File No STD/1074

4 February 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

C-3660

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Rohm and Haas Australia Pty Ltd (ABN 29 004 513 188) of 969 Burke Road Camberwell VIC 3124, and Plastral Fidene Pty Ltd (ABN 68 000 144 132) of 11B Lachlan Street Waterloo NSW 2017.

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 and Structural Formulae, Molecular Weight, Spectral Data, Purity, Hazardous and Non-hazardous Impurities, Additives/Adjuvants, Manufacture/Import Volume, and Site of Manufacture/Reformulation.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA and UK (year not specified)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
C-3660 Intermediate

3. COMPOSITION

DEGREE OF PURITY
High

4. INTRODUCTION AND USE INFORMATION

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

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	3-10	10-30	10-30	10-30	10-30

USE
As a heat stabiliser in PVC compounds for use mainly in extrusion and moulding of PVC pipes (domestic/commercial sewage and stormwater pipes), pipe fittings, construction panels and other building products such as cladding, siding, window profiles and other articles.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne and Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Rohm and Haas Australia Pty Ltd and Plastral Fidene Pty Ltd.

TRANSPORTATION AND PACKAGING
The new chemical C-3660 will be shipped and transported by road in closed head, 200 L steel drums from dockside to the notifier warehouses for storage, then to a number of customer plants for plastics processing. Storage will be under cover in bunded areas of the facilities.

5.2. Operation description

C-3660 intermediate is a liquid, but the final preparation form to be imported has not been yet decided.

At the customer plastics processing plants, C-3660 will be transferred either by gravity feed or means of a pump spear into a weighing container, which then be transferred to a 1000 L vessel for mixing with other ingredients. The mixing vessel is closed and the contents mixed under high speed by a mechanical stirrer until the mixture is homogeneous. The resulting PVC compound is a coarse, free flowing powder absorbing <5% w/w of the notified chemical, and runs via an enclosed chute to a cooling vessel. Once cooled, the powder will be conveyed via chute or auger-fed line into 500 L woven polypropylene bags for storage until it is required for moulding or extrusion.

For manufacturing PVC pipes and panels, the content of the 500 L storage bags will be transferred into hoppers where it is fed into moulding or extrusion machines. The moulded articles will be manually removed and stacked/packed for later sales and distributions to the construction industry.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Waterside, transport and warehouse workers	20-25	1-2 hours/day	10 days/ year
Mixing plant operators	5-10	6 hours/day	30-50 days/year
Moulding/Extrusion plant operators	15-30	8 hours/day	30-50 days/year

Exposure Details
It is anticipated that waterside, transport and warehouse workers would only be exposed to the new chemical in the event of an accidental spill. Should a spill occur, it is expected to be contained and absorbed with inert materials such as sand and earth, and placed into suitable containers for recovery or disposal in accord with the MSDS and government regulations.

In the mixing and moulding/extrusion plants, the potential routes of worker exposure to the notified chemical will be dermal contact and inhalation. Spillages and dust generation during pumping, mixing, cleaning, and moulding operations may also potentially cause mechanical irritation of the eyes, skin, nose, throat and mucous membranes. In addition, high dust concentrations within the manufacturing plant have a potential for combustion or explosion. The notifier indicates that adequate ventilation will be in place to prevent workers from breathing dust and particulates. The mixing and moulding equipment will also be fitted with local exhaust ventilation. A technical data sheet for a typical PVC resin used in the extrusion of unplasticised vinyl products indicates that up to 90% of dust particles are in the range of 80-250 μm which are not expected to remain airborne long enough to present an inhalation problem.

At the moulding machine where the PVC compound is heated at high temperatures for an extended period, fumes and vapours can be evolved, by breakdown of the notified chemical, containing oxides of

carbon, sulfur and other organic compounds. It is expected that these fumes will be captured and scrubbed. Cross contamination can be avoided by thorough cleaning of moulding and other processing equipment with purging compound prior to product changeover. Any incidents of accidental spillages will be contained and removed by mechanical means such as vacuuming or sweeping. It is intended that dust formation will be avoided and the release will be kept out of water supplies and sewers.

Operators of the mixing and moulding plants will wear appropriate respirators, dust goggles and safety glasses. Protective clothing and gloves will also be worn at all times. Copies of the MSDS will be readily accessible in all work areas.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Environmental exposure associated with the manufacture of the notified chemical will not occur in Australia. Release of the notified chemical to the environment during the mixing and moulding/extrusion processes is expected to be minimal. Approximately 100 kg per annum of the imported notified chemical is expected to be released as residue in import containers. When import drums are sent to drum reconditioners the residues removed during the cleaning process are flushed to on-site water treatment plant. The majority of the residue is expected to be adsorbed to sediments.

The mixing equipment and downstream pipe work are cleaned by vacuuming out any remaining powder resulting in approximately 25 kg of the notified chemical as waste. Any spills or leaks that occur during formulation of the PVC compound will be contained through bunding. A maximum of 100 kg of the notified chemical per annum is expected to be released via spills and leaks. Approximately 200 kg per annum of the notified chemical is estimated to be released in scrap generated during the extrusion process.

The majority of waste generated during formulation and extrusion/moulding (a total of up to 425 kg per annum of the notified chemical) will be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority (>95%) of the notified chemical will be encapsulated in the PVC products (eg PVC pipes, panels). Approximately 50% of the notified chemical will be used in PVC pipes and pipe fittings, the majority of which will be used in domestic and commercial sewerage and storm water pipes. The majority of the products will be disposed of to landfill at the end of their useful lives.

Although the new chemical is bound within the polymer matrix there may be some release from the surface of the PVC pipes and other articles through slow diffusion to the surface of the articles (a process called “blooming”) followed through loss via abrasion or slow dissolution in water (eg rain, drainage).

While no specific information on the blooming or surface migration of the notified chemical from the PVC products under typical conditions was provided, a summarised report (Rohm and Haas, 2003) was submitted by the company on the amount of extraction that occurs when PVC containing the chemical is immersed in water. Four different PVC blends using the OFS stabiliser technology were prepared. PVC sheets from the mill after 4 minutes were pressed using a heated hydraulic press into uniform plaques of 0.076 cm in thickness. The sample plaques were cut into 5.72 cm x 4.19 cm and combined to form a free-standing “X” shape. The total surface area exposed to the extraction media was 0.96 dm^2. The plaques were wiped clean with a paper towel soaked with distilled water and placed in 150 mL of distilled water for 10 days at 40ºC.

The water samples were analysed by performing a 10:1 extraction of the water with heptane to allow GC analysis of volatile components that migrated from the plaques over the 10 days. The heptane fraction was then analysed by GC/AED using the S-181 channel for detection. The method detection limit for the notified chemical was determined to be 0.953 ppb. The test results showed that the amounts of the chemical present in all water samples were less than the detection limit (and the limits for food contact). The 4 unknown peaks found in the carbon 193 trace (in all samples and blanks) were believed to be contaminants in the glass jar.

This was conducted on fresh material and it is unclear whether leaching would be higher from aged

PVC. According to the study the amount of the notified chemical released was less than $1.49x10^{-4}$ mg/dm^2. The percentage of chemical leached was estimated based on the data provided and using following assumptions and calculations.

Assumptions made were that:

- the detection limit of the method was equal to $1.49x10^{-4}$ mg/dm^2; and
- the specific gravity of PVC plaques was 1.45.

The total amount of the notified chemical released from the total exposed area was calculated to be less than $1.43x10^{-4}$ mg ($1.49x10^{-4}$ mg/dm^2 x 0.96 dm^2). Based on the thickness and sizes of the 2 plaques used to form the "X" shaped structure used in the study, its volume and weight were calculated to be 3.64 cm^3 and 5.28 g, respectively. The amount of the chemical in the "X" shaped structure was 20.6 mg (0.5% of the PVC weight) thus the amount of the notified chemical leached into the water (as a percent of the amount present in the PVC plaques) was estimated to be less than $6.9x10^{-4}$ %.

5.5. Disposal

Spilled material should be contained by absorbing onto dry inert material (eg sand), collected and disposed of to a licensed waste landfill. Spills and cleaning runoff should not be allowed to enter municipal sewers and open bodies of water. The MSDS recommends that the waste should be landfilled or incinerated in accordance with local, state and federal regulations.

The emptied import drums are sent to licensed drum reconditioners or sent directly to licensed waste landfill sites. The majority of the residue removed during the cleaning process is expected to be adsorbed to sludge during the wastewater treatment.

5.6. Public exposure

The notified chemical will not be sold to the public except in the form of finished articles (pipes, panels, cladding, etc). There is potential for widespread public exposure through dermal contact with plastic articles containing small amounts of the notified chemical. Indirect exposure will also potentially occur as the new chemical can migrate from PVC to the potable water or other food as beverages in contact with PVC pipes. Testing of extraction of the notified chemical from PVC plaques (notified chemical present at up to 0.5%) for 10 days at 40°C showed concentrations of notified chemical of less than the detection limit of the method of $1.5x10^{-4}$ mg/L (Rohm and Haas, 2003).

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa White, clear liquid with a slight odour

Boiling Point 257-261ºC

Remarks Test report not provided.

Density 1010 kg/m^3

Remarks Test report not provided.

Vapour Pressure $1.7x10^{-5}$ kPa at 25ºC

METHOD OECD TG 104 Vapour Pressure – Gas Saturation Method.
EC Directive 92/69/EEC A.4 Vapour Pressure.

Remarks The vapour pressure at 25ºC was extrapolated by linear regression from the values determined at 50ºC, 60ºC, and 70ºC.
The notified chemical is slightly to moderately volatile (Mensink et al., 1995).

TEST FACILITY RCC (2001b)

Water Solubility $5.76x10^{-3}$ g/L at 20ºC

METHOD OECD TG 105 Water Solubility.

EC Directive 92/69/EEC A.6 Water Solubility.

Remarks A flask method together with HPLC analysis was used. The pH of the saturated test solutions was in the range of 3.48-3.53.
The notified chemical is slightly soluble (Mensink et al., 1995).

TEST FACILITY HLS (2000)

Hydrolysis as a Function of pH Not determined

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.

Remarks As the solubility of the notified chemical in the different buffer solutions pH 4.0, pH 7.0 and pH 9.0 is low, a hydrolysis test could not be performed. Additionally, its solubility could not be increased with solubilisers as methanol, acetonitrile and acetone.

TEST FACILITY RCC (2001c)

Partition Coefficient (n-octanol/water) log Pow = 5.4 at 20°C

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks HPLC method was used.

TEST FACILITY HLS (2000)

Adsorption/Desorption log Koc = 3.22 or higher (based on water solubility)
log Koc = 4.31 (based on log Pow)

Remarks The Koc estimates using regression equations were 1666 (or higher) and 20635 based on a water solubility of 5.76 mg/L and a log Pow of 5.4 respectively.
The notified chemical is poorly mobile to mobile in soils (Mensink et al. 1995).

TEST FACILITY RCC (2001d)

Dissociation Constant Not determined

Remarks The notified chemical does not contain any dissociable groups.

Particle Size Not applicable

Remarks The notified chemical is a liquid.

Surface Tension 52 mN/m at 21°C

Remarks Test report not provided.

Flash Point 97°C (Pensky-Martens Closed Cup)

Remarks Test report not provided.

Flammability Limits Not flammable

Remarks Test report not provided.

Autoignition Temperature 245°C

Remarks Test report not provided.

Explosive Properties Not explosive

Remarks Based on UN recommendation on the transport of dangerous goods, the notified chemical was considered not a potential explosive and not to have potential for

rapid energy release.

Reactivity Stable under normal environmental conditions

Remarks The notified chemical may react with strong oxidisers.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rat, acute inhalation	no data available
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation (1% notified chemical)
Rat, repeat dose oral toxicity - 28 days	NOEL = 2000 ppm; NOAEL = 8000 ppm
90 days	NOEL = 3000 ppm; NOAEL = 10000 ppm
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	non geno toxic
in vitro gene mutation test	non geno toxic
Pharmacokinetic/Toxicokinetic studies	no data available
Developmental and reproductive effects	no data available
Carcinogenicity	no data available

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 96/54/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain Rat/HanCrl: Wist Han (Glx: BRL)BR
Vehicle PEG 300: dose volume 10 mL/kg bw
Remarks – Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 males	2000	0/3
II	3 females	2000	0/3

LD50 >2000 mg/kg bw
Signs of Toxicity One female showed slight sedation, ataxia and hunched posture on the day of treatment. No further clinical signs were recorded. The body weight was within the historical range.
Effects in Organs No macroscopic findings were observed at necropsy.
Remarks – Results None.

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

TEST FACILITY RCC (2001e)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD OECD TG 402 Acute Dermal Toxicity.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain Rat/HanCrl: Wist Han (Glx: BRL)BR
Vehicle None – applied undiluted as supplied
Type of dressing Semi-occlusive.
Remarks – Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 males	2000	0/5
II	5 females	2000	0/5

LD50 >2000 mg/kg bw
Signs of Toxicity – Local Slight scaling on the back was seen for one male on days 7 to 9.
Signs of Toxicity – Systemic No systemic signs of toxicity were observed.
Effects in Organs No macroscopic findings were observed at necropsy.
Remarks – Results None.

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

TEST FACILITY RCC (2001f)

7.3. Acute toxicity – inhalation

Remark Test was not performed due to low volatility of the notified chemical.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 1 male, 2 females
Vehicle None – applied undiluted as supplied
Observation Period 10 days
Type of Dressing Semi-occlusive
Remarks – Method No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.33	1.33	1.33	2	7 days	0
Oedema	0.00	0.00	0.00	0	0 days	0

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

Remarks – Results Slight to well-defined erythema was observed in all animals 1 h after treatment and persisted in the male for 24 h, in one female for 72 h and in the other female for 7 days. The latter female was also noted with scaling 7 days after treatment. Oedema was not noted at any scoring interval. On day 10 at termination, no signs of irritation were observed at the test site of any animal. Primary irritation index = 1.17 (slightly irritating).

CONCLUSION	The notified chemical is slightly irritating to skin.
TEST FACILITY	RCC (2001g)

7.5. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	1 male, 2 females
Observation Period	7 days
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.7	0.7	1.0	1	72 h	0
Conjunctiva: chemosis	0	0	0	0	0 h	0
Conjunctiva: discharge	No abnormal findings			--	--	--
Corneal opacity	0	0	0	0	0 h	0
Iridial inflammation	0	0	0	0	0 h	0

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

Remarks - Results	Slight reddening of the sclera was seen in two animals at the 1 h observation. All effects cleared by 7 days.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	RCC (2001h)

7.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation – Maximization Test. EC Directive 96/54/EC B.6 Skin Sensitisation – Maximization Test.
Species/Strain	Guinea pig/Albino Himalayan spotted
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 100% test substance topical: 1% test substance in PEG 300
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal injection (day 1): 100% test substance topical application (day 8): 100% test substance
Signs of Irritation	Discrete/patchy erythema was observed in all test animals 24 h and 48 h after epidermal induction, whereas no skin reaction was observed in the control animals.
CHALLENGE PHASE	
1st challenge	topical application: 1% test substance in PEG 300
Remarks - Method	In the irritation pretests, slight erythema was observed for all concentrations tested between 5% and 100% notified chemical.

The intradermal induction was stated in the report to include two injections of 100% notified chemical. Based on the control group, one of those would have been expected to be 50% notified chemical in Freund's Complete Adjuvant and saline.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*	
		24 h	*48 h*
Test Group	1%	0/10	0/10
Control Group	1%	0/5	0/5

Remarks - Results

No skin reaction was observed in any test and control animal after the challenge with either 1% test substance or PEG 300 alone. Positive controls with 1% 2-mercaptobenzothiazole in mineral oil confirmed the sensitivity of the test system.

One control animal showed a loss of body weight (3%) whereas two animals of the test group did not gain weight during the acclimatisation period. The body weight of the other animals was within the historical range.

CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test (1% notified chemical).

TEST FACILITY

RCC (2001i)

7.7a. Repeat dose toxicity – 28 day oral

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 407 Repeated Dose 28-Day Oral Toxicity in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
US EPA OPPTS 870.3050: Repeated Dose 28-Day Oral Toxicity in Rodents.

Species/Strain: Rat/Crl:CDBR
Route of Administration: Oral – diet
Exposure Information: Total exposure days: 28 days;
Dose regimen: 7 days per week;
Post-exposure observation period: none
Vehicle: Acetone
Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose ppm*	*Mortality*
I (control)	5 males, 5 females	0	0/10
II (low dose)	5 males, 5 females	500	0/10
III (mid dose)	5 males, 5 females	2000	0/10
IV (high dose)	5 males, 5 females	8000	0/10

Mortality and Time to Death

There were no mortalities in either sex at any dose level.

Clinical Observations

No treatment related systemic or neurologic effects were seen in the daily clinical observations, the Detailed Clinical Observations or Functional Observational Battery parameters, or motor activity in either sex at any time at any dose level. There were no treatment related effects on body weight, cumulative body weight gain,

or feed consumption in either sex at any dose level.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No treatment related effects on haematology parameters, white blood cell differential counts, or clinical chemistry parameters were observed in either sex at any dose level.

Effects in Organs

There were no treatment related effects on organ weights in females at any dose level, or in males treated at 500 or 2000 ppm. A statistically significant increase in relative liver weight (13%) was observed in Group IV (8000 ppm) males. Absolute liver weight was also increased (15%) in this male group although not statistically significant. No treatment related gross or microscopic pathological findings were observed in either sex at any dose level.

Remarks – Results

Changes in the following parameters were recorded as statistically significant:

Platelets: 12% and 17% decreases in Groups II and III males respectively.
Haematocrit: 7% decrease in Group IV females
RBC: slight decrease in Group IV females (not significant)
Cholesterol: 49% increase in Group IV males

However, these changes were not considered treatment related since they were small in magnitude, observed only in one sex, no evidence of a dose response, and there were no corresponding changes in histopathology (bone marrow or spleen) or other haematologic parameters. Regarding cholesterol, a couple of males in the control group had cholesterol values at the low end of the range, which was expected to cause the high dose group to be flagged as statistically significant.

The observed effects in organs above were also not considered adverse since they were small in magnitude and there were no correlative gross or histopathological findings.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 8000 ppm (equivalent to 549.0 and 603.4 mg/kg bw/day in males and females, respectively), which is the highest dose tested in this study. The NOEL was 2000 ppm (equivalent to 134.1 and 155.0 mg/kg bw/day in males and females, respectively).

TEST FACILITY RHC (2001a)

7.7b. Repeat dose toxicity – 90 day oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 408 Repeated Dose 90-Day Oral Toxicity in Rodents. EC Directive 87/302/EEC B. Subchronic Oral Toxicity Test. US EPA OPPTS 870.3100: 90-Day Oral Toxicity in Rodents. Japan MAFF, 59 NohSan No. 4200: Subchronic Oral Toxicity Test.
Species/Strain	Rat/Crl:CDBR
Route of Administration	Oral – diet
Exposure Information	Total exposure days: 90 days; Dose regimen: 7 days per week; Post-exposure observation period: none
Vehicle	Acetone
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose ppm/day*	*Mortality*
I (control)	10 males, 10 females	0	0/10
II (low dose)	10 males, 10 females	1000	0/10
III (mid dose)	10 males, 10 females	3000	0/10

IV (high dose)	10 males, 10 females	10000	0/10

Mortality and Time to Death
There were no mortalities in either sex at any dose level.

Clinical Observations
No treatment related systemic or neurologic effects were seen in the daily clinical observations, the Detailed Clinical Observations or Functional Observational Battery parameters, or motor activity in either sex at any time at any dose level. There were no treatment related effects on body weight, cumulative body weight gain, or feed consumption in either sex at any dose level.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment related effects on haematology parameters, white blood cell differential counts, or clinical chemistry parameters were observed in either sex at any dose level.

Effects in Organs
There were no treatment related effects on organ weights in either sex treated at 1000 or 3000 ppm. A statistically significant increase in absolute (14%) and relative (9%) kidney weight was observed in Group IV (10000 ppm) females. Relative liver weight was significantly increased in Group IV (10000 ppm) males (10%) and females (8%). Absolute liver weight was also increased although not statistically significant in Group IV males (7%) and females (14%). No treatment related gross or microscopic pathological findings were observed in either sex at any dose level. All findings were low in incidence, occurred sporadically, and provided no evidence of a dose-response.

Remarks – Results
In Group IV (10000 ppm) males, statistically significant decreases in haematocrit (9%), haemoglobin (8%), and RBC count (11%) were observed. These changes were considered resulted from one male animal in the control (0 ppm) group whose values for haematocrit, haemoglobin, and RBC count were unusually high. Also, similar changes were not seen in the high dose (10000 ppm) females, where compound intake was greater (22% on average) than that observed in the high dose males.

Statistically significant decreases in total protein (6%), creatinine (18%), and globulin (13%) observed in Group IV (10000 ppm) males were judged incidental since they were small in magnitude, observed only in one sex, and there were no corresponding changes in histopathology or other clinical chemistry parameters.

The observed effects in organs above were also not considered adverse since they were small in magnitude and there were no correlative gross or histopathological findings.

Overall, it is noted that changes in liver weight, haematocrit, RBC count were seen in both 28- and 90-day studies, with haematology not being consistent by sex.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 10000 ppm (equivalent to 657.4 and 801.1 mg/kg bw/day in males and females, respectively), which is the highest dose tested in this study. The NOEL was 3000 ppm (equivalent to 193.5 and 236.9 mg/kg bw/day in males and females, respectively).

TEST FACILITY RHC (2002)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 92/69/EEC B.14 Bacterial Reverse Mutation Test. US EPA OPPTS 870.5100: Bacterial Reverse Mutation Test. Plate incorporation procedure.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in	a) With metabolic activation: 48.5 – 5000 µg/plate.

Main Test	b) Without metabolic activation: 48.5 – 5000 µg/plate.
Vehicle	Acetone
Remarks – Method	Two independent tests were conducted in triplicate.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation (Oily residue)*	*Genotoxic Effect*
Absent				
Test 1	Not performed	>5000	≥2000	Negative
Test 2	Not performed	>4800	≥1940	Negative
Present				
Test 1	Not performed	>5000	≥2000	Negative
Test 2	Not performed	>4800	≥1940	Negative

Remarks – Results	The vehicle and positive controls responded appropriately.

CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	RHC (2001b)

7.9a. Genotoxicity – in vitro (Chromosomal aberration)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test. EC Directive 92/69/EEC B.10 Mutagenicity - In vitro Mammalian Cytogenetic Test. US EPA OPPTS 870.5375: In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Chinese Hamster Ovary (CHO-WBL) cells
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Vehicle	Acetone
Remarks – Method	No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	20.4, 29.2, 41.7, 59.5*, 85.0, 122, 173*, 248, 354, 505*, 720, 1030*, 1470, 2100, 3000	3.0 h	20.3 h
Test 2	31.8*, 63.5*, 127*, 253*, 505, 1010	17.6 h	20.0 h
Present			
Test 1	20.4, 29.2, 41.7, 59.5, 85.0, 122, 173*, 248*, 354, 505*, 720, 1030*, 1470, 2100, 3000	3.0 h	20.3 h
Test 2	63.5, 127*, 253*, 505*, 1010*	3.0 h	20.0 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	Not performed	>3000	≥1030	Negative
Test 2	Not performed	≥253	≥1010	Negative
Present				
Test 1	Not performed	≥20.4	≥1030	Negative

Test 2	Not performed	≥1010	≥1010	Negative

Remarks – Results The vehicle, negative and positive controls responded appropriately.

CONCLUSION The notified chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test

TEST FACILITY Covance (2001a)

7.9b. Genotoxicity – in vitro (Gene mutation)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
US EPA OPPTS 870.5300: In vitro Mammalian Cell Gene Mutation Test.

Cell Type/Cell Line Chinese Hamster Ovary (CHO-K1-BH_4) cells
Metabolic Activation System S9 fraction from Aroclor 1254 induced rat liver.
Vehicle Acetone
Remarks – Method No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Preliminary Test	5.9, 11.8, 23.5, 47, 94, 188, 375, 750, 1500, 3000	4 h	6 days	--
Test 1	50, 75, 100, 200, 300*, 400*, 500*, 600*, 750*, 1000*, 1500, 2000, 3000	4 h	7 days	7 days
Test 2	25*, 50*, 100*, 200, 400*, 600, 800*, 1000, 1200*	4 h	7 days	7 days
Present				
Preliminary Test	5.9, 11.8, 23.5, 47, 94, 188, 375, 750, 1500, 3000	4 h	6 days	--
Test 1	125*, 250*, 500*, 750*, 1500*, 3000*	4 h	7 days	7 days
Test 2	31.3*, 62.5*, 125*, 250, 500*, 750*, 1500, 3000*	4 h	7 days	7 days

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥94	≥300	≥300	Negative
Test 2	--	≥1200	≥100	Negative
Present				
Test 1	>3000	>3000	≥1500	Negative
Test 2		>3000	≥3000	Negative

Remarks - Results The vehicle, negative and positive controls responded appropriately.
High cytotoxicity seen in the absence of metabolic activation in the preliminary test ≥94 µg/mL was not replicated in the main tests.
Mutant frequencies in a number of cultures, both in the presence and absence of metabolic activation, showed significant increases compared with controls. However, no dose-response was seen in any case, and the increases were not reproducible. In addition, none of the treated cultures induced a mutant frequency higher than the criterion for a position response of $15x10^6$.

CONCLUSION The notified chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test

TEST FACILITY Covance (2001b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test (Edition 1993). EC Directive 92/69/EEC Annex L 383 A C.4-D.
Inoculum	Activated sludge obtained from a communal wastewater treatment plant (a mixture of polyvalent bacteria)
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical Oxygen Demand (BOD)
Remarks - Method	In addition to the test substance (100 mg/L), samples containing a reference substance (sodium benzoate at 100 mg/L) and inoculum, inhibition and abiotic sterile controls were measured. The test substance was introduced directly to the test system as it was not completely soluble in the test medium.

RESULTS

	% degradation	
Day	*Test substance*	*Sodium benzoate*
2	7	51
4	32	58
8	39	66
10	42	66
14	45	74
22	48	83
28	48	85

Remarks - Results	The test substance degraded only up to 48% in 28 days and did not achieve the 60% biodegradability either within the 10-day window or after 28 days. Degradation of the reference substance up to 85% validates the test system.
CONCLUSION	The test substance is not readily biodegradable according to the OECD criteria.
TEST FACILITY	Solvias AG (2001a)

8.1.2. Bioaccumulation

No bioaccumulation data were provided. The substance is a lipophilic, neutral organic molecule of relatively low molecular weight thus has a potential to bioaccumulate as it can be expected to passively diffuse across biological membranes. However, the notifier expects it will metabolise readily as it contains heteroatoms and ester functionality, which typically break down quickly.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical

METHOD	OECD TG 203 Fish, Acute Toxicity Test EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Semi-static
Species	Rainbow trout (*Oncorhynchus mykiss)*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	142 mg $CaCO_3$/L
Analytical Monitoring	Samples from test solutions and control medium were drawn from the approximate centre of the test vessels at the beginning and end of each renewal period (every 24 hours) and analysed by HPLC.
Remarks – Method	Based on preliminary test results that showed no mortality at 100 mg/L (nominal) the definitive test was carried out as a limit test at 100 mg/L. The stock solution (of 100 mg/L) was prepared by stirring 1 g of test substance in 10 L fish water continuously for about 48 hours and filtered through a 0.45 µm filter after equilibration. The stock solutions were changed every 24 hours due to the tendency of the test substance to form droplets in the test medium. The measured start concentrations of test media varied from 3.10 mg/L to 22.2 mg/L and the end concentrations varied from 1.55 mg/L to 10.2 mg/L. The fluctuations within the start values were stated to be due to small amounts of undissolved test substance that escaped through the filter. Attempts to use a smaller size filter (0.22 µm) were not successful due to clogging up of its pores. Since large volumes of test medium were required the use of the larger filter remained the practical option. The report indicated that the concentrations of the test solution always remained above the limit of water solubility of the test substance. Oxygen content, pH and temperature were all satisfactorily maintained.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*				
Nominal		*2-4 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0	0
100	10	0	0	0	0	0

LC50	>100 mg/L (nominal) or >9.3 mg/L mean measured concentration at 96 hours.
NOEC (or LOEC)	100 mg/L (nominal) or 9.3 mg/L mean measured concentration at 96 hours (the highest concentration tested).
Remarks – Results	No sublethal effects were observed in the control or in the test concentration of 100 mg/L.
CONCLUSION	The test substance is not toxic to fish up to the limit of its water solubility.
TEST FACILITY	Solvias AG (2001b)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation and Reproduction Test EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None

Water Hardness	160 mg $CaCO_3$/L
Analytical Monitoring	Samples from test solutions and control medium were drawn from the approximate centre of the test vessels at the beginning and end of the exposure period and analysed by HPLC.
Remarks - Method	A range finding test was performed with a nominal test concentration of 100 mg/L. The stock solution for the definitive test was prepared by dissolving 100.3 mg of test substance in 1000 mL of test medium, which was then homogenised by ultrasonic treatment for 20 minutes. The solution was stirred continuously for about 48 hours and filtered through a 0.45 µm filter after equilibration. The filtrate was used to prepare the diluted test solutions. Oxygen content, pH and temperature were all satisfactorily maintained.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*% Immobilised*	
		24 h	*48 h*
Control	20	0	0
4.3	20	0	0
9.4	20	0	0
21	20	0	0
45	20	0	0
100	20	25	100

LC50	>45 mg/L (nominal)* or >2.24 mg/L (measured concentration at 48 h)
NOEC	>45 mg/L (nominal)* or >2.24 mg/L (measured concentration at 48 h) *Considered as the functional water solubility of the test substance, see below.
Remarks - Results	Small droplets of the test substance were observed at the surface of the water in the 100 mg/L nominal test concentration. The starting concentrations in tests with the nominal concentrations of 45 and 100 mg/L were measured to be 2.24 and 5.54 mg/L, respectively. After 48 hours, the concentration of the test substance could be determined only in the highest test concentration as 3.38 mg/L. The concentrations in the other test solutions and control were below the detection limit of the analytical method. At the highest test concentration, all the daphnia were trapped in the test substance droplets formed at the surface of the test solution. Trapping of the test organism in droplets was considered as a physical effect, therefore the results of the highest test concentration were regarded as invalid and excluded from determination of the final results. The next highest test concentration of 45 mg/L (nominal) was considered as the functional water solubility of the test substance. No sublethal effects were observed in the control or in any of the test concentrations after 48 hours.
CONCLUSION	The test substance is not toxic to *Daphnia magna* up to the limit of its water solubility.
TEST FACILITY	Solvias AG (2001c)

8.2.3. Algal growth inhibition – Test 1

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 (Pseudokirchneriella subcapitata)*
Exposure Period	72 hours
Concentration Range	
Nominal	0, 4.3, 9.4, 21, 45 and 100 mg/L (based on the results of a range finding test)
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Duplicate samples from test media (without algae) freshly prepared (at the start of test), or incubated under the same conditions as in the actual test without algae (at the end of test) of all test concentrations and the control were obtained for analysis by HPLC.
Remarks - Method	The stock solution for the definitive test was prepared by dissolving 100.0 mg of test substance in 1000 mL of test medium, which was then homogenised by ultrasonic treatment for 15 minutes. The solution was stirred continuously for about 48 hours and filtered through a 0.45 µm filter after equilibration. The filtrate was used to prepare the test solutions. The highest test concentration was also tested without algae to determine the particle background. The lighting and temperature were satisfactorily maintained. The pH of the control increased from 7.7 at the start to a maximum of 10.1 at the end of the test exceeding the tolerance of 1 unit recommended by the guideline. This effect was attributed to the increased consumption of CO_2 due to the rapid growth within the 72 hours (increasing the cell density to 66.6 x 10^4 cells per mL).

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOEC mg/L at 72 h*	*E_rC50 mg/L at 72 h*	*NOEC mg/L at 72 h*
>4.67*	2.02	≈4.67*	2.02

* Confidence intervals not determined.

Remarks – Results	The actual concentration of the highest test concentration at the start was measured as 4.67 mg/L and was considered to be the functional water solubility of the test item in algae medium. Only the two highest test concentrations (45 and 100 mg/L nominal) could be determined analytically at the start of the test (2.02 and 4.67 mg/L) due to the poor solubility and the relatively high limit of quantification of the test substance (1.1 mg/L). The measured concentration of 4.67 mg/L corresponded to the measured concentration of the stock solution. Using the dilution factor used in the test, the three lowest actual test concentrations at the start of test were estimated to be 0.20, 0.44 and 0.98 mg/L. The EC50 values are determined based on the measured concentrations. After 72 hours, no mis-shaped cells or cell debris were observed microscopically.
CONCLUSION	The test substance is toxic to algae.
TEST FACILITY	Solvias AG (2001d)

8.2.4. Algal growth inhibition – Test 2

TEST SUBSTANCE	Notified chemical

METHOD	OECD TG 201 Alga, Growth Inhibition Test EC Guideline Annex V - Part C.3 Algal Inhibition Test OPPTS Draft Guideline 850.5400
Species	*Selenastrum capricornutum (Pseudokirchneriella subcapitata)*
Exposure Period	96 hours
Concentration Range	
Nominal	5.9, 12, 24, 47 and 94 mg/L (derived from a water accommodated fraction (WAF) of a 94 mg/L mixture).
Actual (geometric mean)	
72 hour	0.089, 0.22, 0.79, 1.5 and 3.3 mg/L
96 hour	0.058, 0.11, 0.37, 1.1 and 2.8 mg/L
Auxiliary Solvent	None
Water Hardness	Standard algal assay procedure (AAP) medium was used to prepare the test solutions.
Analytical Monitoring	Gas chromatography
Remarks - Method	Due to the limited solubility of the test substance in the algal medium, the stock solution was prepared as a WAF. A 94 mg/L mixture was prepared by adding 0.4004 g of the C-3660 to 400 mL of algal medium and stirring for approximately 24 hours. The solution was cloudy white with fine particulates of undissolved test substance and was observed to be cloudy with test substance settled at the bottom after allowing to settle down to approximately 1.5 hours. The WAF was siphoned from just below the solution surface and centrifuged at 2500 rpm for 30 minutes. The solution removed by pipette (slightly cloudy white) was used to prepare the test solutions. An algistatic/algicidal recovery phase was initiated at the termination of the definitive test with a composite sample of the three replicate vessels at the 94 mg/L treatment. The sample was diluted with fresh AAP medium to a nominal concentration of 5.9 mg/L to prepare a subculture that was incubated for six days under conditions consistent with those maintained in the definitive test. The subculture was microscopically examined every other day to monitor cell growth. The lighting and temperature were satisfactorily maintained. The pH of the test and control solutions ranged from 7.1 to 7.2 at the start and from 7.0 to 7.9 at 96 hours; variation was considered to be due to photosynthesis.

RESULTS

End Point	*EC50* *mg/L*	*NOEC* *mg/L*
96 h cell density	0.34	0.11
95% Confidence limits	0.28–0.43	
72 h Biomass	$E_bC50 = 0.52$	<0.089
95% Confidence limits	0.41–0.60	(EC10 = 0.069)
72 h Growth rate	$E_rC50 = 0.90$	0.22
95% Confidence limits	0.73–1.0	

Remarks - Results	The analysis of the WAF at the beginning of the test indicated that the amount of the test substance present in the solutions (3.9 mg/L) was representative of its water solubility limit. The EC50 and NOEC values were based on the geometric mean measured concentrations. A sample from the 24 mg/L (nominal) tested without algae present indicated that as the algal cell density increased, the concentration of the test substance decreased at faster rate. The recovery phase results indicated that the test substance has an algistatic, rather than an algicidal effect on the growth of *Selenastrum capricornutum* at a geometric mean

	concentration of 2.8 mg/L.
CONCLUSION	The test substance is very toxic to algae although the inhibition of cell density was determined to be algistatic rather than algicidal.
TEST FACILITY	Springborn Smithers (2002)

8.2.5. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test EC Directive 67/548/EEC, Annex L 133 Part C (Edition 1988)
Inoculum	Activated sludge from a communal wastewater treatment plant
Exposure Period	3 hours
Concentration Range	
Nominal	25.6, 64, 160, 400 and 1000 mg/L
Remarks – Method	Test concentrations of the reference substance (3,5-dichlorophenol) were 3.2, 10 and 32 mg/L.
RESULTS	
IC50	> 1000 mg/L
NOEC	1000 mg/L (highest concentration tested)
Remarks – Results	The percentage inhibition of the respiration rate caused by the test substance was between 3.8 and 22.3. Therefore, an IC50 value for the test substance was not calculated. However, it was concluded as higher than the highest test concentration tested (1000 mg/L, which is far above the limit of water solubility of the test substance). The IC50 of the reference substance was 7.9 mg/L, thus validating the test.
CONCLUSION	The test substance was not toxic to bacteria in activated sludge.
TEST FACILITY	Solvias AG (2001e)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The majority of waste containing the notified chemical generated during formulation and extrusion or moulding is expected to be disposed of to landfill. Some of this may be recycled or incinerated. Up to 100 kg per annum of the notified chemical will be flushed to on-site water treatment plants during cleaning of import drums at the drum reconditioning facilities. The high log Pow and log Koc values and the low water solubility of the notified chemical indicates a high affinity for the organic phase and component of soils and sediments. Therefore, the majority of the notified chemical entering the treatment facility is expected to be adsorbed to sludge, which will be disposed of to landfill.

At the end of their serviceable lives it is expected that most of the PVC pipes and other construction materials would be placed into landfill. Some may be incinerated destroying the new chemical with production of water vapour and oxides of carbon and sulphur. Very little PVC is currently recycled due to the presence of additives. In landfill, the PVC matrix is expected to be slowly broken down through biological and abiotic processes and will release the new chemical. Even if released to the soil, the new chemical is expected to be relatively immobile due to being adsorbed to soils and sediments. Although not ready biodegradable, it is anticipated that prolonged residence in an active landfill environment would eventually degrade

the notified chemical due to abiotic or slow biotic processes to give water vapour and oxides of carbon and sulphur.

Some slow and continuing release of the notified chemical is also expected from the surfaces of PVC pipes and other articles during their service lives, and though difficult to quantify, it is not anticipated to be large. The results of an extraction study are summarised under Section 5.4. Based on the results of this study, the amount of the notified chemical leached into the water (as a percent of the amount present in the PVC plaques) was estimated to be 6.9×10^{-4} %. This suggests that the notified chemical is not very mobile in the PVC and that loss through leaching can be expected to be very low.

The lipophilic nature and the relatively low molecular weight of the notified chemical indicates a potential to bioaccumulate as it can be expected to passively diffuse across biological membranes. However, metabolism is expected to limit this potential.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests (all end points are based on measured concentrations) are listed below.

Organism	*Duration*	*End Point*	*mg/L*
Fish	96-h	LC50	> 9.3
Daphnia	48-h	EC50	> 2.24
Green algae - Test 1	72-h	E_bC50	>4.67
	72-h	E_rC50	4.67
Green algae - Test 2	96-h	EC50 Cell density	0.34
	72-h	E_bC50	0.52
	72-h	E_rC50	0.90

A predicted no effect concentration (PNEC - aquatic ecosystems) of 3.4×10^{-3} mg/L (3.4 µg/L) has been derived by dividing the end point value of 0.34 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels).

9.1.3. Environment – risk characterisation

The majority of the notified chemical will eventually be disposed of to landfill, including the PVC products at the end of their useful lives. The majority of the small amount of residue chemical in empty containers is expected to be adsorbed to the sludge in the on-site wastewater treatment plants, thus limiting release to the aquatic environment

Considering the potential of the notified chemical to be released slowly and continuously from the surfaces of PVC pipes and other articles during their service lives, the following worst-case scenario was used to determine the predicted environmental concentrations (PECs). It is estimated that approximately 50% of the notified chemical will be used in PVC pipes and fittings of which the majority will be used in domestic and commercial sewerage and storm water pipes. It is assumed that 50% of the chemical (up to 15 tonnes) is used in sewerage pipes and pipe fittings and that 10% is released from the pipes to the sewer annually.

Assuming a national population of 19.5 million and that each person contributes an average 200 L/day to overall sewage flows, the daily release on a nationwide basis to receiving waters is estimated to be 4.11 kg/day, the predicted concentration in sewage effluent on a nationwide basis is estimated as 1.05 µg/L. Based on dilution factors of 1 and 10 for inland and ocean discharges of STP-treated effluents, the PECs of the notified chemical in freshwater and marine water may approximate 1.05 µg/L or 0.105 µg/L, respectively.

The risk quotient (PEC/PNEC ratio) for the aquatic environment assuming nationwide use, based on the worst-case assumptions given above is 0.31. The actual PEC and risk quotient values could be expected to be considerably lower, given that the level of exposure of the notified chemical will further reduce due to:

- the much lower (than the assumed values) release of the chemical to the sewer system via

pipes and pipe fittings;
- the removal via treatment and/or degradation in sewerage treatment facilities; and
- the chemical adsorbing to the sediments in the aquatic environment.

The notified chemical is also used in storm water pipes and pipe fittings. Based on the results of the extraction study summarised under Section 5.4, the concentration of the notified chemical migrated to the water was less than the method detection limit of 0.953 μg/L. If it is assumed that the PEC of the notified chemical in stormwater is equal to 0.953 μg/L, the resulting risk quotient is 0.28. The concentration of the chemical can be expected to be considerably lower than the above due to dilution in the stormwater system, and due to lack of time for equilibration, thus reducing the quotient further.

Therefore, although the notified chemical has a potential to bioaccumulate, it is unlikely that it would exist at levels which could pose a threat to aquatic organisms or to bioaccumulate. Based on the proposed use pattern, the release of the notified chemical to the environment is expected to be very low. Abiotic or slow biotic processes are expected to be largely responsible for the eventual degradation of the notified polymer as it is not readily biodegradable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During transport and storage, workers are unlikely to be exposed to the notified chemical. In the event of an accident, spills will be removed in accord with the MSDS and government regulations.

Inhalation, dermal and ocular exposure will potentially occur during certain formulation and plastics processing procedures due to spillages and possible splashes if the chemical is to be imported in a liquid form, particularly when it is presented as pure or in concentrated products. However, exposure to significant amounts of the notified chemical is limited because of the engineering controls and personal protective equipment worn by workers. Employers are responsible for maintaining the level of atmospheric nuisance dust below the NOHSC exposure standard of 10 mg/m^3 TWA (NOHSC, 1995). Personal protective equipment (impervious gloves, dust/vapour respirators, safety glasses and protective clothing) is also required for protection of workers against hot processes.

9.2.2. Public health – exposure assessment

The notified chemical is intended only for use in the plastic manufacturing industry. It will not be sold to the public except in the form of finished articles, which is inert, chemically stable and unlikely to be bioavailable. The public exposure is therefore determined to be low.

With regard to the indirect exposure, the notified chemical has a low migration rate and will be diluted in a large volume of potable water (or others) circulating in pipes, thus the amounts can be assessed negligible. The results of an extraction test (Rohm and Haas, 2003) showing that the amounts of C-2330 in the water were well below the limits for food contact have substantiated this conclusion.

9.2.3. Human health - effects assessment

The notified chemical has a low acute oral and dermal toxicity in rats (LD50>2000 mg/kg/bw). It is slightly irritating to the skin and eyes of the rabbit, and shows no sensitising activity at 1% solution in an adjuvant study in guinea pigs. The NOAEL were established to be 8000 ppm and 10000 ppm in a 28- and 90-day repeat dose oral study in rats respectively. Changes recorded in liver weight, haematocrit, RBC count were not considered adverse since they were small in magnitude and there were no correlative gross or histopathological findings, however these were noted in both studies, with haematology not being consistent by sex.

It was not a mutagenic in a bacterial reverse mutation assay, and did not reveal any genotoxic potential in vitro.

Based on the available data, the notified chemical will not be classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002). However, the MSDS indicates that dust and/or mist generated from processing of the notified chemical may cause mechanical irritation to the eyes and respiratory tract if inhaled. Repeated or prolonged skin contact with the chemical may result in mild irritation.

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low, given the low hazard of the chemical, the automated process and engineering controls, the good work practices and safety measures including use of appropriate personal protective equipment by workers.

The notified chemical may be present in formulations containing hazardous ingredients. If these formulations 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.

9.2.5. Public health – risk characterisation

Members of the public may make dermal contact with plastic articles containing the notified chemical. However, the risk to public health will be negligible because the chemical is present at low concentrations, bound within a matrix and not bioavailable. Furthermore, it has a low toxicity profile.

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 Substances*.

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

According to the criteria of the GHS, the notified polymer is classified as Chronic I (very toxic to aquatic life with long lasting effects).

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, 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 in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of 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, 2003).

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

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to dust and mist of the notified chemical:
  - Enclosed and automated processes at the mixing and moulding/extrusion sites, including enclosed and automatic transfer lines/pumps for loading and emptying of the mixing and cooling vessels;
  - Adequate local exhaust ventilation for the plant operators.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to dust and mist of the notified chemical:
  - Dust masks (or appropriate respirators) and safety glasses;
  - Industrial standard protective clothing and gloves.

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

- Occupational exposure to dust or decomposition products during formulation and extruding articles made from the notified chemical should be maintained below the NOHSC and ACGIH Exposure Standards (10 mg/m^3 TWA for nuisance dust and 3 mg/m^3 for respirable dust, respectively).

- 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.

Disposal

- The notified chemical should be disposed of in a licensed waste landfill or by incineration in accordance with local, state, and federal regulations.

Emergency procedures

- Spills/release of the notified chemical should be handled as outlined in the MSDS.

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 Section 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.

13. BIBLIOGRAPHY

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