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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Sylvares ZT 5100

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Director
Chemicals Notification and Assessment

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Sylvares ZT 5100

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
National Starch & Chemical Pty Ltd (ABN 37 000 351 806).
7 Stanton Road Seven Hills NSW 2047.

NOTIFICATION CATEGORY
Standard: Polymer with NAMW < 1000 (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical identity information
Import volume
Site and details of formulation
Details of use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Analogue data used for toxicological testing. No ecotoxicity data submitted.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, 1987.
Canada, 1997.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sylvares ZT 5100.
Component of Dispo-Melt-X-502A

CAS NUMBER
Not assigned

MOLECULAR FORMULA
Undefined

SPECTRAL DATA
Infrared

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD Gel permeation chromatography

3. COMPOSITION

DEGREE OF PURITY
> 99 %

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured locally. It will be imported as a component of another chemical.

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

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

USE
Hot-melt adhesive for use in the manufacture of disposable nappies.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
The notified chemical will be imported a component of another chemical, which is supplied as solid pellets in lined paper bags of 25 kg net weight and delivered to the notifier's warehouse for formulation and packaging. It will then be distributed by road to customer sites.

5.2. Operation Description

The notified chemical (as a minor component of another chemical) will be blended with other ingredients at the formulation site(s) to form part of a hot melt adhesive. This will involve weighing, addition to a tumble blender, followed by mixing and heating in a closed batch process. The molten hot-melt adhesive will be packed into 700 g EVA (ethylene vinyl acetate) containers, which after cooling and solidification are packed in 15 kg boxes.
At the end-use site(s) the hot melt adhesive containing the notified chemical will primarily be used as an adhesive in the manufacture of diapers (nappies). The adhesive will be applied to the nappy components as part of an automated continuous process. The adhesive application station is an enclosed area of the process with exhaust ventilation. Workers would go to the adhesive application area to replace used containers of adhesive.

5.3. Occupational Exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
At formulation site(s)			
Transport and storage workers	4	2-3 hours/day	10-15 days/year
Blending operators	2-4	8 hours/day	50 days/year
Packaging operations	4	8 hours/day	50 days/year
Cleaning of equipment	1-2	2 hours/day	10-15 days/year
At customer site(s)			
Transport and storage	4-6	2-3 hours/day	10-15 days/year
Laminating machine operators	2-4	8 hours/day	50 days/year
Cleaning of equipment	1-2	2-3 hours/day	50 days/year

Exposure Details
Transport and Storage

The notified polymer (as a minor component of another chemical) will be transported by road in 25kg lined paper bags to the notifier's warehouse The formulated adhesive containing the notified resin will be transported to end-use sites in 700 g plastic containers and cardboard outer packaging. Waterside workers, transport drivers and warehouse workers would only be exposed to the material in the event of an accident. Accidental exposure would be minimised by the physical form of these materials – the notified polymer is supplied as solid pellets and the adhesive is packaged as solid blocks.

Blending

At the hot melt adhesive formulation site(s), the required amount of the polymer will be transferred manually to a tumble blender where it will be melted and mixed with other ingredients in a closed batch process. Weighing and introduction to the blender will be carried out under local exhaust ventilation, to capture any fugitive dust and thus reduce inhalation exposure to particles. After formulation with other ingredients the molten adhesive formulation containing the notified polymer at < 20% will be filled into 700 g packages and allowed to set. While the adhesive is liquid, there is the possibility of exposure of blending, packaging and QC workers to vapours emitted from the adhesive. These may include the more volatile components of the notified polymer. Dermal exposure would be reduced by the precautions needed to avoid burns from the hot adhesive, and from the solid nature of the polymer and the formulated adhesive at ambient temperature.

Cleaning and maintenance of the formulation and filling equipment is carried out monthly, by rinsing residual adhesive from the mixer and lines with hot solvent. During this process workers could be exposed through inhalation to both the solvent and the more volatile components of the adhesive.

Application of hot-melt adhesive

At the end-use site(s) of nappy manufacture, cardboard boxes each containing several small containers of hot melt adhesive will be stored in the warehouse until transferred to the laminating area for use. Here operators will melt the adhesive packages for use in the laminating machine and when necessary attend to any problems with the equipment. The area is provided with local exhaust ventilation, and PPE including gloves and face shields or safety glasses will be worn as protection from accidental splashes of hot adhesive. Dermal and inhalation exposure to the adhesive would be minimised by the enclosed nature of the equipment, the engineering controls and PPE used, and the fact that the operators are near the melted adhesive only intermittently.

At the completion of each production run, the dried adhesive will be cleaned from the machine manually with a scraper and a soap water mixture.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The resin containing the notified polymer is shipped as solid pellets in lined paper recyclable bags which should result in little contamination. As the resin is melted and mixed with other additives to form the hot-melt adhesive (Dispo-Melt-X-502A), losses are not expected to be significant as wastes can be melted and reused. The overall material loss is expected to be <0.5% (maximum of 50 kg/year) which will be collected and disposed of by incineration or to landfill.

Manufacture of the adhesive containing a low proportion of the notified polymer is a batch process in closed blending equipment operating at about 180°C. The molten adhesive is pumped into ethylene vinyl acetate packaging, cooled till solid and then packed into cardboard boxes.

The monthly cleaning of equipment involves draining residual molten adhesive and rinsing with a hot

solvent. Used solvent is collected and disposed of by a licensed waste contractor.

RELEASE OF CHEMICAL FROM USE

The hot melt adhesive (containing the notified polymer) will be used in the construction of disposable diapers. Any spill or accidental release during manufacture will be contained, cleaned up and sent to landfill.

There is no release of the polymer expected during use as disposable diapers.

5.5. Disposal

Empty import bags and any residual resin will be disposed of to landfill. Cleaning of application equipment for diaper manufacture is done manually by scraping and scrubbing of the dried adhesive followed by rinsing with soap and water. The rinsate would be disposed of to the sewer while the ultimate fate of soiled diapers containing the notified polymer will be to landfills via municipal garbage collection.

5.6. Public exposure

Consumer use of babies' nappies containing the notified polymer can potentially lead to exposure of those handling or wearing the nappies. It is estimated that each nappy would contain up to 0.02 g of the notified polymer.

Nappy handling

Dermal exposure to those handling the nappies is expected to be negligible because the nappy does not contain adhesive on its outside surface. Inhalation exposure would be similarly low, even if a proportion of the polymer in the adhesive was volatile, because of the short exposure period, the small amount of adhesive in each nappy, and the solid form of the adhesive.

Nappy users

Babies and young children could potentially be exposed to the notified polymer through its use in the adhesive contained in nappies they are wearing. Because nappies are worn for up to 24 h/day and are close to both skin and airways, a detailed evaluation of potential exposure is required, including worst case scenarios.

Although no adhesive is present on the outside surfaces of the nappy (including the surface in contact with the skin), it is possible that urine or faeces could leach some of the polymer components from the adhesive, leading to dermal exposure until the soiled nappy was replaced. This potential exposure would be limited by the small amount of adhesive in each nappy. It may be increased by enhanced absorption from the occluded skin under nappies and from any already-irritated skin (IPCS, 1986).

Babies could potentially be exposed by inhalation to the low boiling point components of the notified polymer, if these volatilised from the adhesive at any time after it was used in manufacture of the nappy. This could occur from the time the nappies are folded and packed at the manufacturing site, through storage, and for the time each nappy is worn. Some vapours could be trapped within the nappy until it is opened and used. It is estimated that such exposure would be very low, because it is unlikely that the small quantity of notified polymer in each nappy could produce a significant concentration of vapour in the inhalable zone near the baby's face.

6. PHYSICAL AND CHEMICAL PROPERTIES

Note on physico-chemical properties: the data is based on Sylvares ZT 5100 resin. As the molecular weight of the notified chemical may be lower, the physico-chemical properties may also vary.

Appearance at 20ºC and 101.3 kPa	Pale yellow solid.

Melting Point/Freezing Point 90-96°C (softening point)

Remarks No test report provided

Boiling Point > 148.9°C

Remarks No test report provided. Thermal decomposition occurs at > 240^0C.

Boiling Point 0 % volatile

METHOD EPA Method 24.
Remarks Test report not provided.

Density > 1000 kg/m^3

Remarks No test report provided.

Vapour Pressure Not determined.

Water Solubility <2.43 mg/L at 20°C

METHOD OECD TG 105 Water Solubility.
Remarks The Column Elution Method was performed on a related analogue chemical (which contains an extra monomer) rather than the notified polymer itself. About 0.1 g of the test material was dissolved in water with glass beads and packed into a column. After conditioning of the column and elution with distilled water, duplicate aliquots were measured spectrophotometrically. The pH of the solution was 6.7-6.9 at 20.0±0.5°C. Since the polymer is a hydrocarbon, the actual result should be much lower than indicated. A QSAR estimate of the simplest combination indicated this to be <0.1 µg/L.
TEST FACILITY SafePharm (1996)

Hydrolysis as a Function of pH The notified polymer contains no groups generally considered as hydrolysable.

Partition Coefficient (n-octanol/water) log Kow > 3.06 at 21.5°C

METHOD OECD TG 107 Partition Coefficient (n-octanol/water).
Remarks The Shake-Flask Method was performed on the related analogue chemical rather than the notified polymer itself. Different volumes (replicated twice) of mutually saturated n-octanol and water containing the analogue were shaken about 180 times over 5 minutes before separation and analysis by spectrophotometer. The pH of the aqueous solutions were 6.2-6.6 at 21.5±0.5°C.
TEST FACILITY SafePharm (1996)

Adsorption/Desorption Not determined.
– screening test
Remarks Based on the expected relatively high log Kow, the notified polymer should bind strongly to soil organic matter

Dissociation Constant The notified polymer has no groups capable of dissociation.

Particle Size Not determined. Supplied as resinous solid granules.

Flash Point > 232°C

METHOD Setaflash Closed Cup
Remarks Report not provided.

Flammability Limits	Not determined. Material is stated to be non-flammable.
Autoignition Temperature	Not determined. Material is stated to be non-flammable.
Explosive Properties	MSDS notes that high concentrations of airborne dust may form an explosive mixture with air.

Reactivity

The notified resin is stable. Decomposition expected at > 240ºC. Contact with strong oxidising agents should be avoided. May form hazardous decomposition products such as smoke, carbon monoxide, carbon dioxide and other products of combustion. Hazardous polymerisation will not occur.

Some oxidation is expected at 180^0C, the upper end of temperature range for end-use of the notified chemical. Test reports not provided.

7. TOXICOLOGICAL INVESTIGATIONS

No studies were available on the notified polymer. However, toxicology data on analogue resins have been provided below. The analogues were accepted as suitable for providing a toxicological profile of the notified polymer. However, it should be noted that the notified polymer will have a lower molecular weight than the analogues tested, increasing absorption and the likelihood of toxicological effects.

List of studies provided for the analogue resins

CODE NAME	RELATIONSHIP TO NOTIFIED CHEMICAL	TEST PERFORMED	RESULTS/CONCLUSIONS	STUDY NO. AND DATE
Experimental Resin XR 5001	Contains same monomers as notified polymer.	Acute Oral Toxicity (Rats)	LD50 > 5000mg/kg	PH-402-AZ-005-87 12/12/87
Zonatac 85LT, Lot#NRH 1159	Contains same monomers as notified polymer.	Acute Oral Toxicity (Rats)	LD50 > 5000mg/kg	PSL 3973 11/13/95
ASL 5263 Zonatac Alternate #1	Contains same monomers as notified polymer.	Acute Oral Toxicity (Rats)	LD50 > 10 g/kg	8219_A 10/30/84
ASL 5264 Zonatac Alternate #1 Lite	Contains same monomers as notified polymer.	Acute Oral Toxicity (Rats)	LD50 > 10 g/kg	8219_B 10/30/84
Experimental Resin XR5001	Contains same monomers as notified polymer.	Acute Dermal Toxicity (Rabbits)	LD50 > 2000 mg/kg	PH 420-AZ-005-87 1/15/88
Zonatac 85LT, Lot NRH 1159	Contains same monomers as notified polymer.	Acute Dermal Toxicity (Rats)	LD50 > 5000 mg/kg	PSL 3974 12/5/95
ASL 5264 Zonatac Alternate #1 Lite	Contains all monomers plus one additional monomer	Acute Dermal Toxicity (Rabbits)	LD50 > 2 g/kg	8219_B 10/30/84
ASL 5264 Zonatac Alternate #1 Lite	Contains same monomers as notified polymer.	Acute Inhalation Toxicity (Rats)	LC50 > 0.13 mg/l	8219_B 10/30/84
Experimental Resin XR-5001 Lot # PCP-8727	Contains same monomers as notified polymer.	Primary Dermal Irritation (Rabbits)	No signs of erythema or oedema observed. Not a D.O.T corrosive.	PH 420-AZ-008-87 12/18/87
XR-5144 Resin Lot# I1B02002	Contains fewer monomers than the notified polymer.	Primary Dermal Irritation (Rabbit)	Primary Irritation Index 0 – not an irritant	MB 01-9651.03 Volume 1 1/28/02
XR-5144 Resin Lot #I1B02002	Contains fewer monomers than the notified polymer.	Delayed Contact Dermal Sensitization Test – Buehler Method (Guinea pigs)	Not a sensitizer	MB 01-9651.06 Volume II 1/28/02
ASL 5263 Zonatac Alternate #1	Contains same monomers as notified polymer.	Ames Salmonella/Microsome Plate Test Assay	Non mutagenic	PH 301T-AC-014-84 10/30/84
ASL 5264 Zonatac Alternate # 1 Lite	Contains same monomers as notified polymer.	Ames Salmonella/Microsome Plate Test Assay	Non mutagenic	PH 301T – AC-015-84 10/30/84
Sylvares ZT 105LT Resin	Contains fewer monomers than the notified polymer.	Cytotoxicity study using the ISO Elution method	Showed no evidence of causing cell lysis or toxicity.	NAMSA G1B02002 10/19/01

XR-5144 Resin	Contains fewer monomers than the notified polymer.	Cytotoxicity study using the ISO Elution method	Showed no evidence of causing cell lysis or toxicity.	NAMSA I1B02002 10/19/01

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion based on testing of analogue resins of higher molecular weight than the notified polymer*
	Low toxicity
Rat, acute oral	LD50 > 10 g/kg.bw
Rat, acute oral	LD50 > 10 g/kg bw
Rat, acute oral	LD50 > 5000 mg/kg bw
Rat, acute oral	LD50 > 5000 mg/kg bw
	Low toxicity
Rat, acute dermal	LD50 > 5000 mg/kg bw
Rabbit, acute dermal	LD50 > 2000 mg/kg bw
Rabbit, acute dermal	LD50 > 2 g/kg bw
	Not classifiable
Rat, acute inhalation	LC50 > 0.13 mg/L/4 hour
Rabbit, skin irritation	Non-irritating
Rabbit, eye irritation	Slightly irritating. Study not provided.
Respiratory irritation	Dust or vapours formed on heating may cause respiratory irritation. No studies provided.
Guinea pig, skin sensitisation - Buehler Method	No evidence of sensitisation.
Human patch test studies	No skin sensitisation
Repeat dose toxicity	Not determined
Genotoxicity - bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro	Not determined
Cytotoxicity study (ISO Elution Method)	No evidence of cell lysis or toxicity

7.1. (a) Acute toxicity – oral

TEST SUBSTANCE	Zonatac Alternate #1 (ASL 5263) Study 8219_A 10/30/84
METHOD	Stated as OECD method. Analogous to TG 401 Acute Oral Toxicity – Limit test
Species/Strain	Rat/Sprague-Dawley
Vehicle	Corn oil
Remarks – Method	Gavage

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*

1	5/sex	10.0 g/kg	None

LD50	> 10.0 g/kg bw
Signs of Toxicity	Diarrhoea in 5/5 males and 2/5 females, which reversed by day 3. Salivation in 3/5 males and 1/5 females on day 1 only. Wet abdomen in 3/5 males and 3/5 females, which reversed by day 3. 1/5 males experience hair loss and a sore on a hind leg from day 6 onwards. Reduced activity and increased respiratory rate in 1/5 females was observed from day 4 to end of the observation period.
Effects in Organs	The female rat in which persistent clinical signs were observed was found at necropsy to have abscessed lobes of the lung which adhered to the rib cage.
Remarks – Results	Abscessed lung in 1/5 females and hair loss/sore on leg in 1/5 males are likely to be unrelated to the test substance.

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

TEST FACILITY Food and Drug Research Laboratories (1984a)

7.1. (b) Acute toxicity – oral

TEST SUBSTANCE Zonatac Alternate #1 Lite (ASL 5264)
Study 8219_B 10/30/84

METHOD Method analogous to OECD TG 401 Acute Oral Toxicity – Limit test.

Species/Strain	Rat/Sprague-Dawley
Vehicle	Corn oil 25% solution
Remarks – Method	Gavage. Observations carried out to Day 15.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	10g/kg	None

LD50	> 10 g/kg bw
Signs of Toxicity	Diarrhoea in all males and females, clearing after two days of the study. Wet abdomen in 2/5 males and 3/5 females on days 2-3 only.
Effects in Organs	None.
Remarks – Results	

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

TEST FACILITY Food and Drug Research Laboratories, Inc (1984b).

7.1. (c) Acute toxicity – oral

TEST SUBSTANCE Experimental Resin XR 5001, Lot #PC8727
Study PH-402-AZ-005-87 12/12/87

METHOD According to EPA Federal Register Vol 50, No. 188, Friday, September 27, 1985.
Method analogous to OECD TG 401 Acute Oral Toxicity – Limit Test.

Species/Strain	Rat/Sprague-Dawley
Vehicle	Methylcellulose (0.25%) + Tween 80 to facilitate suspension formation.

Remarks – Method	Gavage. 14-day observation period.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5000 mg/kg	None

LD50	> 5000 mg/kg bw
Signs of Toxicity	No signs were observed throughout the study.
Effects in Organs	Terminal necropsy revealed a pitted kidney in one male. No visible lesions were observed in any of the remaining animals.
Remarks – Results	It is not known whether the occurrence of pitted kidney in 1/5 males was related to the test material.

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

TEST FACILITY Pharmakon (1987a).-

7.1. (d) Acute toxicity – oral

TEST SUBSTANCE Zonatac 85LT, Lot #NRH 1159
Study No. PSL 3973 13/11/95

METHOD Method analogous to OECD TG 401 Acute Oral Toxicity – Limit test

Species/Strain	Rat/Sprague-Dawley derived, albino
Vehicle	30% solution in corn oil
Remarks – Method	Due to large volume of dose (approx 3.5 mL) it was administered in two lots, two hours apart.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5000 mg/kg	None

LD50	> 5000 mg/kg bw
Signs of Toxicity	One male exhibited ano-genital staining from days 5 to 8.
Effects in Organs	No gross necropsy at terminal sacrifice apart from red lung discoloration consistent with euthanasia by CO2 inhalation, all tissues and organs appeared normal.
Remarks – Results	

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

TEST FACILITY Product Safety Labs (1995a).

7.2. (a) Acute toxicity – dermal

TEST SUBSTANCE Zonatac Alternate #1 Lite (ASL 5264)
Study No. $8219_{B.}$ 10/30/84

METHOD Stated as OECD method. Analogous to TG 402 Acute Dermal Toxicity – Limit test

Species/Strain	Rabbits/New Zealand White
Vehicle	Protocol states that solids are moistened with physiological saline (approx 1mL/g) before application.
Type of dressing	Occlusive
Remarks – Method	14-Day observation period used. Protocol does not state whether material was ground before application.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2.0g/kg	None

LD50	> 2 g/kg bw
Signs of Toxicity - Local	No erythema or oedema was observed throughout the 14 day study.
Signs of Toxicity - Systemic	There were no deaths. 1/5 males demonstrated intermittent diarrhoea, anorexia and decreased activity persisting to day 14, with soft stools on days 9 and 12. Soft stools were seen in 1/5 females on days 2-3, and anorexia in 1/5 females on days 12-13.
Effects in Organs	On gross necropsy 1/5 males (not same animal as demonstrated clinical signs) had pitted kidneys and multiple 1mm white spots through the large lobe of the liver. 1/5 females (same animal as demonstrated anorexia) had white areas through the small lobe of the liver. No dermal irritation was noted throughout the study.
Remarks – Results	The significance of the organ and clinical effects is not clear.

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

TEST FACILITY Food and Drug Research Laboratories, Inc (1984c).

7.2. (b) Acute toxicity – dermal

TEST SUBSTANCE Experimental Resin XR5001 (Lot #PCP8727)
Study No. PH 420-AZ-005-87 15/1/88

METHOD Method analogous to OECD TG 402 Acute Dermal Toxicity – Limit Test.

Species/Strain	Rabbits/Albino New Zealand White
Vehicle	None mentioned in study description.
Type of dressing	Semi-occlusive.
Remarks – Method	Protocol does not state whether material was ground before application.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2.0 g/kg	None

LD50	> 2.0 g/kg bw
Signs of Toxicity - Local	None
Signs of Toxicity - Systemic	None
Effects in Organs	No visible lesions were observed in any animal at terminal necropsy.
Remarks – Results	The form of the material tested – as a solid of unknown particle size – may have limited dermal absorption.

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

TEST FACILITY Pharmakon (1988)

7.2. (c) Acute toxicity – dermal

TEST SUBSTANCE	Zonatac 85LT (Lot #NRH1159) Study No. PSL 3974 5/12/95
METHOD	Method analogous to OECD TG 402 Acute Dermal Toxicity – Limit test.
Species/Strain	Rat/Sprague-Dawley derived, albino
Vehicle	Corn oil (1 ml corn oil/1g test article)
Type of dressing	Semi-occlusive.
Remarks – Method	Prior to application, the material was ground to a fine powder in a coffee mill, and was moistened with corn oil prior to application. Observation period was 14 days.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5000 mg/kg/bw	None

LD50	> 5000 mg/kg bw
Signs of Toxicity - Local	None
Signs of Toxicity - Systemic	None
Effects in Organs	Gross necropsy findings at terminal sacrifice revealed dark foci on the lungs of one male rat. Apart from red lung discoloration consistent with euthanasia by CO_2 inhalation, all tissues and organs appeared normal.
Remarks – Results	Raw data not submitted. Results were presented in tabular form. It is not known whether the dark lung foci were test-related.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Product Safety Labs (1995b).

7.3. Acute toxicity – inhalation

TEST SUBSTANCE	Zonatac Alternate # 1 Lite (ASL 5264) Study No. $8219_{B.}$ 30/10/84
METHOD	Stated to be OECD method. Analogous to OECD TG 403 Acute Inhalation Toxicity.
Species/Strain	Rat/Sprague-Dawley
Vehicle	None
Method of Exposure	Whole-body exposure
Exposure Period	4 hours
Physical Form	Solid aerosol (particulate). The test material was used as supplied in powder form by the sponsor.
Particle Size	• Mean particle size (MMAD): 3.6µm • Geometric Standard deviation: 2.3µm • Estimated percent of collected particles < 12 µm: 93%
Remarks – Method	Rats were exposed to dust aerosol at the average measured concentration of 0.13 mg/l. This was the highest concentration achievable.

RESULTS The average actual concentration of ASL 5264 was 11% of the nominal concentration.

Group	*Number and Sex of Animals*	*Concentration mg/L*		*Mortality*
		Nominal	*Actual*	
1	10/sex	1.2	0.13	None

LC50 > 0.13 mg/L/4 hours
Signs of Toxicity
Effects in Organs At necropsy two female rats had firm, multi-nodular subcutaneous masses located on their lower abdomen. One of these masses had been noted in daily observations from day 4.
Remarks – Results It is not known if the abdominal masses were test-related.

CONCLUSION The 4 hour LC50 was > 0.13 mg/L. However this does not allow classification against this endpoint, as the maximum concentration tested was below the Approved Criteria.

TEST FACILITY Food and Drug Research Laboratories, Inc (1984d).

7.4. (a) Irritation – skin

TEST SUBSTANCE Experimental Resin XR-5001 (Lot #PCP-8727)
PH 420-AZ-008-87 18/12/87

METHOD Method analogous to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 6 (3 males and 3 females)
Vehicle None mentioned in protocol.
Observation Period 72 hours. Observations were made at 30 minutes, 60 minutes, 24 h, 48 h and 72 h.
Type of Dressing Occlusive
Remarks – Method Solid test material was ground in mortar and pestle before application directly to the intact skin. After 4 h the wrappings were removed, but protocol does not state if test material was cleaned from skin.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0	0	-	0
Oedema	0	0	-	0

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

Remarks – Results No erythema or oedema was noted

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY Pharmakon (1987b)

7.4. (b) Irritation – skin

TEST SUBSTANCE XR-5144 Resin (Lot #l1BO2002)
Study No. MB 01-9651.03, Volume 1

28/1/02

METHOD: Stated to comply with the FHSA standards set forth by 16 CFR 1500.41.

Species/Strain	Rabbit/New Zealand White
Number of Animals	6 (3 male and 3 female)
Vehicle	Distilled water
Observation Period	72 hours
Type of Dressing	Occlusive
Remarks – Method	The material supplied as off-white pellets was ground (method not described) and each dose of 0.5 g was moistened with 0.2 mL of distilled water before application. The test material was applied to the shaved backs of the rabbits, to one site with intact skin and another site with abraded skin. After application the sites were occluded for 24 h. Residual test material was gently wiped from the test sites at the end of this exposure period, prior to scoring for dermal reactions. Skin reactions were noted 24 h and 72 h after dosing.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0	0	-	0
Oedema	0	0	-	0

*Calculated on the basis of the scores at 24- and 72 hours for all animals, on intact and abraded skin.

Remarks – Results	There was no erythema or oedema noted at any observation period. There were no abnormal physical signs noted during the observation period. The primary Irritation Index was calculated by adding the mean values (6 rabbits) for erythema/eschar and edema on intact skin at 24 h and 72 h (a total of 8 values) and dividing the sum by 4. The primary irritation index was calculated as 0 (>5 is a primary irritant).

CONCLUSION: The notified chemical is non-irritating to skin.

TEST FACILITY: MB Research Labs (2002a)

7.5. Irritation – eye

TEST SUBSTANCE: No test results submitted. MSDS states that a primary eye irritation study in rabbits determined the material to be mildly irritating. Varying degrees of conjunctival irritation was noted in all unwashed eyes, clearing by day 10.
The MSDS also notes that the notified chemical may cause eye irritation in humans.

7.6. Skin sensitisation

TEST SUBSTANCE: Xr-5144 Resin Lot #l1B02002
MB 01-9651.06 Volume II 28/1/02

METHOD: Buehler Method.
Complies with EPA Health Effects Guidelines, OPPTS 8702600, final guideline, August 1998.

Analogous to OECD TG 406 Skin Sensitisation – Buehler method.

Species/Strain	Guinea pig/Hartley Albino
PRELIMINARY STUDY	No information supplied on a preliminary study In skin irritation study no irritation was observed at 100% concentration. Therefore, the concentration used in this study was the maximum non-irritating dose.
MAIN STUDY	
Number of Animals	Test Group: 20 (10 male and 10 female) Control Group: 10 (5 male and 5 female)
induction phase	Induction Concentration: 100%. The solid test material was ground and moistened with 0.1 mL of distilled water for each 0.4 g dose. topical application 0.4 g of the test article at 100% was applied and occluded for 6 h before the site was cleansed with distilled water and dried with soft towelling. This procedure was performed once/week for a 3-week period.
Signs of Irritation	None
CHALLENGE PHASE	
1st challenge	topical application: 0.4 g at 100% concentration topical application:
2nd challenge	Not conducted
Remarks – Method	Observations for any skin reactions were carried out at 24 h and 48 h after patch removal. Test and control animals were observed once daily during the study for mortality, toxicity and pharmacological effects. As the test material was non-irritating at 100%, the induction could not be carried out at a mildly irritating concentration as specified.

RESULTS

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%	0	0	N/A	N/A
Control Group	100%	0	0	N/A	N/A

Remarks – Results	Induction – Erythema was absent Challenge – Erythema was absent in both induced and uninduced animals. The body weight changes were normal in all animals. During observation period, diarrhoea and soiling of the anogenital area were noted.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	MB Research Laboratories (2002b).

7.7. Repeat dose toxicity

TEST SUBSTANCE Not determined.

7.8. (a) Genotoxicity – bacteria

TEST SUBSTANCE Zonatac Alternate #1 Lite (ASL 5264)

PH 301T – AC-015-84 30/10/84

METHOD: Method analogous to OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation method.
Species/Strain: *S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100.
Metabolic Activation System: S-9 fraction from Aroclor 1254-treated rat liver.
Concentration Range in Main Test: a) With metabolic activation: 100 – 10,000µg/plate. b) Without metabolic activation: 100 – 10,000µg/plate.
Vehicle: Tetrahydrofuran (THF)
Remarks – Method: No *Escherichia coli* strains were tested. Preliminary test carried out without metabolic activation.

RESULTS .

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	*Cytotoxicity in PreliminaryTest**	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	N/A	>10,000µg/plate	≥ 100 µg/plate	Negative
Absent				
Test 1	>10,000µg/plate	>10,000µg/plate	≥ 100 µg/plate	Negative

*TA1538, TA100 used in preliminary test

Remarks – Results: There were no observed increases in mutation frequencies in strains TA1535, TA1537, TA1538, TA98 and TA100 of *Salmonella typhimurium* with and without metabolic activation preparation at doses of 100, 333, 1000, 3333 and 10,000 µg/plate. Results of positive and negative controls were within historical control data.

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

TEST FACILITY: Pharmakon (1984a)

7.8. (b) Genotoxicity – bacteria

TEST SUBSTANCE: Zonatac Alternate #1 (ASL 5263) PH 301T-AC-014-84 30/10/84

METHOD: Method analogous to OECD TG 471 Bacterial Reverse Mutation Test.
Species/Strain: *S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100.
Metabolic Activation System: S-9 fraction from Aroclor 1254-treated rat liver.
Concentration Range in Main Test: a) With metabolic activation: 100 – 10,000 µg/plate. b) Without metabolic activation: 100 – 10,000 µg/plate.
Vehicle: Tetrahydrofuran (THF)
Remarks – Method: No *Escherichia coli* strains were tested. Preliminary test was performed without metabolic activation.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	*Cytotoxicity in PreliminaryTest**	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	N/A	>10,000µg/plate	≥ 3333 µg/plate	Negative

Absent				
Test 1	>10,000µg/plate	>10,000µg/plate	≥ 3333 µg/plate	Negative

*TA1538, TA100, used in preliminary test.

Remarks – Results: There were no observed increases in mutation frequencies in strains TA1535, TA1537, TA1538, TA98 and TA100 of *Salmonella typhimurium* with and without metabolic activation preparation at doses of 100, 333, 1000, 3333 and 10,000 µg/plate.

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

TEST FACILITY: Pharmakon (1984b)

7.11 (a) Cytotoxicity Study using the ISO Elution method

TEST SUBSTANCE: XR-5144 Resin
NAMSA I1B02002 19/10/01

METHOD: An *in vitro* biocompatibility study, based on the International Organisation for Standardization 10993: Biological Evaluation of Medical Devices Part 5: Tests for Cytotoxicity: *in vitro* Methods guidelines.

Species/Strain: ATCC CCL 1, NCTC Clone 929, of strain L

Cell Type/Cell Line: L-929, mouse fibroblast cellss

Metabolic Activation System:

Vehicle: Single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM)

Physical Form: Liquid

Remarks – Method: The test was performed to determine whether leachables extracted from the test material would cause cytotoxicity. Positive, negative and reagent controls were also tested.

RESULTS: No cell lysis, pH change or change in cellular characteristics was noted. The controls reacted as expected.

Remarks – Results:

CONCLUSION: Under the conditions of this study, the notified chemical showed no evidence of causing cell lysis or toxicity.

TEST FACILITY: NAMSA (2001a)

7.11 (b) Cytotoxicity Study using the ISO Elution method

TEST SUBSTANCE: Sylvares ZT 105 LT resin
NAMSA G1B02002 19/10/01

METHOD: An *in vitro* biocompatibility study, based on the International Organisation for Standardization 10993: Biological Evaluation of Medical Devices Part 5: Tests for Cytotoxicity: *in vitro* Methods guidelines.

Species/Strain:

Cell Type/Cell Line: L-929, mouse fibroblast cells, (ATCC CCL 1, NCTC Clone 929, of strain L or equivalent source)

Metabolic Activation System	
Vehicle	Single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM)
Physical Form	Liquid
Remarks – Method	The test was performed to determine whether leachables extracted from the test material would cause cytotoxicity. Positive, negative and reagent controls were also tested
RESULTS	No cell lysis, pH change or change in cellular characteristics was noted. The controls reacted as expected.
Remarks – Results	
CONCLUSION	Under the conditions of this study, the notified chemical showed no evidence of causing cell lysis or toxicity.
TEST FACILITY	NAMSA (2001b)

7.12. Respiratory irritation

TEST SUBSTANCE	No studies submitted. However MSDS notes that inhalation of dust may cause respiratory irritation. MSDS also notes that inhalation of vapours/fumes generated by heating the material may cause respiratory irritation, with throat discomfort, coughing or difficulty breathing; these effects may be due to residual monomers, low boiling components or vapours generated during decomposition of the polymer.

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted. The notifier claims that the expected low water solubility of the polymer (based on that of a related analogue chemical) and the low expected release to the aquatic environment preclude the necessity of these data. Based on the polymer's hydrocarbon structure, biodegradation is expected to be slow. While bioaccumulation is possible base on the NAMW, there will be little if any exposure to the aquatic compartment.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted. The notifier claims that the expected low water solubility of the polymer (based on that of a related analogue chemical) and the low expected release to the aquatic environment preclude the necessity of these data. Attempted QSAR modelling of the simplest combination of the monomers indicated the water solubility is too low to reliably estimate aquatic toxicity.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release of the polymer to the environment during transport, manufacture and use in the construction of diapers should be low as any losses can be easily collected, reused or disposed of by incineration, to landfill or by a licensed waste contractor. Empty bags or cardboard boxes are not expected to contain large amounts of adhesive residue and will be disposed of to

landfill. Wastes from cleaning equipment in contact with the polymer during diaper manufacture are not expected to be highly contaminated and will go to the sewer while the ultimate fate of used diapers will be to landfill. While the polymer's biodegradability is unknown but expected to be slow, it will eventually degrade due to biotic and abiotic processes.

9.1.2. Environment – effects assessment

The toxicity of the notified chemical to aquatic organisms could not be assessed as no data were submitted.

The acute oral toxicity of analogue polymers to rats showed low toxicity with LD50 values of ≥5 g/kg body weight (bw).

9.1.3. Environment – risk characterisation

In the worst case scenario of about 1,000 kg/year of the amount of adhesive released to sewers in the course of a year across Australia, the predicted environmental concentration (PEC) of the notified polymer in river waters would be 0.007 µg/L with 90% removal by the sewage treatment plants to biosolids. The PEC in soils receiving the biosolids would be 0.006 mg/kg soil. Given the polymer's expected low water solubility (<<2.43 mg/L) and moderately high octanol-water partition coefficient (log Kow > 3.06), it is expected to strongly partition to soils and sediments.

Although no comparison can be made between the PEC and the PNEC (due to the lack of ecotoxicity data), the risk is expected to be acceptable due to the low PEC and the chemical's expected strong partitioning to soils and sediments. The bioavailability to aquatic and terrestrial organisms will be reduced due to this binding.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Exposure to workers during transport and storage would be low. It would only occur through accidental breaching of the packaging, and would be minimised by the solid form of the notified polymer and the adhesive formulation containing it.

During the early stages of the adhesive blending process the potential for dermal, ocular or inhalation exposure to solid particles of the notified polymer would be minimised by use of exhaust ventilation and suitable PPE. After the melting step there would be potential for blending and filling operators to be exposed to vapours of lower-boiling components of the notified polymer. Dermal and ocular exposure would be controlled by PPE used for handling the hot materials.

Cleaning of the blending and filling equiprnent with a hot solvent wash is carried out monthly. Dermal, ocular or inhalation exposure are possible in this process, depending on the engineering and PPE controls available to workers.

During end-use of the adhesive containing the notified polymer, a combination of engineering controls and the enclosed nature of the hot-melt application process would minimise worker exposure.

Cleaning of the hot melt application equipment with soap and water could produce dermal exposure if gloves were not worn.

9.2.2. Public health – exposure assessment

The public is not expected to come into contact with the notified polymer or hot melt adhesives containing it, unless exposed through a transport accident. The solid form of these materials would reduce exposure in such a situation.

The public could be exposed to the notified polymer through its presence in the adhesive used in disposable nappies. The proportion of polymer that could evaporate from the adhesive at ambient temperature would be limited by its incorporation in the solid matrix of the adhesive. Dermal exposure from dry nappies would be unlikely because the adhesive is inside the nappy.

Because there is only a small quantity of notified polymer in each nappy (up to 0.02 g) and it is situated in the inner layers, the exposure of people handling nappies intermittently would be very low.

The potential for inhalation contact of babies and young children wearing nappies containing up to 0.02 g of the notified chemical would be greater because they wear nappies close to their bodies for up to 24 hours/day. However the exposure concentrations would be very low, because the volatile components released would be diluted in air before reaching the baby's breathing zone.

For dermal exposure to occur during nappy wearing, the polymer components would have to be leached out by urine or faeces, and transferred to the surface of the nappy in contact with the baby's skin. While possible, this scenario has not been demonstrated and can be considered a worst case scenario. Dermal contact would in any case be reduced by the properties of modern nappies, which hold liquids away from the skin and the low concentration of the notified polymer in the adhesive. Dermal exposure would be enhanced by the long periods of contact with nappies, their occlusive nature, and the possibility that some babies would have enhanced absorption because their skin was irritated.

9.2.3. Human health - effects assessment

The notified chemical is a polymer with low levels of monomers but a substantial proportion of oligomers of molecular weight < 500. It would therefore be expected to pass biological membranes. No toxicokinetic data was supplied.

Testing of the notified chemical has only been carried out on some endpoints, with most tests carried out on higher molecular weight analogues containing the same monomers. It is noted that some tests were carried out in powder form and that dermal absorption may be higher if a vehicle was used.

The notified chemical is of low acute oral and dermal toxicity, based on several studies. Adverse effects in some animals surviving a high dose included transient effects on the gastrointestinal tract, pitted kidneys and white spots/patches in the liver. Limited testing of acute inhalation toxicity in powder form produced no deaths, but solid abdominal masses were noted in two animals. A higher concentration of the powder in air could not be generated, and the chemical was not tested up to the level that would allow hazard classification in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

In powder form the chemical was not a skin irritant, nor a skin sensitiser when tested by the Buehler method and by human patch testing (test not submitted). The method used in the Buehler test was less than optimal, as an irritating concentration was not obtainable for challenge. No cytotoxicity was found in in vitro studies. Based on MSDS information only, the chemical is a slight eye irritant, and may cause respiratory irritation in both powder form and from vapours if heated. These effects may be due to residual monomers, low boiling components or degradation products.

Negative results were obtained in a bacterial mutation test of Salmonella strains. No other genotoxicity testing was carried out, nor repeat dose, reproductive or carcinogenicity tests. No data was supplied to support the eye and respiratory irritation effects stated on the MSDS.

On the basis of the data submitted the notified chemical is not classified under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

In order to supplement the incomplete toxicological profile of the notified chemical, the known health effects of the monomers, adjuvants and related compounds should also be taken into account, particularly as the notified polymer contains low MW oligomers. Monomers and adjuvants are present at low levels (monomers up to 200 ppm). They are more volatile than the

notified chemical and could be released on heating, or when they are not trapped in a solid matrix. Possible hazards of the monomers and adjuvants are varied and include formation of hazardous oxidation products, sensitisation, reproductive effects and possible carcinogenicity.

As the notified polymer is terpene based and contains a complex mix of ingredients, the characteristics of other terpene based materials can also be considered as part of the likely toxicological profile. Under the revised NOHSC *List of Designated Hazardous Substances* to take effect from 31/12/04, limonene/dipentene is classified as a skin irritant, and is classified as a skin sensitiser on the basis of sensitising oxidation products that can form in it. The NICNAS assessment of limonene/dipentene as a Priority Existing Chemical (NICNAS, 2002) also noted that there is limited data on the potential to cause eye irritation, respiratory irritation and respiratory sensitisation. From 31/12//04 oil of turpentine will be classified under NOHSC as an eye and skin irritant, skin sensitiser and harmful by inhalation, skin contact and ingestion. Rosin derivatives, extracted from similar sources to turpentine, are classified as skin sensitisers.

The physico-chemical properties of the notified polymer may also cause health effects, if static electric charges formed during handling lead to a fire. Burns are also possible during handling of the polymer at high temperatures during blending and application.

9.2.4. Occupational health and safety – risk characterisation

The notified polymer will be imported as a component of another chemical as solid granules and incorporated into a solid hot melt adhesive formulation through a process of melting, blending and cooling. Blocks of the adhesive are melted for application to components during the manufacture of nappies. Hot solvent cleaning is carried out on the blending and filling equipment at intervals, and the hot melt application equipment is cleaned manually with soap and water.

Exposure to workers is expected to be low through some steps of the process, when the polymer will be in solid form. Appropriate engineering controls are in place to control dust during weighing and transfer during formulation. Dermal exposure could be controlled through use of suitable clothing and gloves.

While the notified chemical is in a molten state, there is also the potential for inhalation exposure. This could occur at the later stages of the formulation process, during QC processes, and during application of the adhesive to nappies. Filling of the molten adhesive into containers is an enclosed process and little inhalation exposure is expected. Priha and Ahonen (1998) found that hot melt fumes from a variety of adhesive formulations in Finland were mainly formed from evaporation of the glue components including the polymers, but noted that degradation also occurs.

It is considered that the formulation of adhesive and adhesive application are the processes with highest potential exposure.

Based on animal testing carried out on higher molecular weight analogues of the notified polymer, it is of low acute oral and dermal toxicity. Limited acute inhalation testing of the powder did not reach concentrations that would allow classification. Skin irritation, skin sensitisation (method less than optimal) and cytotoxic tests were negative. Limited testing for bacterial mutagenicity was negative. It should be noted that some tests were carried out on the materials in powder form, which might limit dermal absorption and reduce any effects. On the basis of this testing a NOAEL cannot be determined.

The characteristics of monomers, adjuvants and other terpene-related materials suggest that eye, skin and respiratory irritation are possible, and that oxidation products formed in storage, handling and use could be sensitisers. Although the notifier did not report health effects from use of the notified polymer overseas, the MSDS warns of skin and eye irritation, and local effects from inhalation of dusts and fumes. Priha and Ahonen (1998) report that complaints of respiratory irritation from exposure to hot-melt fumes (various formulations) are relatively common, but that few cases of occupational asthma are related to such exposure.

On the basis of the above specific and general health effects, and the possibility of inhalation and dermal exposure to the notified polymer, it is considered that the risk to workers is low if engineering and PPE measures are in place to reduce exposure.

9.2.5. Public health – risk characterisation

The members of the public with greatest exposure to the notified polymer are babies and young children wearing disposable nappies. While the potential exposure in worst case scenarios cannot be accurately calculated, it is considered that inhalation exposure to components of the notified polymer is unlikely to be significantly higher than levels in ambient air. Significant dermal exposure is also considered unlikely because the majority of any leached material would be held away from the skin by modern nappy technology. Therefore the risk to the public is considered low. It should be noted that there are significant uncertainties in both the health effects of very low quantities of the notified polymer and the potential levels of exposure.

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

10.1. Hazard classification

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

Based on the available data, the notified chemical is not classified under the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003).

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described, dependent on controls being in place.

10.3.2. Public health

There is No Significant Concern to public health as a component of hot-melt adhesive for use in the manufacture of disposable nappies.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical and products containing it:
  - Enclosure of formulation, filling and application processes as much as possible
  - Local exhaust ventilation where process not enclosed
  - Where possible guards to protect workers from spills of molten material that could cause burns.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical or products containing it:
  - In handling the notified chemical, avoid spills and dust generation
  - In handling the notified chemical, avoid the generation of static electric charge that in contact with flammable vapours may lead to flash fire
  - In handling the notified chemical or products containing it in molten form, take precautions to avoid accidental spills or splashes that could cause thermal burns. Avoid excessive heating that may produce hazardous oxidation or degradation products, or lead to combustion.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical and products containing it
  - Safety glasses;
  - Industrial standard protective clothing and gloves;
  - Dust masks or appropriate respirators if high levels of dust or fumes are present.

  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

Disposal

- The notified chemical should be disposed of by placing contaminated material in containers and disposed of according to the applicable regulations.

- The notified chemical should not be disposed of in waterways and stormwater drains.

Emergency procedures

- If adhesive is molten, allow to cool. Scrape up and place into suitable containers for disposal as per state/federal regulations.

- Do not allow to enter the aquatic environment.

12.1. Secondary notification

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

(1) Under sub-section 64(1) of the Act; if
- The notified polymer is used in applications other than as a component of a hot melt adhesive; or
- the use pattern greatly increases the release of the chemical to the aquatic environment; or
- the use pattern of the notified chemical changes in such a way as to increase occupational exposure, either through inhalation or dermal contact, eg change to a dispersive use, or increase in exposure to the polymer in molten form; or
- the use pattern of the notified chemical changes in such a way as to increase public exposure
- further toxicological data on the notified chemical or close analogues becomes available.

or

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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