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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

CRVT 1488 Ingredient

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
General Electrics Plastics (Australia) Pty Ltd
175 Hammond Rd Dandenong
Victoria 3175

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

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
None

NOTIFICATION IN OTHER COUNTRIES
USA (TSCA/USEPA PMN reference TS-GES006))

2. IDENTITY OF CHEMICAL

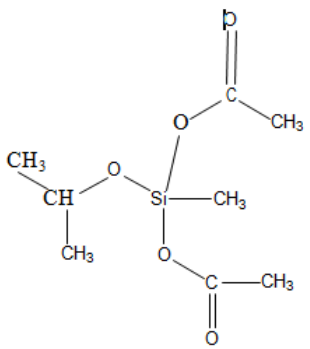
CHEMICAL NAME
Silanediol, methyl (1-methylethoxy)-,diacetate

OTHER NAME(S)
CRVT 1488 Ingredient
Diacetoxyisopropoxymethylsilane
Methyldiacetoxyisopropoxysilane

CAS NUMBER
329039-38-5

MOLECULAR FORMULA
$C_8H_{16}SiO_5$

STRUCTURAL FORMULA



MOLECULAR WEIGHT 220.30

SPECTRAL DATA

METHOD	UV-vis, OECD TG 101
Remarks	Absorption maximum 235 nm • Molar Extinction coefficient 14.9 AU/cm/M (80% notified chemical) UV/Vis absorbance spectrum was determined for the notified chemical in chloroform solution
TEST FACILITY	BC Research Inc (2001a)

3. COMPOSITION

DEGREE OF PURITY
Purity by GC/MS:
79.30-79.69 %

Purity by GC (FID detector):
85.8 % (on standing the notified chemical will disproportionate and reach an equilibrium value of approximately 72%)

HAZARDOUS IMPURITIES

Chemical Name	Methyltriacetoxysilane		
CAS No.	4253-34-03	*Weight %*	2.0-2.1%*
Hazardous Properties	Hazardous (as a group, the alkoxysilanes tend to be irritant/corrosive (Micromedex; Meditext 2002))		
Chemical Name	Acetic anhydride		
CAS No.	108-24-7	*Weight %*	0.8-0.93%*
Hazardous Properties	Hazardous: causes burns (on the *List for Designated Hazardous Substances* (NOHSC, 1999a))		
Chemical Name	Methylacetoxydiisopropoxysilane		
CAS No.	No CAS number	*Weight %*	16.67-15.90*
Hazardous Properties	Hazardous (as a group, the alkoxysilanes tend to be irritant/corrosive (Micromedex; Meditext 2002))		

Chemical Name	Acetic acid		
CAS No.	64-19-7	*Weight %*	0.23-0.26%*
Hazardous Properties	Hazardous: R35: causes severe burns R10 Flammable (on the *List for Designated Hazardous Substances* (NOHSC, 1999a))		

* Impurities determined by GC/MS

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported as a minor ingredient in silicone caulking compounds (GE Silicone rubber compound CRTV1488), containing up to 0.6% of the notified chemical.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	2-4	4-8	4-8	4-8	4-8

USE
The notified chemical will be used as a curing/cross linking agent (catalyst) in acetoxy silicone sealants (CRTV1488) at concentrations of 0.45% to 0.6 %. It becomes part of the polymer matrix during curing, rapidly becoming a curing rubber.

The product (sealant) will be used for sealing and weather proofing buildings, glazing, roofing, rainwater and cladding joints.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not provided

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will be transported directly from wharf or GE warehouse to the packing plants.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported already packaged in airtight dispensing tubes (cartridges), or in lined 200 kg drums for packing into cartridges

5.2. Operation Description

Packaging

The packaging process is a closed and automatic system so that no air (and thus moisture) comes into contact with the paste. The caulking paste will be transferred from the lined 200 kg drums via pneumatic ram and lift pump to the automatic filling machines. In the filling machine, the cartridge tube is automatically filled and then sealed to prevent the entry of air and moisture. The cartridges are packed into cartons and stored until customers require them.

End use

The cartridge containing the sealant is inserted into the caulking gun. The sealant is applied manually in a steady flow to completely fill the joints.

5.3. Occupational exposure

Number and Category of Workers

The notifier estimated three workers to be involved in packing. One warehouse person will bring the full drums to the packing line and take empty drums away (3 minutes/day). One operator will be attending the packing machine and connecting drums for pumping into the machine and one worker will attend the packing equipment that places cartridges into cartons. These workers will handle the notified chemical in the commercial form for 8 hrs/day up to 200 days per year. Two of those workers may use closed system handling.

One maintenance worker is expected to service the packing equipment.

The number of workers involved in using the product was not estimated, but is likely to be high.

Exposure Details

Worker exposure may occur when transferring the notified chemical in GE Silicone rubber compound CRTV1488 via pumping via a closed system from a drum liner to the automatic cartridge filling machine. The connection of the pumping equipment to the drums is likely to be under local exhaust ventilation.

There is also a potential for workers exposure that exists when rolling up the emptied drum liners and transferring the remaining residues into the next full drum to be packed off. This process will be carried out under local exhaust ventilation.

Following packing, worker exposure may occur when filling cartridges. This process involves passing the sealed cartridges from the filling line into the transport cartons. Local exhaust ventilation will be used.

The notifier estimated that considering all caulker is imported to be packed, worker duration may take 2.8 minutes per operator per day.

Exposure during use of the sealant may occur for home handymen and building contractors when cutting the cartridge seal, inserting the cartridge in a gun, filling the gaps and when cleaning up spills and equipment.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Very little of the notified chemical will be released from the packaging process. The drum liners are rolled-up and any residual paste is squeezed out and added to the top of the next drum. A thin film of paste may remain in the liner but this is allowed to react with the moisture in the air and becomes silicone rubber. The notifier has estimated that approximately 0.2 kg of the notified chemical per 200 kg drum (i.e. approximately 0.1%) will become waste in this manner. If all the imported material was packaged in Australia then the maximum amount of notified chemical wasted in this manner is approximately 8 kg. It is likely that this material would be disposed of to landfill. However, it will actually be much less since a significant proportion of the imported material will come into ready-to use-cartridges.

Small amounts of the paste may be spilt due to accident. Any spilt material will solidify in the air and will then be cleaned up and disposed of to landfill.

With this type of process it is unlikely that the equipment will be cleaned between jobs due to its specific nature. If the equipment needs maintenance it is likely that rags will be used to remove any excess paste and then the remaining film will be allowed to solidify and then the rubber would be removed. All waste material generated will then be disposed of to landfill in general rubbish.

RELEASE OF CHEMICAL FROM USE

When the caulking paste is applied, the empty cartridge, containing a small amount of residue will be disposed of in mixed construction rubbish or domestic garbage. In both cases it will go to landfill. The notifier has not indicated how much will be left in the cartridge at the time of disposal. It is therefore estimated that less than 1% of the paste contents will remain in the cartridge when it is disposed of, which represents approximately 80 kg (maximum) of waste notified chemical annually at a worst case scenario. This material will slowly react with the moisture in air and solidify to rubber. Since the caulking material will be used across Australia the release will be widespread and diffuse.

There will be some excess solidified rubber that is removed after application. This will be minimal and will be disposed of to landfill.

Any spilt material will solidify in the air and will then be cleaned up and disposed of to landfill.

5.5. Disposal

From packaging activities, less than 8 kg of the notified chemical will be disposed of to landfill. While, from the use of the caulking material, at worst case, approximately 80 kg of waste notified chemical will be disposed of to landfill. Any paste that is disposed of will react with the moisture in the air or surrounds to form a solid inert rubber mass.

5.6. Public exposure

Public exposure is not expected during transport, packing, or disposal, except in the event of spills. The notified polymer in commercial forms will be available for sale to the general public at up to 0.6%.

Public exposure to the notified polymer may occur through the use of the sealants by consumers. The public may have direct contamination with the product containing the notified chemical when cutting the seal, inserting the cartridge in a gun, filling up the joints and when cleaning spills. However, given the use pattern of the product, exposure to large amounts is not expected.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Colourless liquid with pungent odour

Melting Point Not determined

Remarks	The melting point was not determined due to the presence of significant proportions of impurities in the chemical, which can affect the melting point.
TEST FACILITY	Reimer Analytical and Associates, Inc (2001b)

Boiling Point 171.3°C at 102.4 kPa

METHOD	OECD TG 103 Boiling Point.
Remarks	Observed boiling point of 175°C was corrected to give 171°C
TEST FACILITY	Reimer Analytical and Associates (2001c)

Density 1044.7 kg/m^3 at 22°C

METHOD	OECD TG 109- Density of liquids and solids
Remarks	Density measured in duplicate by measuring the weight of 5 mL of notified chemical in volumetric flasks
TEST FACILITY	Reimer Analytical and Associates (2001d)

Vapour Pressure 0.028 kPa at 25°C (calculated)

Remarks	Experimental determination was not possible due to impurities causing interference The vapour pressure was calculated using ACD computer software/v3.6 (Volatile, Mensink (1995))

TEST FACILITY Reimer Analytical and Associates (2001e)

Water Solubility Not determined due to hydrolytic instability

METHOD OECD TG 105-Solubility in water
Remarks The half life in water to complete hydrolysis is in the region of minutes (see below). It was not possible to perform the test.

The notified silane is highly reactive to moisture. Exposure to water will rapidly hydrolyse the silane, generating acetic acid and isopropanol, and eventually methylsilsesquioxane

TEST FACILITY Reimer Analytical and Associates, Inc (2001f)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	*$T_{½}$ mins*
4	25	1 (% isopropanol present 63-86%)
		10 (% isopropanol present 81-101%)
		19 (% isopropanol present 72-86%)
7	25	1 (% isopropanol present 53-77%)
9	25	1 (% isopropanol present 49-73%)
		10 (% isopropanol present 59-82%)
		19 (% isopropanol present 68-92%)

Remarks This method was modified due to the rapid hydrolysis.
The hydrolysis was monitored by GC and GC/MS by tracking the evolution of acetic acid or isopropanol. The hydrolysis was measured in deionised water in buffered solutions at pH 4, 7 and 10.
Due to the nature of the material and the hydrolysis products care needs to be taken with these results. The results do indicate that the hydrolysis of the notified chemical will be in minutes in the pHs tested.
TEST FACILITY General Electric (2001)

Partition Coefficient (n-octanol/water) Not determined

METHOD OECD TG 107 Partition Coefficient (n-octanol/water), Shake Flask Method.
Remarks The notified chemical was hydrolytically unstable in aqueous solution; test was not performed
TEST FACILITY Reimer Analytical and Associates, Inc (2001g)

Adsorption/Desorption Not determined
– screening test

Remarks Not possible to perform the soil adsorption test, due to its hydrolytic instability
TEST FACILITY Reimer Analytical Associates, Inc (2001h)

Dissociation Constant Not determined

Remarks No dissociable groups present.

Particle Size Not applicable (notified chemical is a liquid)

Flash Point 81°C (closed cup)

METHOD Method was based on ASTM Method D 3828 (Setaflash closed tester)

Remarks Duplicate samples
TEST FACILITY Reimer Analytical and Associates Inc. (2001i)

Flammability Limits Not determined

Autoignition Temperature 390°C

METHOD ASTM E659-78
92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The observed duplicate ignition delay times of test chemical were 7 sec and 6 sec.

Explosive Properties Not determined

Remarks The notified chemical does not contain any of the 'explosive' groups.
TEST FACILITY Reimer Analytical and Associates Inc. (2001j)

Reactivity

Remarks The notified chemical reacts spontaneously with water. It is also incompatible with calcium hypochlorite, water and methanol.

ADDITIONAL TESTS

Oxidizing/Reducing Properties and Chemical Compatibility

METHOD US EPA OPPTS 830.6314, OJEC A.17
Remarks During the study, the temperature of the mixture containing notified chemical, an oxidising agent water and methanol, was increased by more than 5°C.

The notified chemical was found to be compatible with zinc (reducing agent), ammonium phosphate (fire-fighting agent) and carbon dioxide, but incompatible with calcium hypochlorite, methanol and water due to an exothermic reaction.

The notified chemical is expected to be chemically compatible with aprotic organic solvents such as acetonitrile, acetone, petroleum ether and chloroform.
TEST FACILITY Reimer Analytical and Associates (2001k)

Stability and Dose Analysis

Remarks Analysis of doses of the notified chemical mixed in corn oil was performed at 2 and 50 mg/mL for 7 days. A storage stability study was performed on samples prepared for 2 days at 5 and 50 mg/mL using different protocols.

Homogeneity studies showed a 1.4% variation in dose concentration among the three sampling locations for the low dose (2 mg/mL) and a 2.8 % variation for the high dose (50 mg/mL).

Storage stability study showed that the notified chemical was unstable after one day of storage when stored in amber bottles in a refrigerator. Storage under nitrogen indicated that the 5 mg/mL was unstable after one day of storage.

Dose formulations of the notified chemical at 5, 15 and 50 mg/L used in the animal study (See Section 7.7.) were found to contain 81.3 to 156% of the nominal concentrations.

No acetoxysilane was detected in the vehicle control formulations with an estimated limit of detection of 0.4 mg/mL.

TEST FACILITY RTI International (2002)

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	Not provided
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	severely irritating
Guinea pig, skin sensitisation –	
Magnusson and Kilgman	Inadequate evidence of sensitisation
Buehler method	Evidence of sensitisation
Rat, repeat dose with reproductive toxicity	NOAEL 75 mg/kg/day maternal systemic toxicity NOAEL 225 mg/kg/day reproductive toxicity
Genotoxicity - bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro [Mammalian Chromosomal Aberration Test]	Non genotoxic
Genotoxicity – in vivo [Micronucleus Erythrocyte test]	Non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method
USEPA OPPTS 870.1100, Acute Oral Toxicity

Species/Strain	Rat/Outbred Albino
Vehicle	None (notified chemical was used undiluted)
Remarks – Method	Administration by intragastric intubation Observation period: 14 days

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 males	2000	None
2	3 females	2000	None

LD50	>2000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	Piloerection was observed in all treated animals for the first 5 days.

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

TEST FACILITY Toxikon Corporation (2001a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD OECD TG 402 Acute Dermal Toxicity.
US EPA OPPTS 870.1200, Acute Oral Toxicity

Species/Strain	Rabbit/New Zealand White
Vehicle	None
Type of dressing	Occlusive

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males	2000	None
2	5 females	2000	None

LD50	2000 mg/kg bw
Signs of Toxicity - Local	Necrosis was observed in 7 out of 10 animals. Erythema and oedema were observed in all the test sites and persisted for the first 7 days
Signs of Toxicity - Systemic	None
Effects in Organs	None
Remarks - Results	The notified chemical was corrosive as necrosis was observed in 7 out of 10 application sites

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

TEST FACILITY Toxickon Corporation (2001b)

7.3. Acute toxicity – inhalation

Remarks Not provided

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)
USEPA 40/798.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (2 males and 1 female)
Vehicle	None
Observation Period	Not known
Type of Dressing	Semi-occlusive.
Remarks - Method	Four hours topical application to intact skin

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	0.67	0.67	0.67	1	48 hours	0
Oedema	0	0	0			0

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

Remarks - Results Very slight to well defined erythema was observed in all rabbits (3) after 1 hour of application. All three rabbits exhibited very slight erythema at both 24 and 48 hour observation periods. The irritation was reversed with no signs of erythema present at the 72 hour observation.

CONCLUSION The notified chemical is slightly irritating to skin.

TEST FACILITY Toxikon Corporation (2001c)

7.5. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. US EPA OPPTS EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/Albino
Number of Animals	3
Observation Period	14-15 days
Remarks - Method	Scoring was continued beyond 72 hours due to signs of irritation and was terminated where reversibility was observed in each animal (before 21 days)

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	3	2	2.7	3	Day 10	0
Conjunctiva: chemosis	4.25	3	4	4	Day 14	0
Cornea: area involved	3	1.3	2.7	3	Day 8	0
Corneal opacity	4	2.7	2.7	4	Day 8	0
Iridial inflammation	2	1	1.7	2	Day 13	0

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

Remarks - Results	Corneal opacity, iris response, conjunctival redness and chemosis were observed in all treated eyes. The notified chemical caused severe irritation, which resolved slowly and returned to normal by days 14 and 15.
CONCLUSION	The notified chemical is severely irritating to the eye.
TEST FACILITY	Toxikon Corporation (2001d)

7.6.(a) Skin sensitisation

TEST SUBSTANCE	Notified chemical	
METHOD	OECD TG 406 Skin Sensitisation – Kligman Maximisation Test	
Species/Strain	Guinea pig/Hartley	
Vehicle	Notified chemical was diluted in cottonseed oil	
PRIMARY IRRITATION STUDY	Animals were injected with adjuvant 24 hours before the study: intradermal: 1, 10, 50, 100 % topical: 25, 50, 75 and 100%	
MAIN STUDY		
Number of Animals	Test Group: 10 males and 10 females	Control Group: Negative (5 males and 5 females) Positive (2 males and 3 females)
INDUCTION PHASE	Induction Concentration: intradermal injection 1% (day 0) (with adjuvants) topical application 100% (day 7)	
CHALLENGE PHASE (DAY 21)		
1st challenge	topical application: 100%	

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after treatment 1st challenge*	
		24 hr	*48 hr*
Test Group 10 males and 10 females	100%	0	0

Remarks – Results

In the primary irritation study, irritation was noted at 10% and 1%; corrosion was observed at 100% and 50% (intradermal injection). No initiation was observed on topical application with 100% notified chemical.

The notified chemical exhibited no reaction to the challenge. A grade 1 reaction was scored according to the scoring system of Kligman.

CONCLUSION

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

TEST FACILITY

Toxicon Laboratory (2002)

7.6.(b)Skin sensitisation

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 406 Skin Sensitisation – Buehler test

Species/Strain

Guinea pig/Hartley

PRELIMINARY STUDY

topical: 100, 50, 25 and 10% in cottonseed oil

MAIN STUDY

Number of Animals

Test Group: 10 males and 10 females

Control Group: negative (5 males and 5 females)
Positive (3 males and 2 females)

INDUCTION PHASE

Induction Concentration: 100%
topical application (occlusive, day 0, 7 and 14)

Signs of Irritation

CHALLENGE PHASE

Challenge

topical application: 100% (day 28)

Re-challenge

topical application: 100% (day 35)

Remarks - Method

Epicutaneous application

RESULTS

Incidences of erythema of 60% (12/20) and 55% (11/20) and severities of 0.8 (16/20) and 0.7 (14/20) at 24 and 48 hours respectively, at the challenge exposure following an induction phase. At the 2nd challenge, the notified chemical showed incidences of 80% (16/20) erythema and 40% (8/20) and severities of 1.0 (20/20) and 0.45 (9/20) at 24 and 48 hours, respectively.

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	12/20	11/20	16/20	8/20
Control Group	Positive	5/5	5/5	5/5	5/5

	Negative	0/5	0/5	0/5	0/5

Remarks - Results

CONCLUSION	There was strong evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Toxikon Laboratory (2001e)

7.7. Repeat dose with reproductive/developmental toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test. Modified Combined Repeat Dose Toxicity Study with the Reproductive/Developmental Toxicity Screening Test of Methyldiacetoxyispropoxy Silane (Acetoxysilane) Administered via Oral Gavage to CD (Sprague Dawley) Rats
Species/Strain	Rats/ CD (Sprague dawley) 50 males and 40 females
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: • F0: 14 days (prebreed and mating period); 3 weeks (Gestation period) 3 weeks (Lactation period) • F1 offspring: Min. 7 weeks post weaning (From weaning through scheduled sacrifice-pnd 22 to 70)) • Recovery group: 5 males dosed daily at 0 and 225 mg/kg/day during the pre-breed and mating periods and an additional 2 weeks without dosing, ie after the F0 male dosing period. Dose regimen: once daily over 7 days per week.
Vehicle	Corn oil
Remarks - Method	The study exceeds the OECD 422 study design by following the offspring to adulthood with continued exposure and assessment of neurologic, immunologic, and reproductive structures and functions in these animals. The study evaluated adverse effects during pre-breed, mating (for both sexes), gestation and lactation (for F0 females) for F0 parents and direct dosing to F1 offspring from weaning to scheduled sacrifice, at least 7 weeks post weaning. Homogeneity and stability of the notified chemical in corn oil was determined by gas chromatography (See Section 6). Protocol deviations: Documented weights were lower than the specified weights. However, these deviations were minor and do not compromise the study.

RESULTS

Group	*Number and Sex of Animals (F0 generation)*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10 males and 10 females*	0	
II (low dose)	10 males and 10 females	25	No mortality
III (mid dose)	10 males and 10 females	75	
IV (high dose)	10 males and 10 females	225	
V (control recovery)	5 males	0	
VI (high dose recovery)	5 males	225	

* one female in the control group had no live litter and was necropsied prior to week 7;

Effects on Parental (F0) animals:

Sporadic effects on haematologic and neurobehavioural parameters and histopathologic lesions in the stomachs of F0 males at 225 mg/kg/day. F0 parental females exhibited minor systemic toxicity at 225 mg/kg/day.

No treatment- or dose-related effects on absolute organ weights or organ weights relative to terminal body or brain weights or on gross findings, clinical chemistry, or urinalysis.

No evidence of reproductive toxicity in either sex at any dose. No effects on any F0 reproductive indices during the production of F1 offspring. Mating, fertility, pregnancy, and gestational indices were equivalent across all groups.

Effects on 1st Filial Generation (F1)

Live birth, still birth indices, litter sizes at birth, or survival indices were unaffected. F1 male (but not female) anogenital distance (AGD) at birth was significantly increased (lengthened) at 25 and 225 mg/kg/day. This was due to smaller litter size and increased male pup body weights at birth at this dose.

Significant increase in the incidence of retained areolae in F1 pre-weanling males in all dosed groups but no significant increases in the incidence of retained nipples. However, there were no adverse consequences in the F1 generation in reproductive development, reproductive structures, or functions. Therefore, the increased incidence of retained areolae was not considered an adverse effect.

Remarks – Results
Mild adult F0 parental toxicity was seen at 225 mg/kg/day. There was no F0 reproductive toxicity at any dose. No F1 offspring toxicity was observed pre- or post-natally at any dose, although there were treatment- and dose-related increases in retained areolae (but not nipples) in all acetoxysilane-dosed groups.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) for systemic parental toxicity was established as 75 mg/kg bw/day in this study, based on sporadic effects on haematologic and neurobehavioural parameters and histopathologic lesions in the stomachs of male rats at 225 mg/kg/day. For reproductive and developmental toxicity, the NOAEL was 225 mg/kg/day.

TEST FACILITY Centre for Life Sciences (2001)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Assay.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.

Strain *S. typhimurium*:

	TA1535, TA1537, TA98, TA100 *E. coli*: WP2 uvrA.
Metabolic Activation System	Arochlor induced rat liver-S9
Concentration Range in Main Test	a) With metabolic activation: 75, 200, 600, 1800 and 5000 μg/plate. b) Without metabolic activation: 75, 200, 600, 1800 and 5000 μg/plate.
Vehicle	Dimethyl sulphoxide

RESULTS

Remarks - Results	Neither precipitate nor appreciable toxicity was observed. Based on the findings of the toxicity assay, the maximum dose plated in the mutagenicity assay was 5000 μg per plate. No positive responses were observed with any of the tester strains in the presence and absence of S9 activation
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BioReliance (2001a)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type	Chinese Hamster Ovary cells
Metabolic Activation System	Arochlor-induced S9 activation system
Vehicle	Dimethyl sulphoxide
Remarks - Method	Doses: 625, 1250, 2500 and 5000 μg/mL for the non activated 4 and 20 hour exposure groups and for the S9 activated 4 hr exposure group

Metabolic Activation	*Exposure Period*	*Harvest Time*	*Mitotic index reduction*	*Toxicity at highest dose scored (5000 μg/mL)*
Absent				
Test 1	4 hr	20 hr	5%	17%
Test 2	20 hr	20 hr	7%	31%
Present				
Test 1	4 hr	20 hr	None	24%

RESULTS

Remarks - Results	At least 50% reduction in cell growth shown at 5000 μg/mL. The percentage of cells with structural and numerical aberrations in the notified chemical treated groups was not statistically increased above that of the solvent control.
CONCLUSION	The notified chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test.
TEST FACILITY	BioReliance (2001b)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mice/ICR
Route of Administration	Intraperitoneal injection
Vehicle	Initial study- water (soluble in 100 mg/mL) Repeat study-corn oil (soluble in 100 mg/mL)
Remarks - Method	

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
Initial Study	5 males and 5 females	50	24 and 48 hrs
	5 males and 5 females	100	24 and 48 hrs
	5 males and 5 females	200 (Maximum tolerated dose)	24 and 48 hrs
Repeat study	5 males and 5 females	87.5	24 and 48 hrs
	5 males and 5 females	175	24 and 48 hrs
	5 males and 5 females	350 (maximum tolerated dose)	24 and 48 hrs

RESULTS	
Doses Producing Toxicity	Initial study: Animals treated with 200 mg/kg bw showed clinical signs of toxicity including lethargy in male and female mice and piloerection in males. Repeat study: clinical signs following dose administration included lethargy in male and female mice at 87.5, 175 and 350 mg/kg
Genotoxic Effects	Initial study: Reduction (up to 12%) in the ratio of polychromatic erythrocytes (PCE) to total erythrocytes were observed in some of the notified chemical treated groups. Repeat study: Reductions (up to 10%) in the ratio of polychromatic erythrocytes to total erythrocytes were observed in some of the treated groups.
Remarks - Results	No significant increase in micronucleated polychromatic erythrocytes in treated groups compared with controls at 24 and 48 hrs.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo micronucleus test.
TEST FACILITY	BioReliance (2001c)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

The biodegradability was not determined as the chemical hydrolyses rapidly.

8.1.2. Bioaccumulation

Bioaccumulation was not determined, since its rapid hydrolysis it will not be available to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Methyldiacetoxyisopropoxysilane
METHOD	OECD TG 203 Fish, Acute Toxicity Test -
Species	Oncorhynchus mykiss
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	18-20 mg $CaCO_3$/L
Analytical Monitoring	Since the test material hydrolyses rapidly, GC-FID and DB-wax capillary column were used to analyse for the hydrolysis product, isopropanol, thus indicating the concentration of the test material via a linear relationship.
Remarks – Method	Three definitive tests each using 9 fish per concentration and a fourth using 10 fish per concentration were done. However, tests 1-3 did not deliver sufficient data to determine the LC_{50}, therefore the data was not presented in the final report. A reference toxicant, phenol at 5, 7, 10, 13, and 22 mg/L, was used as a positive control. A trimmed Spearman Karber method was used to determine the 96 h LC_{50} via the Toxcalc computer program. However, for the reference toxicant the Lotus Notes-based application, Bioassay Program, was used.

RESULTS

Definitive studies 1-3 data not presented

Definitive study 4:

Concentration mg/L	*Number of Fish*	*Mortality*				
Nominal		*1h*	*24h*	*48h*	*72h*	*96h*
0	10	-	0	0	0	0
203	10	-	0	0	0	0
438	10	-	0	0	0	0
938	10	-	0	0	0	0
2094	10	-	7	8	9	9
4594	10	-	10	10	10	10
10000	10	-	10	10	10	10

LC50	1517 mg/L at 96 hours (95% C.I. 1413 – 2239).
NOEC (or LOEC)	938 mg/L at 96 hours.
Remarks – Results	Via Binomial calculation the reference toxicant gave a 96 h LC_{50} of 10.8 mg/L (95% C.I. 7-13).
CONCLUSION	This result indicates that the test material is practically non-toxic to fish.
TEST FACILITY	BC Research Inc, 2001

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Methyldiacetoxyisopropoxysilane
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	18-20 mg $CaCO_3$/L
Analytical Monitoring	Since the test material hydrolyses rapidly, GC-FID and DB-wax capillary column were used to analyse for the hydrolysis product, isopropanol, thus indicating the concentration of the test material via a linear relationship.

Remarks - Method	A reference toxicant, zinc sulphate at 0.1, 0.32, 1.0, 3.2, 10 and 32 mg/L, was used as a positive control. Each concentration of the test material was done in quadruplicate with 5 daphnia in each.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
0	20 (4x5)	0	0
440	20 (4x5)	0	0
520	20 (4x5)	0	0
610	20 (4x5)	0	0
720	20 (4x5)	0	0
850	20 (4x5)	0	0
1000	20 (4x5)	0	0

LC50	> 1000 mg/L at 48 hours
NOEC (or LOEC)	> 1000 mg/L at 48 hours
Remarks - Results	The LC_{50} for the reference toxicant of 0.87 mg/L (95% C.I. 0.32–3.2).

CONCLUSION	This result indicates that the test material is practically non-toxic to Daphnia.
TEST FACILITY	BC Research Inc, 2002a

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Methyldiacetoxyisopropoxysilane
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range Nominal	0, 312.5, 625, 1250, 2500, 5000 and 10000 mg/L
Concentration Range Actual	Not determined
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	Since the test material hydrolyses rapidly GC-FID and DB-wax capillary column were used to analyse for the hydrolysis products, isopropanol and acetic acid. The initial concentration of the test material could be determined due to a linear relationship between the parent material and the hydrolysis products. To verify this a spike and recovery experiment was conducted.
Remarks - Method	A reference toxicant, zinc sulphate at 0.0001, 0.001, 0.01, 0.05, 0.1, 0.5 and 1.0 mg/L, was used as a positive control. The EC_{50} was determined via non-linear analysis.

RESULTS

Growth	
EC_{50} mg/L at 72 h	*NOAEC Mg/L*
931.3	*312.5*
95% C.I. 839.0 – 1039.7	

Remarks - Results	The reference toxicant study delivered a 72 h EC_{50} of 0.43 mg/L with a

	95% C.I. of 0.25-0.49. This result indicated that the study methods were valid.
CONCLUSION	This result indicates that the test material is practically non-toxic to algae.
TEST FACILITY	BC Research Inc, 2002b

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

When the caulking paste is applied, the notified chemical will become locked into the matrix as it cures and thereby becomes immobile.

The sources of release are discussed in section 5.4 Release. In summary, a maximum of approximately 8 kg of notified chemical per year will go to landfill due to repackaging if all the imported product is repackaged. This amount will be less since a proportion of the imported product will be in ready-to-use cartridges. The proportion of cartridge verses bulk drum imports is unknown. While it is estimated that approximately 80 kg of notified chemical will go to landfill due to the use of the caulking paste, generally in residual paste in the empty cartridges. Thus a total of 88 kg of notified chemical (ie 1.1%) will go landfill annually.

Ultimately it is likely that the majority (98.9%) of the imported notified chemical will be disposed of to landfill as the life of the article to which it has been applied comes to an end. It is possible some will be incinerated.

9.1.2. Environment – Fate assessment

The unused waste notified chemical which is disposed of to landfill will quickly react with the moisture in air or sediment to form the cured rubber, and as such will not be available to either react with the soil or leach from the landfill.

Once used, the notified chemical will have been consumed in the formation of the inert rubber. Thus when disposed to landfill with the article the notified chemical will not be available to react with the soil or move from the landfill.

If incinerated, the notified chemical would be rapidly destroyed and converted to water vapour, oxides of carbon and silicone.

9.1.3. Environment – effects assessment

Acute tests of the notified polymer were supplied for a fish species, an invertebrate species and an algal species and the results are provided in Section 8.2. The results indicate that the notified chemical is not toxic to aquatic organisms.

A predicted no effect concentration may be determined based on the algae result (EC_{50} = 931.3 mg/L) and applying an assessment factor of 100 (justified because acute tests are available on three trophic levels). The resultant PNEC is 9.3 mg/L.

9.1.4. Environment – risk characterisation

Since the notified chemical hydrolyses rapidly, and is designed to react rapidly with the moisture in air, it is unlikely that any of the unreacted notified chemical will enter the environment. Since the PEC is likely to be nearly 0, the PEC/PNEC ratio will be close to 0.

On the basis of the nature of the chemical and the use pattern specified in the submission the risk associated with is use is low.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Categories of workers likely to be exposed to the low concentration of the notified chemical in imported product (at 0.6%) are those involved in packaging (when transferring from the drums, filling the cartridge tubes and emptying left over commercial product containing notified chemical into the full drums for packing) and end-use. Dermal contamination is the most likely route of exposure. Ocular exposure may occur in the event of splashes. Inhalation exposure to vapours (acetic acid) is limited during packaging as the process is largely enclosed and conducted under local ventilation or respiratory protection is worn by workers.

Because of the rapid reactivity of the chemical with moisture, for example water in humid air, closed systems are used during packing operations and hence in general significant worker contamination is not likely.

Inhalation exposure to acetic acid vapours during end use may occur as workers may apply the sealant in small areas with no adequate ventilation. However, as a small amount of sealant is usually required to fill the gaps and workers are likely to avoid direct contact with the sealant because of its reactive nature, inhalation and dermal exposure to the notified chemical is not expected be significant.

9.2.2. Public health – exposure assessment

During packing, public exposure is not expected. In the case of accidental spills during transport, public exposure may occur and is considered low because the caulker is a semi solid.

During end-use, there is potential of exposure to the sealant used by consumers; however, due to the reactivity of the sealant, it expected that the public will avoid dermal contact as much as possible during use. Considering the use pattern and packaging of the sealant in the cartridge, public exposure is considered low.

9.2.3. Human health - effects assessment

The notified chemical is of low acute oral and dermal toxicity. Acute inhalation toxicity was not provided. It has a low vapour pressure and is highly reactive with water.

The notified chemical is described as a liquid with a pungent odour. However, it exists with other impurities (acetic acid and methyldiisopropxyacetoxysilane), which may be volatile and may irritate the respiratory tract. The notifier has assigned the risk phrase R37 (Irritating to respiratory system) for the notified chemical. Alkoxysilanes as a group are highly irritant and can cause lung damage.

The notified chemical is a slight skin and severe eye irritant. Necrosis of skin was observed in an acute dermal study. In an eye irritation study in rabbits, corneal opacity, iris response, conjunctival redness and chemosis were observed in all treated eyes. The notified chemical caused severe irritation, which resolved slowly and returned to normal by days 14 and 15. Based on these effects, the notified chemical is assigned the risk phrase R41 (Risk of serious eye damage) in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

A skin sensitisation study in guinea pigs using the Magnusson-Kligman maximisation test gave no evidence of causing skin sensitisation. A grade 1 (weak) reaction was scored according to the scoring system of Kligman. However, a strong response was observed in the Buehler test, where the notified chemical exhibited incidences of erythema of 60% (12/20) and 55% (11/20) and severities of 0.8 (16/20) and 0.7 (14/20) at 24 and 48 hours respectively, during the challenge exposure period. At the 2nd challenge, the notified chemical showed incidences of 80% (16/20) and 40% (8/20) erythema and severities of 1.0 (20/20) and 0.45 (9/20) at 24 and 48 hours, respectively. The Buehler test is considered to be relevant to potential human hazard. Since the notified chemical induced more than 15% positive response in the Buehler test, it is classified as a skin sensitiser and assigned the risk phrase R43 (May cause sensitisation by skin contact) in accordance with the Approved Criteria.

An oral repeat dose study in rats with a reproductive and development toxicity screen was provided. The NOAEL for systemic parental toxicity was established at 75 mg/kg bw/day in this study, based on sporadic effects on haematologic and neurobehavioural parameters and histopathologic lesions in the stomachs of male rats at 225 mg/kg/day. For reproductive and developmental toxicity, the NOAEL was 225 mg/kg/day, the maximum dose used in the study.

In genotoxicity studies, the notified chemical was not genotoxic in the in vivo and in vitro tests conducted.

The Material Safety Data Sheet (MSDS) for the product containing about 72% notified chemical indicates that repeated exposure may cause dermatitis and respiratory effects.

The product CRTV1488 was classified by the notifier as non-hazardous. The notified chemical is imported in the silicone products (sealant) at 0.6%. The hazards identified for the notified chemical are below the lowest cut-off limit (≥1%) for skin sensitisation.

9.2.4. Occupational health and safety – risk characterisation

The main hazards to the notified chemical are eye irritation, skin sensitisation and respiratory irritation due to generation of acetic acid vapour.

Workers at the packing site will handle the notified chemical present in commercial form at 0.6% and will not be exposed to the pure form. The risk of adverse effects during packaging is not expected to be significant as the process of packing is automated and largely enclosed and contained under local exhaust ventilation. However, workers will need to use respiratory protection if the ventilation is not adequate and skin and eye protection such as gloves, overalls and goggles when opening the drums, making the connections to the pumping line, moving drums and emptying residues from drums and when cleaning up spills and equipment. Because of the high reactivity in water, the process of packaging should be enclosed.

End use workers such as home handymen may handle the commercial products frequently; however, given the use pattern and the low concentration of notified chemical in sealant, the risk of adverse health effects arising from exposure to the notified chemical in commercial products is low. Nevertheless, given the hazards associated with the notified chemical (ie skin sensitisation, eye and respiratory irritation), workers should use respiratory protection if the ventilation is not adequate and skin and eye protection such as gloves, overalls and goggles when applying the product.

9.2.5. Public health – risk characterisation

The notified chemical will be available for sale to the general public in cartridges in the commercial form. Although the notified chemical is expected to cause skin sensitisation, slight skin and severe eye irritations, and respiratory irritation, the risk is not likely to be significant given the low amount of notified chemical in the product and that it is packaged in tightly contained cartridges. Because of the reactive nature of these products, the general public will usually avoid skin and eye contact. It is likely that the sealant will be applied in small quantities. Nevertheless, precautionary statements should appear on the label to warn the public against the risk of eye irritation and other hazards in the products.

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

10.1. Hazard classification

Based on the available data, the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R37 Irritating to respiratory systems

R41	Risk of serious damage to eyes
R43	May cause sensitisation by skin contact

The notified chemical is classified as a Class 8 Dangerous Goods due to its potential corrosivity.

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern and the likely PEC/PNEC ratio will be close to 0.

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 Low Concern to public health when used under the conditions described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical in product GE Silicone Rubber Compound 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 notified chemical in product GE Silicone Rubber Compound 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

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:

• R37	Irritating to respiratory systems
• R41	Risk of serious damage to eyes
• R43	May cause sensitisation by skin contact
S36	Wear suitable protective clothing
S37	Wear suitable gloves
S39	Wear eye/face protection
S24	Avoid contact with skin

- Use the following risk phrases for products/mixtures containing the notified chemical:

≥10%: R37 R41 R43
5 - 10%: R36/37 R43
1 - ≤5%: R43

- Products containing more than 0.5% notified chemical and available to the public must carry the following safety directions on the label:

210 211 Avoid contact with eyes and skin

220 222 Avoid inhaling vapour

- The National Drugs and Poisons Standing Committee (NDPSC) should consider the notified chemical for listing on the SUSDP.

- The notified chemical should be classified as follows under the ADG Code:
  - Class 8-Corrosive Substances

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Enclosure of the process
  - Exhaust ventilation during packing of the products

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical and the products containing it:
  - Prevent splashes and spills

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Chemical resistant gloves, protective overalls, and goggles.

  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 the repackaging companies and by the end user to minimise environmental exposure during (manufacture, formulation, use) of the notified chemical:
  - Collect any spilt or surplus material and store in open container until disposal.

- The MSDS for the product containing the notified chemical should include a section regarding the management and disposal of spilt material (see above).

Disposal

- The notified chemical should be disposed of by incineration or to landfill.

Emergency procedures

- Spills/release of the notified chemical should be handled by containment and then wipe or adsorb liquid and scrape up any solids. Place spilt material and cleaning rags or other contaminated material in an open container and allow to react with air, then dispose of to landfill.

Secondary notification

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

Under Subsection 64(1) of the Act; if

- (a) The notified chemical itself is manufactured locally or imported;
- (b) The notified chemical is contained in commercial products at concentrations above 0.6%

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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