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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT GELPASTE UREA

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Director Chemicals Notification and Assessment

FULL PUBLIC REPORT

GELPASTE UREA

1. APPLICANT

Bostik (Australia) Pty Ltd of 51-71 High Street, Thomastown 3074 has submitted for a standard notification statement with their application for an assessment certificate for Gelpaste Urea. The notified chemical will be used as a component an industrial sealant.

2. IDENTITY OF THE CHEMICAL

Gelpaste Urea 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, composition and manufacturing process have been exempted from publication in the Full Public Report and the Summary Report

Other names: Gelpaste Urea

Marketing name: Marketed as the end-use product Bostik Seal'n'Flex 2637,

containing less than 5% w/w of Gelpaste Urea.

3. PHYSICAL AND CHEMICAL PROPERTIES

All physico-chemical properties of the urea were determined according to the relevant section of OECD Test Guidelines.

Appearance at 20°C and 101.3 kPa: Dry, off-white paste

Melting point: 234-238 °C

Boiling point: Not determined

Density: Relative density 1.097 at 23°C

Vapour pressure: 8 x 10⁻⁶ Pa at 25 °C

Water solubility: $0.05 \pm 0.02 \text{ mg/L}$ at 20 °C

Hydrolysis: Test not performed due to the low solubility

in water. Urea linkages are unlikely to hydrolyse under environmental conditions.

Partition coefficient: Log $P_{OW} = 2.7$, determined by HPLC.

(n-octanol/water)

Adsorption/desorption: Test not performed. The low water

solubility and the log P would indicate good

adsorption with weak desorption.

Dissociation constant: Test not performed. The substance does

not contain ionisable groups and

measurement would be difficult due to the

low solubility in water.

4. PURITY OF THE CHEMICAL

Purity: >95%

Toxic or Hazardous

Impurities: none

Non Hazardous

Impurities: none

5. INDUSTRIAL USE

The notified chemical is intended to be manufactured by Bostik Australia Pty Ltd, and will be used as a component in an industrial sealant, Seal 'n Flex 2637, for industrial application on internal and external building joints.

6. OCCUPATIONAL EXPOSURE

The manufacture of Gelpaste Urea is an exothermic process occurring within a closed system. The resulting compound is in a solid form which will be packaged directly into drums and stored on site before being incorporated into the manufacture of the sealant. The subsequent manufacture of the Seal 'n Flex will involve similar processes within the closed. This process will be controlled by 2 operators wearing as a minimum, overalls, chemical resistant gloves, safety shoes and safety glasses. There is potential exposure to the notified chemical for 8-12 hours/day, 36 days/year during the manufacturing process as well as the packaging. The entire manufacturing area has a fume extraction system, as well as vapour alarms being installed, the area bunded and an automatic sprinkler system in place.

There will be one quality control officer who will potentially come into contact with the notified chemical during sampling for 1 hour/day, 12-24 days/year. The same protective clothing requirements will apply. Sampling will take place during packaging before the drums are lidded.

The on site storage of the notified chemical in drums will be the responsibility of one supervisor who will potentially be exposed to the notified chemical for 4 hours/day, 12 days/year.

All equipment maintenance will be carried out by a single leading hand who will potentially be exposed to the notified chemical for 8-12 hours/day, 36 days/year.

It is anticipated that more than 1000 people could potentially be exposed to the notified chemical within the Seal 'n Flex formulation when applying the sealant in industrial applications. The exposure period may extend from minutes to several hours.

7. PUBLIC EXPOSURE

The sealant will be applied by an estimated number of more than 1000 workers, only in industrial situations. The sealant will cure upon exposure to ambient moisture to form a permanent seal. Public exposure to the chemical during its manufacture and industrial application and use is therefore expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

. Release

The manufacture of Gelpaste Urea will be done in a closed system and involves the reaction of two chemicals. The urea formed is packed directly into drums and stored on site before being used in the manufacture of Seal'n'Flex. This is a continuous process and only requires cleaning if stopped. If the system is cleaned, then the washings are used in the manufacturer of Seal'n'Flex. The drums used to store Gelpaste Urea are expected to be reused on site or sent to a drum recycler for reuse. The drum recycler is expected to send residues in these drums to landfill. It is assumed that there will be minimum residue Gelpaste Urea, therefore there is expected to be minimal release of Gepaste Urea to the environment during manufacture of the urea

The manufacture of Seal'n'Flex involve mixing Gelpaste Urea with plasticiser, pigments and solvents etc., in a closed system and the resulting product is then directly packed into sealed containers. Cleaning of equipment will occur after every 5th batch and involve < 0.5% loss per 5th batch of Seal'n'Flex, corresponding to <240 grams of the urea.

During use Seal'n'Flex will cure to an inert solid upon exposure to ambient moisture and any excess should cure likewise. In this form there should not be any releases of the notified chemical. Seal'n'Flex is to be packaged into 300 mL cartridges and 600 mL "sausages" containers for use in caulking-type guns. This type of packing and method of use will normally ensure that insignificant amounts of the urea are disposed of with the packaging.

. Fate

The fate of most of the notified chemical is identical to that of the products to which it is bound. Seal'n'Flex is expected to be used as a sealant for building joints etc and remain with the jointed surfaces until it is removed or disposed of with the articles

which it is bound to. Therefore most of Gelpaste Urea manufactured will be incorporated in a polymer matrix, most of which will eventually be disposed of by landfill.

A small amount of waste is generated during manufacture, the fate of this waste was not given by the applicant, however it is expected to eventually go to landfill or be incinerated. When tested for biodegradability, (modified Sturm test, OECD Test Guidelines 310C), Gelpaste Urea was not biodegradable,—3.6% degradation at 300 mg/L (nominal concentration) after 28 days. Therefore degradation of the notified chemical is unlikely when it is landfilled.

Gelpaste Urea has chemical properties that indicate potential for bioaccumulation. However, bioaccumulation of the urea is not expected due to the low environmental exposure from the proposed use.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Gelpaste Urea

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD ₅₀ >2000 mg/kg	(1)
Acute dermal toxicity	Rat	$LD_{50} > 2000 \text{ mg/kg}$	(3)
Skin Irritation	Rabbit	non irritant	(4)
Eye irritation	Rabbit	non irritant	(6)
Skin sensitisation	Guinea-pig	non sensitising	(7)

9.1.1 Oral Toxicity (1)

Result: no significant toxicological observations

Number/sex of animals: 5/sex Observation period: 14 days

Method of administration (vehicle): notified chemical administered orally as a white powder in 1% carboxymethyl cellulose in water by gavage at a single fixed dose. Rats were observed 1, 3 and 6 hours after dosing and thereafter for 14 days consecutively.

Clinical observations: no significant observations

Mortality: none Morphological findings: no

significant observations

Test Method: According to OECD Guideline No. 420. (2)

9.1.2 Dermal Toxicity (3)

Result: no significant toxicological observations

 LD_{50} : > 2000 mg/kg Species/strain: SPF Wistar Rats

Method of administration (vehicle): notified chemical (2000 mg/kg) administered as a white powder moistened in sesame oil applied to the shaved flanks and backs of rats and covered with a gauze pack for 24 hours.

Clinical observations: no significant observations

Mortality: none Morphological findings: no significant findings

Test Method: According to OECD Guideline 402. (2).

9.1.3 Skin Irritation (4)

Result: not a skin irritant Species/strain:

Mol:Russian SPF albino rabbits

Number/sex of animals: 4 female

Method of administration: 0.5 g of notified chemical in 0.5g of sesame oil applied to gauze patches which were secured to the shaved backs (left and right test sites) of the rabbits for 4 hours.

Test Method: According to OECD Guideline No.404 (2).

Draize (5) Scores i:

Animal	Time after decontamination							
	1 h	our	24 hours		48 h	ours	72 hours	
ERYTHEMA	L	R	L R		L	R	L	R
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0
OEDEMA								
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0

i: see attachment 1 for Draize scores.

L=left test site; R=right test site

9.1.4 Eye Irritation (6)

Result: not an eye irritant

Method of administration: 0.1 g of notified chemical was placed in the left conjunctival sac of each animal, the right eye serving as a control.

Test Method: According to OECD Guideline No.405 (2).

Draize Scores ii:

Animal	Time after instillation											
	1 hour 24 hours				48 hours 72 hou				rs			
CORNEA:	opa	acity		opacity		opacity		opacity				
	are	а		area		area		area				
1		0		0		0			0			
2		0			0		0			0		
3		0			0			0		0		
4	0			0		0		0				
IRIS												
1	0		0		0		0					
2	0			0			0			0		
3		0			0		0				0	
4	0		0		0		0					
CONJUNCTIVA	r ^a c ^b		ra	c_p	dc	ra	Cp	dc	ra	Cp	dc	
	dc											
1	1	2	1	0	0	0	0	0	0	0	0	0
2	1	1	1	0	1	0	0	0	0	0	0	0
3	1	2	1	0	2	0	0	0	0	0	0	0
4	1	1	1	0	1	0	0	0	0	0	0	0

ii: see attachment 1 for Draize scores

^a redness ^b chemosis ^c discharge

9.1.5 Skin Sensitisation (7)

Result: Notified chemical is not a skin sensitiser

Species/strain: Dunkin/Hartley SPF albino guinea-pigs

Number of animals: 30 females

Induction: 0.4 mL of a 25% (w/w) solution of notified chemical in paraffin oil taped to the shaved left flank of the animal under patches for 6 hours. Repeated on day 7 and 14. Challenge occurred four weeks after induction.

Results:

Challenge	24	hrs	48hrs		
Concentration	test	control	test	control	
25%	0	0	0	0	

Test Method: According to OECD Guideline No.406 (2).

9.2 Repeated Dose Toxicity (8)

Species/strain: SPF (mol:WIST) rats Number/sex: 20/sex

Method of administration (vehicle): Notified chemical suspended in 1% carboxymethylcellulose in distilled water was administered orally by gavage daily.

Dose/ Duration of administration: dose levels of 100 mg/kg, 300 mg/kg, or 1000 mg/kg body weight administered for 28 days. The control group received daily doses of 1% carboxymethylcellulose in distilled water.

Significant Observations:

1. Clinical

No adverse clinical symptoms.

2. Clinical Chemistry/Haematology

No significantly different haematological parameters.

The percentage of γ -gobulins in male rats receiving 1000 mg/kg day was lower than in the male rats in the control group.

3. Necropsy Findings/ Histopathology

The gross pathologic and histopathologic examinations did not show treatment related changes.

Test Method: According to OECD Guidelines No. 407 (2)

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (9)

Result: Notified chemical is not mutagenic.

Strains: Salmonella typhimurium TA 100, TA 98, TA 1537 and TA 1535.

Concentration range: 0.31 to 5.0 mg/plate with and without S9 rat liver metabolic

activation

Test Method: According to OECD Guideline No. 471 (2).

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (10)

Result: No significant increase in micronucleus formation. The notified chemical is not clastogenic *in vivo*.

Species/strain: SPF (Bom:NMRI) mice

Number and sex: 5/sex Doses: 0, 0.5, 1.0 and 2.0 g/kg body weight

Method of administration (vehicle): Notified chemical administered orally by gavage in 1% carboxymethylcellulose.

Test Method: According to OECD Guidelines No.474 (2)

9.4 Overall Assessment of Toxicological Data

From the data provided Gelpaste Urea has low acute oral and dermal toxicity in rats, and is not a skin or eye irritant in rabbits or a skin sensitiser in guinea-pigs. The only effect in 28-day repeat-dose gavage studies in rats was a decrease in the percentage of gamma globulins at the high dose of 1000 mg/kg. Gelpaste Urea was negative in a reverse mutation assay in *Salmonella*, and an *in vivo* bone marrow assay in mice at gavage dose level of up to 2000 mg/kg of body weight.

Gelpaste Urea is not classed as hazardous according to Worksafe Australia's Approved Criteria For Classifying Hazardous Substances (11) in relation to the toxicity data provided.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been provided by the notifier. These studies were conducted according to standard OECD Guidelines for static tests. Due to the low solubility in water, a stock solution of 2 g/L was treated by ultrasonication and stirring, then the water accommodated fraction was used. Chemical analysis determined the concentration of the urea to be <0.05 mg/L in the water accommodated fraction. This water accommodated fraction was used for all tests.

Test	Species	Result (nominal)
Acute toxicity	Rainbow trout	96h LC ₅₀ and
		NOEC > water solubility of Gelpaste Urea
Acute toxicity	Daphnia	48h EC ₅₀ and
	magna	NOEC > water solubility of Gelpaste Urea
Growth	Algae,	96h EC ₅₀ and
inhibition	Selenastrum capricornutum	NOEC > water solubility of Gelpaste Urea
OECD TG 209	Activated	Nitrifying NOEC > water solubility of Gelpaste
	Sludge	Urea
		Respiration NOEC > water solubility of Gelpaste
		Urea

The ecotoxicity studies show that Gelpaste Urea toxicity is greater than the solubility in water and toxicological effects on fish, daphnia, algae and microorganisms are not expected.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The manufacture of Gelpaste Urea and Seal'n'Flex generates minimal waste, estimated by the applicant as <0.5% per 5th batch of Seal'n'Flex. This correspond to <250 grams of the urea. This small amount of waste is expected to be disposed by landfill. The drums used to store the urea are expected to be reused on site, however some drums could be sent to a drum recycler who will dispose of any residue urea as trade waste (landfill). The quantity of the urea disposed as "drum residue' is unknown but is expected to be minimal.

When the end-use product, Seal'n'Flex is used there is not expected to be any significant release of the urea to the environment due to the nature of the product and method of application. On exposure to ambient conditions, Seal'n'Flex is expected to cure to an inert solid (a polyurethane polymer), which will prevent any release of the urea to the environment. Due to the method of use and type of packaging insignificant amounts will be disposed of with the packaging as the cured inert solid.

Incineration of the notified chemical will generate oxides of carbon and nitrogen as well as water. In landfill the urea is not expected to leach and should stay in the landfill. The environmental hazard from the disposal of articles with joints were Seal'n'Flex has been used by landfill or incineration is rated as negligible.

The overall environmental hazard can be rated as negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Gelpaste Urea was found to have low acute oral ($LD_{50} > 2000 \text{ mg/kg}$) and dermal toxicity ($LD_{50} > 2000 \text{ mg/kg}$), was not a skin or eye irritant, was not a skin sensitiser, was not toxic by repeated dosage and was not found to be genotoxic or clastogenic. Gelpaste Urea is not classed as hazardous according to Worksafe Australia's Approved Criteria For Classifying Hazardous Substances (11).

Levels of exposure to the notified chemical of manufacturing operators and quality control workers are expected to be low as the manufacture will take place within a closed system with direct packaging of the product in drums. Any significant exposure to the notified chemical would only occur during sampling of the product or in the instance of a spill, in which case the manufacturing facility is covered by a fume extraction system as well as vapour alarms, automatic sprinkler system and bunding to provide containment should a spill occur. These engineering controls in combination with the appropriate protective clothing, goggles and gloves should minimise any potential occupational exposure. It is also recommended that the appropriate respiratory devices with dust/mist cartridges be employed.

Given that the product will be stored in sealed drums reduces the chance of any significant exposure to Gelpaste Urea occurring unless a spill was to occur. Given that the notified chemical is a paste/solid, any spill should be contained easily. Any cleanup should be performed in appropriate protective clothing, goggles and gloves.

As the manufacture is a continuous process, the cleaning of equipment will only be necessary when the process stops. As any wastage is flushed into the production of the industrial sealant, any potential exposure to the notified chemical during maintenance should be at a minimum. The appropriate protective clothing should be worn however to reduce any exposure further.

In the application of Gelpaste Urea in the industrial sealant Seal 'n Flex 2637 there may be potential for dermal exposure during usage of caulking-type guns to dispense the sealant, however this risk should be minimised by the usage of protective clothing, impermeable gloves in particular. Any subsequent exposure to the notified chemical should be negligible as the product cures to an inert solid, the notified chemical being encased within the polyurethane sealant.

The public will not be exposed to the chemical during its manufacture and industrial application and use as an external and internal building joint sealant.

The overall risk from Gelpaste Urea is considered to be negligible due to the reduced risk of any significant occupational exposure to the notified chemical, as well as the low levels of toxicity observed in the studies provided.

13. RECOMMENDATIONS

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

if engineering controls and work practices are insufficient to reduce exposure to Gelpaste Urea to a safe level during manufacture and reformulation, then:

a vapour/fume extraction system should be employed.

the appropriate respiratory device should be selected and used in accordance to Australian Standard/ New Zealand Standard (AS/ NZS) 1715 (12) and should comply to AS/NZS 1716 (13).

eye protection should be selected and fitted in accordance to AS 1336 (14) and used in accordance to AS/NZS 1337 (15).

industrial clothing must conform to the specifications detailed in AS 2919 (16) and AS 3765.1 (17).

industrial gloves should conform to the standards detailed in AS 2161 (18) and AS 3765.1 (17).

all occupational footwear should conform to the standards detailed in AS/NZS 2210 (19).

if engineering controls and work practices are insufficient to reduce exposure to Gelpaste Urea in the product Seal 'n' Flex to a safe level during application then:

industrial clothing must conform to the specifications detailed in AS 2919 (16) and AS 3765.1 (17).

industrial gloves should conform to the standards detailed in AS 2161 (18) and AS 3765.1 (17).

all occupational footwear should conform to the standards detailed in AS/NZS 2210 (19).

particular care should be taken to avoid spillage of the notified chemical.

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

a copy of the Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Gelpaste Urea was provided in an acceptable format (20).

This MSDS was provided by Bostik (Australia) Pty Ltd as part of their notification statement. The accuracy of this information remains the responsibility of Bostik (Australia) Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Gelpaste Urea shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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- 3. Jacobsen, SD, 1993, Assessment of Acute Dermal Toxicity in Rats, Scantox, Project No. 14134.
- 4. Jacobsen, SD, 1993, Assessment of the Skin Irritant Effect on Rabbits, Scantox, Project No. 14135.
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- 6. Jacobsen, SD, 1993, Assessment of the Eye Irritant Effect on Rabbits, Scantox, Project No. 14136.
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- 10. Jensen, JC, 1993, N, Mouse Micronucleus Test, Scantox, Project No. 14139.
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- 17. Standards Australia, 1990, Australian Standard 3765-1990 Clothing for Protection Against Chemical Hazards, Part 1 Protection Against General or Specific Chemicals, Part 2 Limited Protection Against Specific Chemicals, Standards Association of Australia Publ., Sydney, Australia.
- 18. Standards Australia, 1978, Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves), Standards Association of Australia Publ., Sydney, Australia.
- 19. Standards Australia, Standards New Zealand 1994, Australian/ New Zealand Standard 2210 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.
- 20. National Occupational Health and Safety Commission, *Guidance Note for the Completion of a Material Safety Data Sheet,* 2nd. edition, AGPS, Canberra, 1990.

ATTACHMENT 1

ⁱ 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. 1mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

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

	CValuation	of eye reactions is as to	Jilows.			
CORNEA						
Opacity		rating	Area of Cor	nea 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 translu cent 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		Discharge with moistening of lids and adjacent hairs	2 mod.	
Diffuse beefy red	3 severe	Swelling with lids half- closed	3 mod.	Disharge with moistening of lids and hairs and considerable area around eye	3 severe	
		Swelling with lids half- closed to completely closed	- 4 severe			
IRIS	<u> </u>					
Values						
Normal					0 none	
Folds above normal, cor	ngestion, swe	lling, circumcorneal inject	ion, iris reacts	to light	1 slight	
No reaction to light, haemorrhage, gross destruction						