulated in Australia to produce solvent-based coating formulations containing <10% of notified chemical.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	<5	<5	<5	<5	<5

USE

The notified chemical will be used in solvent-based coatings, mainly for automotive and industrial use (90%). It may also be used in interior/exterior decorative clear coats (10%) that may be used by do-it-yourself decorators.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

Ciba Specialty Chemicals and other industrial formulation establishments.

TRANSPORTATION AND PACKAGING

The notified chemical will be imported as Tinuvin 411L. The packaging will be in 25L tinsplate drums and will be transported from the dockside to Ciba Specialty Chemicals warehouse. No re-packing will be required at this stage. Tinuvin 411L will be transported to the customer sites by road for reformulation.

5.2. Operation description

Coatings will be prepared in controlled, purpose-built, industrial settings where processes such as milling, screening and blending into coatings, will take place in dedicated equipment.

During reformulation, the notified chemical will be pumped from the imported 25 L drums to a “mill-base” stage of preparation where it is added to the base liquid coating. The “mill-base” is milled to comminute the solid pigments in the coating vehicle and following milling, is “let down” into the final vehicle and solvent blend in a blending vessel. The coating solution in the preparation vessel will then be packed off as a liquid product for sale for industrial, commercial or domestic use.

In each case, where there is potential for emission of solvent vapours, local exhaust ventilation away from the worker, is employed.

Industrial application will be undertaken in specially designed premises where the coatings will be applied to the substance typically by spraying. Following application to the substrate, it may be baked in an oven. This process causes the curing of the resin to produce a fully cross-linked polymer matrix.

For clear coat application, the coating is usually applied by brush or roll on.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Pumping	1 per site	Not indicated	Not indicated

Blending and/or milling colours coating bases	1 per site	Not indicated	Not indicated
Filling, packaging, lidded and cartonned for dispatch	1 per site	Not indicated	Not indicated
Maintenance	1 per site	Not indicated	Not indicated
Application	Not indicated	Not indicated	Not indicated

Exposure Details

Waterside, transport and Ciba Speciality Chemicals warehouse workers are not expected to be exposed to notified chemical, as they will only handle closed containers. However, there is potential for exposure during accident (rupture of drums). The applicant has not indicated whether they would be wearing any protective clothing.

At the customer manufacturing facilities, occupational exposure is primarily a potential during blending operation leading to the preparation of end use products. However, blending operations will be a closed system except for QC testing. Dermal exposure to drips and spills may occur when pumps are removed and installed on changing drums. Once blended, the coating will be passed to packaging lines via an enclosed system. Packaging system for coating is almost exclusively an enclosed system and automatic.

The point at which the drum is opened and connected to blending vessels would be under the control of exhaust ventilation to deal with the hazards associated with other ingredients such as pigments and solvents.

The opportunity for skin exposure exists during product changeover and equipment maintenance. In these cases, workers handling connections or equipment will be properly protected with PPE as recommended in the MSDS.

Exposure can also occur during industrial application (spraying) of the finished products. The notifier has stated that, in a professional in-house industrial workplace, the spray (mist) does not come into contact with workers as these operations are either carried out in enclosed systems, or workers are well equipped with combined particulate and organic vapour-element-equipped respirators or the direction of the strong ventilation prevents any contact of workers with the contaminated air. Furthermore, the notified chemical will be present at a very low concentration in finished product at this stage.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will be used in a small number of coating plants. Washings from cleaning of formulation equipment will be kept for the next batch. Hence, it is anticipated that the industrial generation of wastes will be limited to traces remaining from clean-up of spills and trace residues in empty containers. As drums are rinsed with solvent which is also added to formulation batches the residues remaining in the import drums is expected to be small (<20 g of the notified chemical per drum). Hence, the total waste chemical in empty drums is expected to be below 5 kg and will either be disposed of through effluent from drum reclaiming establishments or to landfill.

RELEASE OF CHEMICAL FROM USE

The most significant route for entry into the environment will be disposal of waste from spraying operations. Conventional liquid spray technology relies on air-pressurised sprayers and transfer efficiencies can sometimes be as low as 50%.

The main users of the notified chemical will be OEMs, who will apply the coatings using advanced robotic spraying techniques with less than 20% waste. Hence, up to 900 kg (assuming 90% of the import volume is used by OEMs and generates 20% waste as overspray) of the notified chemical will be disposed of as coatings overspray from OEMs. Overspray in the air is often exhausted through an aqueous scrubber, which removes the waste coating as sludge. The solids are drummed for disposal as hazardous waste, either through incineration or secure landfill.

After application by OEMs, the substrate may be baked in an oven to ensure full cross-linking of the coatings polymer matrix. Once the chemical is within a cured coating, it is likely to share the fate of

the substrate, which may involve recycling or landfill at the end of its useful lifetime.

Waste generated during the application of the interior/exterior decorative clear coats has not been estimated. These products will be applied using brushes and rollers. Based on previous experiences, it is estimated that the amount of chemical that may be lost due to spills and application equipment cleaning may be up to 1% of the volume applied of the chemical or 5 kg/annum, in addition to the 5 kg/annum lost as container residues. This equates to a total release to the environment of 10 kg/annum of the notified chemical, all of which will cure to an inert solid on exposure to ambient conditions. As the coatings are solvent based, application equipment will be cleaned with solvents, and little exposure to the aquatic compartment is expected.

5.5. Disposal

Wastes containing the notified chemical will either be disposed of to landfill or incinerated.

5.6. Public exposure

The most probable public exposure is through the use of clear-coats for timber. Such exposure would be maximum for several occasions per year, probably less than an hour for each occasion unless the person is a hobby cabinetmaker. Due to its low level and the use patterns, the overall exposure to the notified chemical will be very low for a person using products containing the notified chemical.

The public could also be exposed following contact with the treated industrial material. However, following curing, the notified chemical no longer has potential for exposure as it is encapsulated in the solid binder film. Therefore, the exposure to the public will be very low.

6. PHYSICAL AND CHEMICAL PROPERTIES

The physio-chemical properties discussed below, unless otherwise specified, were conducted on an acceptable analogue of the notified chemical. The following tests were conducted on the neat sample after the removal of the solvent.

Appearance at 20°C and 101.3 kPa Pale yellow semi-solid.

Melting Point 59.8°C

METHOD OECD TG 102 Melting Point.

Remarks This is the melting point of crystals in the liquid. Crystallisation of the entire sample may occur. This has been observed with the other neat samples.

TEST FACILITY Cytec Industries, Stamford, Connecticut (1993)

Boiling Point 628°C at 101.3 kPa

METHOD OECD TG 103 Boiling Point.

Remarks The boiling point has been extrapolated from the vapour pressure data. The sample did not decompose up to a temperature of 350°C.

TEST FACILITY Cytec Industries, Stamford, Connecticut (1993)

Density 1117.4 kg/m³ at 25°C

METHOD OECD TG 109 Density of Liquids and Solids.

Remarks The density was measured from 25 to 80 °C.

TEST FACILITY Cytec Industries, Stamford, Connecticut (1993)

Vapour Pressure 0.14 kPa at 25°C

METHOD OECD TG 104 Vapour Pressure.

Remarks Static method.

TEST FACILITY Cytec Industries, Stamford, Connecticut (1993)

Water Solubility 0.0006 ± 0.2 g/L at 20°C

METHOD OECD TG 105 Water Solubility.
 Remarks A flask method together with HPLC analysis was used.
 TEST FACILITY Cytec Industries, Stamford, Connecticut (1993)

Fat Solubility 1024 g/kg standard fat at 37°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
 Remarks The standard fat was Fettsimulans HB 307. By HPLC analysis, solubility in fat ranged from 29-91 g/kg and 299-1024 g/kg for samples initially equilibrated at 30°C and 50°C respectively. These data indicate that the amount of the test substance dissolved in fat depends on the mobility of the sample at different temperatures.
 TEST FACILITY Cytec Industries, Stamford, Connecticut (1993)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
 EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

<i>pH</i>	<i>T (°C)</i>	<i>t</i> _{1/2} <years>
4	25	>1
7	25	>1
9	25	>1

Remarks The hydrolysis was only investigated in detail at pH 4. The preliminary investigation at pH 4 indicated 18% degradation after 5 days at 50°C. However, more comprehensive testing at 55°C over 17 days showed only 8% degradation for the first 5 days indicating that the half-life at 25°C would be in excess of 1 year. Additionally, the decrease in concentration of the notified chemical over time detected in both above tests was doubtful whether it was due to hydrolysis since if the notified chemical were to hydrolyse, the degradation products would be chromophoric and would have been detected using the HPLC conditions used for this study.

TEST FACILITY Safepharm (1997)

Partition Coefficient (n-octanol/water) log Pow = 4.8 ± 0.2 at 23°C

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
 Remarks The test results suggested that the Pow is neither phase nor concentration dependent. In the HPLC performed analysis, ASTM Type I Reagent Water was used instead of double distilled water specified in the OECD TG, however, this variation would not affect the validity of the data.
 TEST FACILITY Cytec Industries, Stamford, Connecticut (1993)

Adsorption/Desorption log K_{oc} = 8.9

Remarks Test report not provided. The method used to determine the estimate is not specified. QSAR modelling of the n-alkyl isomer using PCKOC (version 1.66) afforded an estimate of log K_{oc} = 8.8 suggesting that the provided estimate was also generated by modelling. The comments on the K_{oc} in the notification dossier indicate that the value may be pH dependent due to the presence of aromatic nitrogen atoms. The PCKOC estimate also indicated that the value may be sensitive to pH.

Dissociation Constant Not determined

Remarks The notified chemical contains a triazine moiety which is expected to show typical basicity.

Surface Tension

68.7 mN/m at 20°C

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
 Remarks The test substance is not a surface active agent.
 TEST FACILITY Cytec Industries, Stamford, Connecticut (1993).

Particle Size

Not determined

Remarks The notified chemical will be in the solution form.

Flash Point

Not determined

Remarks The notified chemical is a semi-solid.

Flammability Limits

Not flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
 Remarks The test substance was a sticky semi-solid material and did not fit into any of the three classes of materials listed in EEC protocol A.10. The protocol was modified as melting the test sample at 80°C, then pouring onto a non-porous plate and cooled it to room temperature to form into a mould shape for testing.
 TEST FACILITY Cytec Industries, Stamford, Connecticut (1993)

Autoignition Temperature

Non-auto inflammable

METHOD EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
 Remarks Accelerating Rate Calorimeter (ARC) tests indicated no self-heating and no decomposition up to 350°C.
 TEST FACILITY Cytec Industries, Stamford, Connecticut (1993).

Explosive Properties

Non-explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
 Remarks The test substance was exposed to thermal stress.
 TEST FACILITY Cytec Industries, Stamford, Connecticut (1993).

Reactivity

Stable under normal environmental conditions.

Remarks By Differential Thermal Analysis (DTA), the test substance had an endotherm starting around 90°C and some impurity exotherms starting around 188°C. It showed no impact sensitivity at room temperature when subjected to 2 kg/100 cm impact energy.
 TEST FACILITY Cytec Industries, Stamford, Connecticut (1993).

7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD ₅₀ >5000 mg/kg bw	low toxicity
Rabbit, acute dermal LD ₅₀ >2000 mg/kg bw	low toxicity
Rat, acute inhalation LC ₅₀ >377 mg/L/4 hour	low toxicity
Rabbit, skin irritation	not determined
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – Buehler	no evidence of sensitisation.
Rat, oral repeat dose toxicity – 28 days	NOAEL = >1000 mg/kg bw
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations	non genotoxic
Genotoxicity – in vivo mouse micronucleus test	non genotoxic
Developmental and reproductive effects	not determined

Carcinogenicity not determined

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 401 Acute Oral Toxicity-Limit Test.

Species/Strain Rat/Sprague-Dawley

Vehicle Corn oil suspension (25% w/w)

Remarks - Method None

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	5/sex	5000	None

LD50 >5000 mg/kg bw

Signs of Toxicity No toxic symptoms were observed with the notified chemical at the tested dose.

Effects in Organs There were no direct effects on any particular organ or tissue.

Remarks - Results None

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY Exxon Biomedical Sciences, Inc, East Millstone, New Jersey (1992)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD OECD TG 402 Acute Dermal Toxicity-Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal)- Limit Test.

Species/Strain Rabbit/New Zealand White

Vehicle Normal saline

Type of dressing Occlusive

Remarks - Method The notified chemical was held in contact with the skin for twenty-four hours. Immediately after application, the animals were wrapped with an occlusive bandage to retard evaporation.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose (mg/kg bw)</i>	<i>Mortality</i>
I	5/sex	2000	None

LD50 > 2000 mg/kg bw

Signs of Toxicity - Local None

Signs of Toxicity - Systemic None

Effects in Organs There were no direct effects on any particular organ or tissue.

Remarks - Results None

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY Exxon Biomedical Sciences, Inc, East Millstone, New Jersey (1992)

7.3. Acute toxicity – inhalation

TEST SUBSTANCE Notified chemical

METHOD	OECD TG 403 Acute Inhalation Toxicity – Limit Test. EC Directive 92/69/EEC, 93/21/EEC B.2 Acute Toxicity (Inhalation) – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	None
Method of Exposure	Whole-body exposure
Exposure Period	4 hours
Physical Form	Solid aerosol (particulate).
Particle Size	<15 µm (81%). The test material was in respirable size.
Remarks - Method	Rats were exposed to a dust aerosol atmosphere at a maximum attainable actual concentration of 377 mg/m ³ .

RESULTS

Group	Number and Sex of Animals	Concentration <units>		Mortality
		Nominal	Actual	
1	5/sex	377 mg/m ³	377 mg/m ³	None
LC50	>377 mg/m ³ for 4 hours.			
Signs of Toxicity	Immediately following the exposure, all the rats had yellow material on their fur, seven had yellow material on one or both of the eyes, six animals exhibited irregular breathing, three rats displayed clear ocular discharge from one or both of the eyes, one animals exhibited irregular soft stool while one rat exhibited dry red nasal discharge. The rats recovered on the day following the exposure and appeared normal for the remainder of the study (14 day), apart from intermittent soft stool for 5 days post exposure in three animals.			
Effects in Organs	None			
Remarks - Results	None			

CONCLUSION The notified chemical is of low toxicity via inhalation.

TEST FACILITY Exxon Biomedical Sciences, Inc, East Millstone, New Jersey (1992)

7.4. Irritation – skin

REMARK Test for skin irritation was not conducted. However, the notifier has drawn conclusions from the dermal sensitisation study in guinea pigs. In this test, slight dermal irritation was noted only in the naïve control group. No meaningful differences were observed between the test and the naïve control group. In addition, no dermal irritation was seen in rabbits during the dermal toxicity test. Based on the results, it was concluded that the notified chemical was not skin irritating.

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain Rabbit/New Zealand White

Number of Animals Nine (5 males/4males)

Observation Period 72 hours

Remarks - Method 0.1 g of the notified chemical was placed in one eye of each animal. The treated eyes of six rabbits remained unwashed. The treated eyes of three rabbits were thoroughly flushed with physiological saline beginning 30 seconds after the application of the test material.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Corneal opacity</i>	0.05	1	24 hrs	0
<i>Iridial inflammation</i>	0.00	0	0 hrs	0
<i>Conjunctiva: redness</i>	0.78	2	48 hrs	0
<i>Conjunctiva: chemosis</i>	0.17	1	48 hrs	0
<i>Conjunctiva: discharge</i>	0.11	1	48 hrs	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results	Conjunctival irritation including blistering was seen in all but one animal at 1 hr after test article administration. Washing of eyes resulted in a large reduction in the irritation scores.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Exxon Biomedical Sciences, Inc, East Millstone, New Jersey (1992)
7.6. Skin sensitisation	
TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 84/449/EC B.6 Skin Sensitisation – Buehler Method
Species/Strain	Guinea pig/Albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 80% Additional animals were also exposed to 0.5 g (maximum) of the test material moistened with 0.5 mL of acetone. The induction treatment was chosen, based on the results of this test.
MAIN STUDY	
Number of Animals	Test Group: 10 Challenge Group: 4 Control Group: 6 Positive control: 6
INDUCTION PHASE	Induction Concentration: topical application: 100% (0.5 g of notified chemical moistened with 0.5 mL of acetone)
Signs of Irritation	No dermal irritation was observed following application.
CHALLENGE PHASE	topical application: 100% (0.5 g of notified chemical moistened with 0.5 mL of acetone)
Remarks - Method	None
RESULTS	No significant erythema was noted following the challenge application for either the test or vehicle control group. An allergic sensitisation response was elicited in the animals receiving positive control article.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Exxon Biomedical Sciences, Inc, East Millstone, New Jersey (1992)

7.7. Repeat dose toxicity-I

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 14 days
Vehicle	Olive oil

Remarks - Method

A 14-day repeat dose preliminary test was conducted. No significant clinical signs, body or organ weight changes, haematological or serum chemistry or gross/microscopic findings were noted at dose levels of 50, 250 and 1000 mg/kg. Therefore, the dose levels for the 28-day study were set at 40, 200 and 1000 mg/kg. A 14-day recovery period group was also included for control and high dose groups.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw/day</i>	<i>Mortality</i>
I (control)	6/sex	0	0/12
II (control-recovery)	6/sex	0	0/12
III (low dose)	6/sex	40	0/12
IV (mild dose)	6/sex	200	0/12
V (high dose)	6/sex	1000	0/12
VI (high dose-recovery)	6/sex	1000	0/12

Mortality and Time to Death

No mortality was noted in any group.

Clinical Observations

No significant treatment related clinical signs were noted. Mean body weight increased in both sexes in all dose groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

An increase in the platelet count was noted in the males of 40 mg/kg group and a decrease in the reticulocyte ratio in the females of 1000 mg/kg group. At the completion of the recovery period, decreased lymphocyte ratio was only noted in the females of 1000 mg/kg group.

In male rats, a decrease in gamma glutamyl transpeptidase (GPT) in 40 and 200 mg/kg groups and an increase in calcium in 40 mg/kg group was noted. A decrease in the calcium was also noted in the females in 200 and 1000 mg/kg groups. At the completion of the recovery period, decreases in gamma-GPT, triglyceride, and albumin were noted in the male in 1000 mg/kg group. No abnormalities were noted in the female recovery group.

Urinalysis parameters revealed no abnormalities in either males or females following dosing and recovery.

Effects in Organs

The only organ weight effect noted was a decrease in absolute kidney weight in the females at 200 and 1000 mg/kg. Gross necropsy examination at the completion of dosing revealed a blackish region of the mucosa of the glandular stomach in 1/6 males in the 1000 mg/kg group. Histopathology revealed necrosis of the stomach mucosa in the same animal. No gross or histopathological abnormalities were noted following the recovery period.

Remarks – Results

The notifier noted that these hematologic findings were sporadic and not dose related, therefore, they are of questionable biological significance. The notifier commented that the clinical findings are not clearly dose related and in the absence of accompanying histopathology, the biological significance is not clear.

Overall, most of the findings were judged minimal and considered indicative of a treatment related response.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study.

TEST FACILITY

Kagokuhin Anzen Center, Hita (1992)

7.8. Repeat dose toxicity-II

TEST SUBSTANCE

Notified chemical

METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 29 days; Dose regimen: 7 days per week;
Vehicle	Corn oil
Remarks - Method	A range finding study was performed to determine dose levels for this study.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw/day</i>	<i>Mortality</i>
I (control)	5/sex	0	1/10
III (low dose)	5/sex	250	0/10
IV (mild dose)	5/sex	500	0/10
V (high dose)	5sex	1000	0/10

Mortality and Time to Death

Mortality was limited to one control group male euthanised on test day 7 due to a broken snout.

Clinical Observations

Overall increases in body weight were noted for all animals, without any significant differences between the control and the treated animals. Clinical in-life observations noted during the study were minimal with the majority of the animals showed no observable abnormalities at each observation interval.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

A dose related increase in blood urea nitrogen and gamma glutamyl transpeptidase (GGT) was noted in the serum chemistry analyses. However, there were no significant differences between any of these treated and control values, and these differences were not considered biologically significant.

Analysis of the mean quantitative haematology values revealed a dose related increase in the male mean white blood cell counts, with the high dose male value being significantly higher than the control value. There was also a correlating increase in the male segmented neutrophils in differential counts of blood smears.

Effects in Organs

Gross post-mortem examination of the animals at study termination revealed no observable abnormalities for the majority of the animals. Similarly, no significant histopathological findings were noted. Overall, there were no apparent trends within the treatment or control groups at post-mortem examination.

Remarks – Results

The notifier concluded that the clinical observations noted were considered incidental and not related to test material administration. The notifier also stated that the minor microscopic changes observed were of the type that commonly occur spontaneously in young laboratory rats or were considered to have been incidental and unrelated to treatment. The importance of haematological changes is unclear in the absence of any analogous findings.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the absence of adverse effects in the study.

TEST FACILITY	Exxon Biomedical Sciences, Inc, East Millstone, New Jersey (1990)
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7.9. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
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METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
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Species/Strain	<i>S. typhimurium</i> : A98, TA100, TA1535, TA1537, TA1538.
Metabolic Activation System	S9 fraction from livers of Aroclor-1254 induced rats.
Concentration Range in Main Test	a) With metabolic activation: 667, 1000, 3333, 6667, 10000 µg/plate. b) Without metabolic activation: 667, 1000, 3333, 6667, 10000 µg/plate.
Vehicle	Acetone
Remarks – Method	None

RESULTS

No significant increases in the numbers of revertants were seen for any strain either in the presence or absence of metabolic activation. Moderate precipitation was observed and the background lawn was observed at high doses. Reduction in the number of revertant colonies, indicative of toxicity, were seen at the maximum dose. Plates were handcounted due to precipitate. Appropriate positive controls were used and led to large increases in revertants, indicating that the test system responded appropriately.

CONCLUSION

The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Microbiological Associates Inc., Rockville, Maryland (1988)

7.10. Genotoxicity – in vitro

TEST SUBSTANCE

Notified chemical

METHOD

The test was carried out in accordance with the method of “On the test method of new chemicals substances” a part revision (Articles, Kanhogyo No. 700, Yakuhatsu No. 1039, 61 Kikyoku No. 1014, December 5, 1986). Chinese Hamster Lung Fibroblast Cells

Cell Type/Cell Line

Metabolic Activation System

S9 fractions from livers of phenobarbital and 5,6-benzoflavone-induced rats.

Vehicle

Carboxymethylcellulose sodium (0.5%)

Remarks - Method

Dose of 1250, 2500 and 5000 mg/mL were used. Mitomycin and cyclophosphamide were used as a positive control.

Remarks - Results

The test substance did not induce chromosomal aberration such as structural abnormalities and dicentrics at doses in which toxicity was shown to the cells.

CONCLUSION

The notified chemical was not clastogenic to Chinese Hamster Lung Fibroblast Cells treated in vitro under the conditions of the test.

TEST FACILITY

Society for Test of Chemicals, Oita-ken (1990)

7.11. Genotoxicity – in vivo

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 474 Mammalian Erythrocyte Micronucleus Test.

Species/Strain

Mouse/ICR

Route of Administration

Intraperitoneal injection

Vehicle

Corn oil

Remarks - Method

5 animal/sex were sacrificed for each time interval.

Group	Number and Sex of Animals	Dose mg/kg bw	Sacrifice Time hours
1	15/sex	0	24, 48 & 72
2	15/sex	1250	24, 48 & 72
3	15/sex	2500	24, 48 & 72

4	15/sex	5000	24, 48 & 72
5	15/sex	CP, 30	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity All treated animals appeared clinically normal during the course of this study apart from several cases of rough coat and one each of lethargy and hunched posture among high dose animals. No mortality occurred at any dose level.

Genotoxic Effects None
Remarks - Results The number of micronucleated polychromatic erythrocytes per 1000 polychromatic erythrocytes was not statistically increased in males or females, at any dose level or bone marrow collection time ($p > 0.05$, Kastenbaum-Bowman Tables). No change in the ratio of polychromatic erythrocytes to total erythrocytes was seen. CP induced a significant increase in micronucleated polychromatic erythrocytes in male and female mice relative to the control ($p > 0.05$, Kastenbaum-Bowman Tables).

CONCLUSION The notified chemical was not clastogenic in this in vivo mouse micronucleus test under the conditions of the test.

TEST FACILITY Microbiological Associates Inc., Rockville, Maryland (1992)

8. ENVIRONMENT

The environmental studies were conducted on an acceptable analogue of the notified chemical.

8.1. Environmental fate

Most of the tests presented were summarised in a report prepared by the American Cyanamid Company (1992). The details provided in this summary report are brief.

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE Notified chemical

METHOD OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum Sludge bacteria from 10 locations across Japan
Exposure Period 28 days
Auxiliary Solvent None
Analytical Monitoring BOD and HPLC
Remarks - Method The method used is based on the Modified MITI test, with the addition that the amount of degradation was also determined by HPLC analysis. Samples were prepared at a loading rate of 100 mg/L of medium.

RESULTS

<i>Test substance</i>			<i>Aniline</i>	
<i>Day</i>	% degradation		<i>Day</i>	% degradation
	<i>BOD</i>	<i>HPLC</i>		<i>BOD</i>
28	0	2	28	95

Remarks - Results The extent of degradation of the reference material validates the test.

CONCLUSION The test material is not readily biodegradable under the conditions the

test.

TEST FACILITY Kurume Laboratory (1992)

8.1.2. Bioaccumulation

TEST SUBSTANCE Notified chemical

METHOD Unspecified
 Species Carp (*Cyprinus carpio*)
 Exposure Period Exposure: 56 days
 Auxiliary Solvent HCO-40 dispersing agent
 Concentration Range
 Nominal 0.5 mg/L (Level 1)
 0.05 mg/L (Level 2)
 Analytical Monitoring HPLC
 Remarks - Method Continuous flow system. Test solutions were analysed twice a week for a total of 16 times. Treated fish were analysed after 2, 4, 6 and 8 weeks of exposure (2 fish/analysis). There appears to have been no depuration phase.

RESULTS

Bioconcentration Factor Level 1 0.3-15 times
 Level 2 2.5-5.1 times

CONCLUSION The results indicate that the notified chemical is not likely to bioaccumulate.

TEST FACILITY Kurume Laboratory (1992)

8.2. Ecotoxicological investigations**8.2.1. Acute toxicity to fish****8.2.1.1. Study in Rainbow Trout**

TEST SUBSTANCE Notified chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test
 Species Rainbow Trout (*Oncorhynchus mykiss*)
 Exposure Period 96 h
 Auxiliary Solvent DMF
 Water Hardness 166-184 mg CaCO₃/L
 Analytical Monitoring
 Remarks – Method Water quality parameters of pH, water temperature, O₂ content were measured at 0, 24, 48 and 72 h and remained within normal limits throughout the study.

RESULTS

Concentration mg/L		Number of Fish	Mortality			
Nominal	Actual		24 h	48 h	72 h	96 h
Control		10	0	0	0	0
Vehicle blank		10	0	0	0	0
0.32		10	0	0	0	0
1.0		10	0	0	0	0
3.2		10	0	0	0	0

LC50 >3.2 mg/L at 96 hours.

NOEC 3.2 mg/L at 96 hours.

Remarks – Results The two highest test concentrations contained precipitate during the test.

CONCLUSION The test material is not toxic to rainbow trout up to the limit of its solubility

TEST FACILITY Analytical Bio-Chemistry Laboratories (1992)

8.2.1.2. Study in Bluegill Sunfish

TEST SUBSTANCE Notified chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test

Species Bluegill Sunfish (*Lepomis macrochirus*)

Exposure Period 96 h

Auxiliary Solvent DMF

Water Hardness 166-182 mg CaCO₃/L

Analytical Monitoring

Remarks – Method

Water quality parameters of pH, water temperature, O₂ content were measured at 0, 24, 48 and 72 h and remained within normal limits throughout the study.

RESULTS

Concentration mg/L		Number of Fish	Mortality			
Nominal	Actual		24 h	48 h	72 h	96 h
Control		10	0	0	0	0
Vehicle blank		10	0	0	0	0
0.32		10	0	0	0	0
1.0		10	0	0	0	0
3.2		10	0	0	0	0

LC50 >3.2 mg/L at 96 hours.

LC50 >3.2 mg/L at 96 hours.

NOEC 3.2 mg/L at 96 hours.

Remarks – Results The two highest test concentrations contained precipitate during the test.

CONCLUSION The test material is not toxic to bluegill sunfish up to the limit of its solubility.

TEST FACILITY Analytical Bio-Chemistry Laboratories (1992)

8.2.1.3. Study in Killifish

TEST SUBSTANCE Notified chemical

METHOD Not Specified

Species Killifish (*Oryzias latipes*)

Exposure Period 48 h

Auxiliary Solvent THF and HCO-40 dispersing agent

Water Hardness

Analytical Monitoring

Remarks – Method

Water quality parameters of pH, water temperature, O₂ content remained within normal limits throughout the study.

RESULTS

Concentration mg/L		Number of Fish	Mortality	
Nominal	Actual		24 h	48 h
Control		10	0	0
300		10	0	0

LC50 >300 mg/L at 48 hours.
 NOEC 300 mg/L at 48 hours.
 Remarks – Results

CONCLUSION The test material is not toxic to killifish up to the limit of its solubility

TEST FACILITY Kurume Laboratory (1992)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test.

Species *Daphnia magna*

Exposure Period 48 hours

Auxiliary Solvent

Water Hardness 160-180 mg CaCO₃/L

Analytical Monitoring

Remarks - Method Water quality parameters of pH, water temperature, O₂ content remained within normal limits throughout the study.

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
Control		20	0	0
0.1		20	0	0
1.0		20	0	0
10		20	0	0

LC50 >10 mg/L at 48 hours

NOEC (or LOEC) 10 mg/L at 48 hours

Remarks - Results All test concentrations contained precipitate.

CONCLUSION The test substance is not toxic to daphnia up to the limit of its water solubility.

TEST FACILITY Analytical Bio-Chemistry Laboratories (1992)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.

EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species *Selenastrum capricornutum*

Exposure Period 72 hours

Concentration Range

Nominal 0 and 100 mg/L

Actual 0 and 56 mg/L

Auxiliary Solvent None

Analytical Monitoring HPLC

Remarks - Method Water quality parameters of pH, water temperature, O₂ content remained within normal limits throughout the study. The measured values are based on analysis of the unfiltered solutions. Levels of test substance in filtered (pore size 0.2 µm) samples were below the limit of accurate quantification (0.05 mg/L).

RESULTS

Biomass

Growth

NOEC

<i>E_b</i> C50 mg/L at 72 h	<i>E_r</i> C50 mg/L at 72 h	mg/L at 72 h
>56.0	>56.0	56.0

Remarks - Results	The results of the limit study showed that no inhibitory effect on the growth of <i>Selenastrum capricornutum</i> . The 72-hour NOEC for the test material was determined in the report to be at the highest test level with a nominal concentration of 100 mg/L (actual 56.0 mg/L). The true value of the NOEC may be higher but concentrations in excess of 56.0 mg/L could not be achieved. Similarly, the 72-hour <i>E_b</i> C50 and <i>E_r</i> C50 for the test substance could not be determined for <i>Selenastrum capricornutum</i> as the test substance showed had no inhibitory effect on the test algae up to its highest concentration. Hence, both the 72-hour <i>E_b</i> C50 and <i>E_r</i> C50 are greater than 56.0 mg/L.
CONCLUSION	The notified chemical is not toxic to algae up to and exceeding the limit of its water solubility in the test media.
TEST FACILITY	Huntingdon Life Sciences (1996a)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge from a wastewater treatment plant treating predominantly domestic wastewater.
Exposure Period	3 hours
Concentration Range	
Nominal	1, 10, 100 mg/L
Remarks – Method	The activated sludge study was conducted using sludge obtained from sewage treatment plant in Oakley, UK. The reference material used in the study was 3,5-dichlorophenol. The 3-hour EC50 for the notified substance to activated sludge could not be quantified as there was no inhibition at the highest nominal test concentration. However, the 3-hour EC50 for the notified substance to activated sludge is expected to be greater than 100 mg/L. The EC50 of the reference substance was 18.0 mg/L (95% confidence limits 15.2-21.6 mg/L), therefore confirming the suitability of the activated sludge.
RESULTS	
IC50	>100 mg/L
NOEC	100 mg/L
CONCLUSION	The ecotoxicity data indicates the notified chemical is not inhibitory to activated sludge up to 100 mg/L suspension.
TEST FACILITY	Huntingdon Life Sciences (1996b)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Up to 90% of the coatings containing the notified chemical will be applied to metal surfaces in industrial applications and the remaining 10% will be used as a clear finish for timber surfaces. No environmental exposure is expected at end use once the coating has dried to form a hard and durable paint matrix. The notified chemical in paints is fully encapsulated in the coatings matrix and as such is not likely to be released to the environment.

Up to 900 kg of waste may be generated during coating application by OEMs each year as a result of overspray. The majority of this waste will be sent to landfill for disposal. In landfill, the notified chemical in solid wastes is expected to be immobile, and eventually will degrade through biotic and abiotic processes, and consequently, should not result in a significant exposure to the environment.

A minimal amount of residual chemical (<5 kg per annum) will be disposed of through effluent from drum reclaiming establishments or to landfill. Spills of notified chemical to land are expected to bind to soil and are not expected to be mobile or affect groundwater due to very low water solubility. Spills of notified chemical to waters are not expected to dissolve, and may settle to sediment due to the lack of water solubility.

While no aquatic exposure is anticipated during normal usage of the coatings, there is a potential for aquatic exposure during application to timber surfaces should individual household users improperly dispose of unwanted paint waste to sewer, if the notified chemical is able to pass into discharge effluent from sewage treatment plants. The amount entering the aquatic environment in this manner cannot be determined; however, it is expected to be small owing to the low concentration in the coating products and the coatings are solvent-based, indicating that cleaning in water will not occur. In addition, the chemical is expected to bind to sediments and be retained in sewage sludge.

The majority of the notified chemical will be incorporated into coatings and is expected to remain bound within cured coatings at low levels on metal or timber substrates. Once the chemical is within a cured coating it is likely to share the fate of the substrate, which may involve recycling or landfill at the end of its useful lifetime.

Although the general characteristics of the notified chemical would indicate a moderate to high potential for bioaccumulation (Connell 1990), actual testing in a bioaccumulation study with carp found bioconcentration factors between 0.3-15 indicating that the chemical is not likely to bioaccumulate. In addition, low exposure expected to the aquatic environment would further reduce any potential for bioaccumulation.

9.1.2. Environment – effects assessment

The notified chemical is non-toxic to fish, daphnia, algae and sewage microorganisms up to the limit of its water solubility. The PNEC is calculated by taking the LC50 value and dividing this value by an assessment safety factor of 100 (OECD) for minimal algae/crustaceans/fish acute toxicity endpoints. This would give a PNEC value of >32 µg/L.

9.1.3. Environment – risk characterisation

No aquatic exposure is anticipated during manufacture and normal use of the chemical. During application of coatings, up to 900 kg/annum of notified chemical wastes could be generated. It is expected that practically all of this waste will be disposed of in approved landfills as inert solid waste. In landfill, the solid wastes should be contained and not pose a significant risk to the environment.

Very little will be released to water and it is not possible to calculate a reasonable predicted environmental concentration (PEC). However, as the notified chemical is not toxic to aquatic organisms up to the limit of its water solubility, it is estimated the risk quotient (PEC/PNEC) should be very small.

The above considerations indicate minimal risk to the environment when the notified chemical is used in the manner and levels indicated by the notifier.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported in tinplate drums as a solution at >50% concentration. The exposure for importation and distribution workers is expected to be negligible except in the event that the packaging is breached.

The main potential for occupational exposure is during blending operation leading to the preparation of end use products at the customer manufacturing facilities. Minimal exposure is expected at this stage, as blending/packaging operations will be closed systems except for QC testing.

However, the possibility of exposure to drips and spills exists during the processes of connection and disconnection of drums; preparation, cleaning, maintenance, and during product changeover. Dermal exposure would be the predominant route of occupational exposure to workers during these activities. Workers handling connections or equipment will be properly protected with PPE as recommend in the MSDS. Furthermore, the point at which the drum is opened and connected to blending vessels would be under the control of exhaust ventilation, to deal with the hazards associated with other ingredients such as pigments and solvents.

Exposure can also occur during industrial application (spraying) of the finished products. However, exposure will be minimal as these operations are either carried out in closed systems, workers are well equipped with combined particulate and organic vapour-element-equipped respirators or the direction of the strong ventilation prevents any contact of workers with the contaminated air. Furthermore, the notified chemical will be present at a very low concentration in finished product at this stage.

9.2.2. Public health – exposure assessment

The most prominent public exposure will occur by dermal contact through the use of clear-coats for timber. However, such exposure would be limited to several occasions per year, probably less than an hour for each occasion unless the person is a hobby cabinetmaker. Exposure would be minimal to public following in contact with the treated industrial material, as the notified chemical is encapsulated in the solid binder film following curing.

The public will only be exposed during the transport and handling of the notified chemical if there is an accident resulting in spillage. Therefore, the overall public exposure to the notified chemical will be low, due to the low concentration of the notified chemical handled and its use pattern.

9.2.3. Human health - effects assessment

The notified chemical was shown to be of low acute toxicity via the oral, dermal and inhalation routes in rats. It was not a skin sensitiser. Skin irritation potential was not determined in a separate study, however, it was concluded from an acute dermal toxicity study that the notified chemical was not a skin irritant. Severe irritant effects including conjunctival blistering to the eyes were seen on instillation of the notified chemical, however, these had resolved by 72 hrs and the notified chemical is not classified as an eye irritant.

The notified chemical was not mutagenic in bacteria, and was neither clastogenic in Chinese Hamster lung fibroblasts nor in mouse micronucleus in vivo test. In a 28-day oral repeat dose study, the NOAEL was >1000 mg/kg/day, the top dose.

Based on the available data, the notified chemical would not be classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). Due to the severity of the initial eye irritation reactions, the safety phrase 'Avoid contact with eyes' should be used for this chemical.

9.2.4. Occupational health and safety – risk characterisation

The main occupational exposure is expected for workers handling the notified chemical during blending operation leading to the preparation of end use products at the customer manufacturing facilities. However, for these workers, the risk of exposure is expected to be low, as blending/packaging operations will be closed systems except for QC testing.

The opportunity for skin exposure exists during product changeover and equipment maintenance. In these cases, workers handling connections or equipment will be properly

protected with PPE as recommended in the MSDS. At the formulation sites, the point at which the drum is opened and connected to the blending vessels would be under the control of exhaust ventilation to deal with the hazards associated with other ingredients such as pigments and solvents. Eye contact is only likely in the case of accidental splashes and is controlled by the use of safety glasses or goggles.

During transport, storage and distribution of the notified chemical and products containing the notified chemical, there is unlikely to be any worker exposure, except in the event of an accidental spill. Exposure after a spill should be controlled by the recommended practices for cleaning up of spills stated in the MSDS.

Overall, the occupational risk is low for handlers of the notified chemical, as the notified chemical is expected to have low hazard at the concentration used. The occupational risk would be further reduced due to the use of enclosed systems for blending/packaging, and the wearing of protective clothing during product changeover and equipment maintenance.

9.2.5. Public health – risk characterisation

The public will be mainly exposed to the notified chemical in do-it-yourself paint products and through industrial use of cured coatings. The notified chemical is expected to have low hazard at the low concentration used in finished products. Furthermore, exposure of the general public to the notified chemical as a result of its transport or through its use is assessed as being low. Therefore, the risk to the public resulting from the use of the notified chemical is expected to be very low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substance*.

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- Use the following safety phrase for products/mixtures containing the notified chemical at greater than 20%:
 - Avoid contact with eyes

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Exhaust ventilation when the drum is opened and connected, and enclosed system for blending/packaging.
 - Enclosed spray paint application system for industrial use.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and as diluted for use in the products:
 - Protective gloves, safety glasses or goggles or face shield and industrial clothing

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical.
- Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

- Wastes generated during industrial application should be disposed of through a licensed waste contractor. Wastes generated during domestic use should be disposed of according to the following instructions: "Do not pour leftover paint down the drain."
- Unwanted paint should be brushed out on newspaper, allowed to dry and then disposed of via domestic waste collections. Empty paint containers should be left open in a well-ventilated area to dry out. When dry, recycle steel containers via steel can recycling programs. Disposal of empty paint containers via domestic recycling programs may differ between local authorities. Check with your local council first."

Emergency procedures

- Spills/release of the notified chemical should be handled by absorbing with inert material and collection into a sealed container for disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Subsection 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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