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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

CN-1197

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

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

CN-1197

1. APPLICANT

3M Australia Pty Ltd of 2-74 Dunheved Circuit ST MARYS NSW 2760 has submitted a limited notification statement accompanying their application for an assessment certificate for CN-1197.

2. IDENTITY OF THE CHEMICAL

CN-1197 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae and spectral data have been exempted from publication in the Full Public Report and the Summary Report

Molecular weight:	180.1
Method of detection and determination:	high performance liquid chromatography

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white, crystalline powder
Melting Point:	207.5-213°C (at 760 mm Hg)
Specific Gravity:	1.692 at 20°C
Vapour Pressure:	2.25 X 10^{-8} kPa at 25°C
Water Solubility:	52240 mg/L (av) at 20°C at pH 1.86-1.91
Partition Co-efficient (n-octanol/water):	log P_{ow} = -1.06 at 20°C
Hydrolysis as a Function of pH:	on the basis of treatment at 50°C for 5 days: $T_{1/2}$ at pH 4.0, > 1 year at 25°C (estimated) $T_{1/2}$ at pH 7.0, ~ 1 year at 25°C (estimated) $T_{1/2}$ at pH 9.0, 1d - 1 year at 25°C (estimated)
Adsorption/Desorption:	< 25% adsorption by sandy loam, clay loam and loam
Dissociation Constant:	none
Flash Point:	not determined
Flammability Limits:	not flammable

Autoignition Temperature: > 450°C

Explosive Properties: not explosive

Particle Size: range: 2.0 - 202 μm; 55.72% < 10 μm

Reactivity/Stability: no oxidising properties

Comments on Physico-Chemical Properties

The melting point/range was determined using the metal block method. Shrinkage of the sample occurred at 192°C and darkening at 205°C and finally melted to a clear light brown liquid.

The vapour pressure figure was calculated by the mass difference method.

The chemical has a high water solubility.

As adsorption was determined to be less than 25%, no desorption test was conducted. This is acceptable.

4. PURITY OF THE CHEMICAL

Degree of purity: 94.5% (range 88-100%)

Toxic or hazardous impurities: one hazardous impurity, a category 3 carcinogen (1), is present at a maximum concentration of 0.5% which is below the concentration cutoff of 1%

Non-hazardous impurities (> 1% by weight): one non-hazardous impurity at a concentration of 0.3% (typical) ranging from 0.0% - 10.9%

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical is a component of caulk which is used to fill gaps in fire rated walls. It is to be imported in a formulation at a level of 4-5% (see attached Material Safety Data Sheet (MSDS) for '3M Brand Fire Barrier CP-25 WB+ Caulk') at a rate of < 1 tonne per year for the first five years.

6. OCCUPATIONAL EXPOSURE

The caulking compound of which the notified chemical is a component will be imported in containers of approximately 5 L and 20 L capacity. The caulk will be used in fire rated walls to fill gaps produced by penetrations of pipes or cables. It is to be applied using a caulking gun and/or applying with a putty knife. Exposure of the hands is possible.

7. PUBLIC EXPOSURE

Minimal public exposure may result following contact with cured caulk in fire rated walls, or following accidental removal of the caulk from the walls. The main route of exposure in these situations is dermal, and possibly ocular and inhalational. The potential for minor public exposure exists during transport and disposal of the notified chemical if accidentally spilt.

8. ENVIRONMENTAL EXPOSURE

Release

Environmental release during transportation will result only in the event of accidental spill or mishandling.

The material is used for filling openings as required. It is applied with either a caulking gun or a putty knife. Any spills that occur during application of the caulk can be returned to the pail before setting. It is anticipated that any excess material that has set will be disposed of to landfill. Further release to the environment may occur to the sewer through the washing of tools used to apply formulations containing the notified chemical, or to landfill with the disposal of residual quantities of the formulations within used containers. Loss to the environment from washing is not expected to be significant.

Fate

The substance was examined for biodegradation potential using EEC Directive 92/69, Part C.4-E (Closed Bottle Test), and OECD Test Guideline 301D. The substance exhibited 12% degradation after 28 days, indicating that it is not readily biodegradable under the conditions of the test. It was also found that the substance was not inhibitory to bacteria under these conditions.

No testing of the bioaccumulation potential was conducted. The low partition coefficient and high water solubility of the notified chemical would indicate it is not likely to bioaccumulate.

The K_{oc} for the chemical indicates that it would not strongly adsorb to soils or sediments. However, leaching of the chemical from landfills is not expected to be significant as the chemical will be trapped in the matrix of the solidified caulk (the caulk solidifies on contact with the atmosphere).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of CN-1197

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5000 mg/kg	(2)
acute dermal toxicity	rabbit	LD_{50} > 2000 mg/kg	(3)
skin irritation	rabbit	slight irritant	(4)
eye irritation	rabbit	moderate irritant	(5)
skin sensitisation	guinea pig	non-sensitiser	(6)

9.1.1 Oral Toxicity (2)

Species/strain:	rat/ Crl:CDBR
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	gavage with corn oil as vehicle
Clinical observations:	1 female with soft stool at 3-4 h post-treatment and 1 female with wet, yellow urogenital staining on day 1
Mortality:	none
Morphological findings:	no significant findings
Test method:	US EPA Pesticide Assessment Guidelines (7)
LD_{50}:	> 5000 mg/kg
Result:	the notified chemical was of low oral toxicity in rats

9.1.2 Dermal Toxicity (3)

Species/strain:	rabbit/ New Zealand White
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	a paste in deionised water was applied under a gauze binder for 24 hours
Clinical observations:	no significant findings
Mortality:	none
Morphological findings:	one male had an encysted right kidney; otherwise no significant findings

Draize scores (8):

Time after treatment (days)	***Animal #***									
	1	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***
Erythema										
1	2[a]	2	2	1	1	1	2*	1	2	1
2	1	2	1	1	1	1	1	2	1	1
3	snr[b]	1	1	snr	1	snr	1	2	1	1

[a] see Attachment 1 for Draize scales [b] scored not remarkable * very slight oedema was observed in this animal but in no others

Test method: US EPA Pesticide Assessment Guidelines (7)

LD_{50}: > 2000 mg/kg

Result: the notified chemical was of low dermal toxicity in rabbits and was a slight skin irritant

9.1.3 Skin Irritation (4)

Species/strain: rabbit/ New Zealand White

Number/sex of animals: 3 males, 3 females

Observation period: 3 days

Method of administration: 500 milligrams of test substance moistened with deionised water under a gauze dressing secured by a binder and tape

Test method: US EPA Pesticide Assessment Guidelines (7)

Result: the notified chemical was a slight skin irritant in rabbits; very slight erythema was observed in 2 females at 24 h post-treatment

9.1.5 Eye Irritation (5)

Species/strain: rabbit/ New Zealand White

Number/sex of animals: 3 males, 3 females

Observation period: 7 days

Method of administration: 100 mg of the test substance into the cupped conjunctival sac of one eye of each animal

Draize scores (8) of unirrigated eyes:

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

[1] see Attachment 1 for Draize scales

[a] opacity [b] area [c] redness [d] chemosis [e] discharge

Test method: US EPA Pesticide Assessment Guidelines (7)

Result: the notified chemical was a moderate irritant in rabbits

9.1.6 Skin Sensitisation (6)

Species/strain: guinea pig/ Dunkin-Hartley

Number of animals: 20 /sex - test; 10 /sex -control

Induction procedure: 0.1 mL injections of Freund's complete adjuvant (FCA) diluted 1:1 with water; 7.5% test substance in Alembicol D; FCA diluted 1:1 Alembicol D; on day 7 the sites were treated with 10% sodium lauryl sulphate; 24 hours later topical induction was performed with 70%

	w/v test substance in Alembicol D under occlusive dressing for 48 hours
Challenge procedure:	14 days after topical induction, challenge was performed with 35% and 70% test substance in Alembicol D under occlusive dressing for 24 hours

Challenge outcome:

Challenge concentration	***Test animals***			***Control animals***		
	24 hrs*	***48 hrs***	***72 hrs***	***24 hrs***	***48 hrs***	***72 hrs***
35%	0/20**	0/20	0/20	0/10	0/10	0/10
70%	0/20	0/20	0/20	0/10	0/10	0/10

* time after patch removal

** number of animals exhibiting positive response

Test method:	OECD Guidelines (9)
Result:	the notified chemical was not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (10)

Species/strain:	rat/ Crl:CDBR
Number/sex of animals:	5 males/ 5 females per dose group
Method of administration:	incorporated into food
Dose/Study duration::	0, 160, 400, 1000 and 2500 mg/kg/day for 28 days
Clinical observations:	no toxicologically significant observations
Clinical chemistry/Haematology	no toxicologically significant observations
Histopathology:	no toxicologically significant observations
Test method:	OECD Guidelines (9)
Result:	no target organ for toxicity of the notified chemical was identified in rats

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (11)

Strains:	TA 1535, TA 1537, TA 1538, TA 98 and TA 100
Concentration range:	50 - 5000 μg/plate
Test method:	Ames *et. al* (12), McCann *et. al* (13)
Result:	the notified chemical did not induce back mutation to prototrophy in any of the strains used either in the presence or absence of an exogenous metabolic activation system; positive and negative controls were within acceptable limits

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (14)

Species/strain:	mouse/ ICR
Number and sex of animals:	5 males and 5 females per dose per harvest time (24, 48 and 72 hours post-treatment)
Doses:	0, 200, 667 and 2000 mg/kg
Method of administration:	i.p.
Test method:	Heddle *et. al* (15), Schmid (16,17)
Result:	the notified chemical did not induce a significant increase in micronuclei in bone marrow polychromatic erythrocytes under the conditions of this assay

9.3.3 Chromosomal Aberrations in Human Lymphocytes *in vitro* (18)

Doses:	312.5 - 5000 μg/mL in the absence of metabolic activation (S9 mix) and 625 - 5000 μg/mL plus S9 mix
Duration:	after initiation for 48 h cells were harvested following 18 h or 32 h treatment; colchicine was added 2 h prior to harvesting
Test method:	OECD Guidelines (9)
Result:	the notified chemical was not clastogenic in human lymphocytes *in vitro*

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low acute oral toxicity in rats (LD_{50} > 5000 mg/kg) and low acute dermal toxicity in rabbits (LD_{50} > 2000 mg/kg). It was a slight skin irritant and a moderate eye irritant in rabbits and was not a skin sensitiser in guinea pigs. In a 28-day sub-chronic repeated dose feeding study, no organ toxicity was identified at doses up to 2500 mg/kg/day.

The notified chemical was not mutagenic in *Salmonella typhimurium* and was not clastogenic as judged by lack of induction of chromosomal aberrations in human lymphocytes in culture or micronuclei in bone marrow cells of mice following i.p. injection.

The notified chemical would not be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (19) (Approved Criteria) with respect to acute lethal effects (oral, dermal), irritant effects (skin, eye), sensitising effects (skin), severe effects after repeated or prolonged exposure or mutagenic effects.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although no ecotoxicological data has to be provided for chemicals imported at rates less than 1 tonne per annum according to the Act, the company did provide data, as listed below. All ecotoxicity tests were conducted according to Good Laboratory Practice procedures.

Test	***Species***	***Results***
acute toxicity	rainbow trout	LC_{50} > 110 mg/L NOEC > 110 mg/L (20)
acute toxicity	*Daphnia magna*	EC_{50} > 110 mg/L (24 h & 48 h) (21)
Algal, Growth Inhibition (72 h)	*Selenastrum capricornutum*	NOEC (growth) > 99 mg/L (72 h) E_bC_{50} > 99 mg/L (72 h) E_rC_{50} > 99 mg/L (0-72 h) (22)
Respiration Inhibition Test	Micro-organisms from activated sludge	EC_{50} > 100 mg/L (3 h) (23)

* NOEC - no observable effect concentration

The test reports indicate the chemical is practically non-toxic to fish, *Daphnia* and algae. The activated sludge respiration inhibition test indicated that pentaerythritol phosphate alcohol does not inhibit respiration of microorganisms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The caulk product, CP-25 WB+ Caulk, in which the notified chemical will be imported is water based and intended to replace a solvent based product. The low environmental exposure of the chemical as a result of normal use and its low ecotoxicity indicate that the overall environmental hazard resulting from the use of the product containing the notified chemical is low.

Spillage during transport is possible, however, given that the chemical is a component of a viscous caulk which sets on contact with the atmosphere and low toxicity to aquatic organisms of the chemical such spills should not represent a significant hazard to the environment.

The overall environmental hazard posed by the notified chemical can be rated as negligible when incorporated in CP-25 WB+ Caulk.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical would not be classified as hazardous according to the Approved Criteria with regard to the toxicological data supplied. However, it may be a slight skin and a moderate eye irritant in some individuals.

Exposure to the notified chemical is expected to be low as it is at a low concentration (4-5%) in the formulation to be imported and is applied to cavities in fire rated walls with a caulking gun or putty knife. In these circumstances dermal exposure is dependent upon work practices and can be easily avoided.

The occupational and public health risk from transport, storage, use and disposal of the notified chemical as indicated by the applicant is expected to be minimal given the low intrinsic hazard, low concentration in the imported formulation and limited opportunity for exposure.

13. RECOMMENDATIONS

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

- if engineering controls and work practices are insufficient to reduce exposure to a safe level, then the following personal protective equipment which conforms to Australian (AS) or Australian/New Zealand (AS/NZS) Standards should be worn;

  safety goggles should be selected and fitted in accordance with AS 1336 (24) to comply with AS/NZS 1337 (25),

  industrial clothing should conform to the specifications detailed in AS 2919 (26),

  impermeable gloves or mittens conforming to AS 2161 (27),

  all occupational footwear should conform to AS/NZS 2210 (28);

- spillage of the notified chemical should be avoided, spillages should be cleaned up promptly which should then be put into containers for disposal in accordance with Local, State or Federal government guidelines;

- good personal hygiene should be practised to minimise the potential for ingestion;

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for a formulation containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (29).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

1. National Occupational Health and Safety Commission 1994, *List of Designated Hazardous Substances [NOHSC:10005(1994)]*, Australian Government Publishing Service, Canberra, Australia.

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15. Heddle *et. al* 1983, 'The Induction of Micronuclei as a Measure of Genotoxicity', *Mutat. Res.*, **123**, 61-118.

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19. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra, Australia.

20. Bell, G 1994, *NH-1197 Acute Toxicity for Rainbow Trout* (*Oncorhynchus mykiss*), Project No. GLC 6(c)/941066, Huntingdon Research Centre Ltd., Cambridgeshire, England.

21. Bell, G 1994, *NH-1197 Acute Toxicity of Daphnia magna*, Project No. GLC 6(c)/941065, Huntingdon Research Centre Ltd., Cambridgeshire, England.

22. Bell, G 1994, *NH-1197 Algal Growth Inhibition*, Project No. GLC 6(a)/941064, Huntingdon Research Centre Ltd., Cambridgeshire, England.

23. Bell, G 1994, *NH-1197 Inhibitory Effect on the Respiration of Activated Sewage Sludge*, Project No. GLC 6(d)/941085, Huntingdon Research Centre Ltd., Cambridgeshire, England.

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29. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, AGPS, Canberra, Australia.

Attachment 1

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

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

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

CORNEA

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

CONJUNCTIVAE

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

IRIS

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