

File No: NA/536

March 1998

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Polymer in Hardener BJ

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**Polymer in Hardener BJ****1. APPLICANT**

Sika Australia Pty Ltd of 55 Elizabeth St WETHERILL PARK NSW 2164 has submitted a standard notification statement in support of their application for an assessment certificate for Polymer in Hardener BJ.

2. IDENTITY OF THE CHEMICAL

The notified chemical is considered to be a Type I hazard on the basis of its potential for skin and eye corrosivity and skin sensitisation (1). However, the products to be imported are unlikely to be hazardous due to the low concentration (less than 2%) of the chemical and are not, therefore, considered to be of Type I. Although the level of notified chemical is above 1%, which is the concentration cutoff for sensitisation according to the National Occupational Health and Safety Commission's *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (2), other data in humans suggests that sensitisation will not occur at a level of 2% (see section 12). Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of the polymer composition have been exempted from publication in the Full Public Report and the Summary Report. It should be noted that, if the level of the notified chemical in imported products reaches 5%, a secondary notification will be required.

The notified chemical is a crosslinking agent for polyurethane (isocyanate) based pre-polymers, and is a reactive compound which breaks down to an aldehyde and a reactive amine on exposure to atmospheric moisture. The reactive amine product is the active crosslinking (hardening) agent.

Trade Name: SIKAFLEX 821FR, SIKAFLEX 852FR, SIKAFLEX PRO 2HP

Molecular Weight: 435

Method of Detection and Determination: infrared (IR) spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	liquid
Melting Point:	solidification temperature: -49°C
Density:	966 kg.m ⁻³
Vapour Pressure:	0.37 kPa at 20°C (calculated, based on 2% cyclohexane content)
Water Solubility:	hydrolyses in water to an amine which is miscible in water in all proportions and an aldehyde with a water solubility of 6 850 mg.L ⁻¹
Partition Co-efficient (n-octanol/water):	not determined
Hydrolysis as a Function of pH:	not determined
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined
Flash Point:	147°C
Flammability Limits:	not determined; the limits for the cyclohexane component of Hardener BJ are: Upper Explosive Limit = 8.4% Lower Explosive Limit = 1.3%
Autoignition Temperature:	not determined
Explosive Properties:	not expected to be explosive under normal conditions of use
Reactivity/Stability:	stable

Comments on Physico-Chemical Properties

The environmentally significant physico-chemical properties of the notified chemical would be very difficult to measure due to its high reactivity with water. The notifier indicates that in the presence of water the material hydrolyses rapidly to a reactive amine and an aldehyde (see further below). This is the basis for its action as a hardening agent for isocyanate polymers. From the environmental perspective it is more appropriate to consider the properties of these hydrolysis

products rather than the parent polymer, and of these the amine is the most important. The notifier indicates that the degree of hydrolysis of the notified polymer is governed by usual mass action laws, which means that the degree to which the material is converted to the amine and aldehyde is dependent on the availability of water. The notifier supplied the results of some experiments on the hydrolysis of the new polymer in the presence of a small quantity of water which indicated that the compound remained substantially in the imine state, and in this experiment 98% remained non hydrolysed after establishment of equilibrium. However, in the presence of a large excess of water the laws of mass action indicate that the reaction would go almost to completion. The information provided indicates that the reaction is acid catalysed, but that even in the absence of acids that the equilibrium is established within a few hours under ambient temperature conditions.

No data were provided with the notification, but the amine is a di-functional amine with molecular weight around 260 g.mol^{-1} . The amine groups resulting from hydrolysis will have a pKa of around 10 and consequently would be protonated in the environmental pH region ($4 < \text{pH} < 9$). The amine molecule would be expected to be appreciably water soluble, and is unlikely to partition into the oil/fat phase. However, the positive charges indicate it would associate with suspended negatively charged organic matter, and also would bind to silicate minerals in soils and clay.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 85%

Toxic or Hazardous Impurities: < 15%

Non-hazardous Impurities (> 1% by weight): none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical is a crosslinking agent in fire retardant sealants and adhesives for use in the installation of fire rated partitions in ships, trains etc. Another product containing the notified chemical will be used in high rise buildings for sealing between window frames and facade cladding and expansion joints in facade cladding. The notified chemical will be imported at a concentration of less than 2% in adhesives or sealants containing prepolymers, pigments, fillers, plasticisers and solvents at a rate of less than 15 tonnes per year for the first five years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in sealed 310 mL aluminium cartridges which fit into either a manual application gun or a compressed air assisted application gun. The sealants and adhesives may also be imported in 600 mL aluminium polyester laminated “sausages”. The cartridges and “sausages” will be contained in small plastic wrapped cartons. The potential for exposure of transport or storage workers will be limited to damage caused by accident.

After the product (a tacky material) is applied, excess material is scraped off and the area and tools wiped clean with a cloth. There is a moderate potential for dermal exposure during application. Within 2 to 4 hours after application, products containing the notified chemical cure into a rubber-like substance and exposure will then be negligible.

7. PUBLIC EXPOSURE

Hardener BJ is used in industrial settings for purposes unlikely to leave significant quantities of the notified chemical or the cured product in situations where the public is likely to come in contact with it. The public is therefore unlikely to come into direct contact with the notified chemical either before or after curing. Any contact which may occur is unlikely to lead to significant exposure as the notified chemical will be crosslinked into the matrix of the sealant.

Any spilt or misplaced sealant will be readily removable, and will be disposed of to landfill as construction waste. Public contact with the notified chemical in these circumstances is unlikely. Spills of significant quantities of material are unlikely given its consistency.

The potential for dispersal of the notified chemical during transport or following an accident is low due to the nature of the packaging and the small quantity of notified chemical in end products.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier estimates that around 450 kg total of the notified polymer (4.5-5% of import quantities) are likely to be released each year as a consequence of leaking cartridges (50 kg), application waste (300 kg) and disposal of residuals (100 kg). However, direct release of the notified material is not possible since it is always in contact with isocyanates and other reactive components of the sealant, with which it would react after exposure to the atmosphere. Some release of the reaction products from the material is likely as a consequence of wastage during application, and this would be wiped up with rags or paper towels. Once exposed to the atmosphere the material would react with water vapour and become incorporated into a semi solid (rubbery) mass. The rags and paper would be

disposed of with other waste materials from construction activities. Similarly, small quantities of sealant remaining in the used cartridges or “sausages” would most likely be disposed of with rubble and placed into landfill.

Fate

The majority of the material (or more correctly the hydrolytic degradation products) will be incorporated as part of sealant masses in buildings and ships. At the end of their service lives the buildings and ships would be demolished, and it is likely that the sealant masses would be placed into landfill with masonry rubble, or possibly be incinerated.

In a landfill the sealant mass containing the notified compound and its breakdown products would slowly degrade as a consequence of micro-biological processes with release of gases such as carbon dioxide, methane, ammonia and nitrogen. Incineration would destroy the material with release of water vapour, and oxides of carbon and nitrogen.

The bioaccumulation factor of the aldehyde breakdown product is stated as 4.2 to 7.8 which suggests low accumulation in biota. No equivalent data for the amine were provided, but the chemical structure, and in particular the two terminal amine groups which would be protonated and hence carry a positive charge in the environmental pH region of $4 < \text{pH} < 9$, indicate low lipophilicity and hence low bioaccumulation potential.

No data on biodegradation of the new chemical were included with the notification, but if released in the free state or as a part of the polymer matrix of discarded building, ship or train etc components, it is expected that the new polymer would be slowly degraded through the action of bacteria. In an aerobic environment this would result in the production of water, and oxides of nitrogen and carbon, while under anaerobic conditions methane and ammonia would be the anticipated products.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicology data for the notified chemical were not provided. It was accepted that, as the notified chemical hydrolyses into an amine and an aldehyde on contact with moisture, in the presence of an organic acid, the toxicological profile could be indicated by that for the sum of the components.

The notifier provided a toxicity profile for the aldehyde component summarised by Bibra International (3).

9.1 Acute Toxicity

9.1.1 Acute toxicity of the aldehyde breakdown product of the notified chemical

<i>Test</i>	<i>Species</i>	<i>Outcome</i>
acute oral toxicity	rat	LD ₅₀ = 1.30 - 2.85 g.kg ⁻¹
acute dermal toxicity	rabbit	LD ₅₀ > 1.25 g.kg ⁻¹
acute inhalation toxicity	rat	LC ₅₀ (10 minute) > 7 000 mg.m ⁻³
skin irritation	rabbit	moderate irritant
eye irritation	rabbit	irritant
skin sensitisation	guinea pig	sensitiser

The data suggest that the chemical is of moderate to low acute oral and dermal toxicity in rats and rabbits, respectively. The acute oral LD₅₀ was 1 300 - 2 850 mg.kg⁻¹ and the acute dermal LD₅₀ was greater than 1 250 mg.kg⁻¹. The LC₅₀ in rats exposed for 10 minutes was greater than 7 000 mg.m⁻³. The chemical was a moderate skin irritant in rabbits and a 0.2% solution was irritating to the eyes of rabbits and dogs.

Skin sensitisation in response to a 5% solution of the chemical in petrolatum has been observed in dermatitis patients previously shown to be sensitised to Balsam Peru. Balsam Peru contains esters of the related carboxylic acid as major components. Other evidence of urticarial reactions has been observed. However, an attempt to induce sensitisation with a 4% solution of the chemical in petrolatum in human volunteers using a maximisation protocol was unsuccessful. In animal studies, sensitisation was not induced by repeated topical application but was induced by a regime involving intradermal administration.

Repeated doses of 200, 400 and 800 mg.kg.dy⁻¹ for 5 days per week for 13 weeks resulted in several deaths at the highest dose. Histopathological examination revealed damage to the brain and kidneys at this dose and mild injury to the forestomach at this dose and the mid dose of 400 mg.kg.dy⁻¹. The NOAEL was 200 mg.kg.dy⁻¹ in this study.

A report on reproductive toxicity showed that there were fewer pregnancies in rats given 5 mg.kg^{-1} by gavage on alternate days for 32 weeks when mated with untreated males 75 and 108 days after the initial dose. No changes were observed in the number of pups born, their weight or their viability.

Genotoxicity studies showed increases in sister chromatid exchange in mammalian cells in culture, including human lymphocytes in the presence or absence of metabolic activation. Both positive and negative studies on chromosomal damage in Chinese Hamster cells were reported. Mutagenicity was not evident in either *Salmonella typhimurium*, *Drosophila melanogaster* or *Neurospora crassa*.

Preliminary reports from long term feeding studies noted benign tumours of the forestomach in mice, but no evidence of carcinogenicity in rats.

Toxicological data were provided for the amine breakdown product of the notified chemical and these data are evaluated below.

9.1.2 Acute toxicity of the amine breakdown product of the notified chemical (4)

<i>Test</i>	<i>Species</i>	<i>Outcome</i>
acute oral toxicity	rat	$\text{LD}_{50} = 1.66 \text{ g.kg}^{-1}$
acute dermal toxicity	rabbit	$\text{LD}_{50} = 0.76 \text{ g.kg}^{-1}$
acute inhalation toxicity	rat	no deaths in atmosphere near saturation for 7 hours
skin irritation	rabbit	corrosive
eye irritation	rabbit	corrosive

A summary report only was provided for the above data. Therefore the full study details cannot be given in this report. These data were obtained at a single laboratory.

In the acute oral toxicity study, Wistar rats were given oral doses of 0.59, 1.18, 2.35 and 4.70 g.kg^{-1} and numbers of deaths were 0, 2, 3 and 5 animals (respectively) out of 5 animals treated were recorded. Autopsy of survivors revealed no abnormalities.

Acute dermal toxicity was tested by applying doses of 0.29, 0.59, 1.18 and 2.35 g.kg^{-1} of the amine under an impervious cuff for 24 hours. All animals died at the 2 highest doses, 1 animal at the lowest dose and none at the dose of 0.59 g.kg^{-1} . Signs of intoxication were diarrhoea, exudate around mouth and nose and hind leg weakness. Skin corrosion was observed.

To determine acute inhalation toxicity, Wistar rats were exposed to air near-saturated with the amine for 7 hours at 25°C . Of 10 animals treated none died and gross autopsies were normal. Signs of intoxication were discomfort, irritation and

dyspnoea within 15 minutes; moderate skin irritation within 30 minutes followed by decrease in motor activity.

The amine was corrosive to both skin and eyes of rabbits. Irreversible tissue destruction within 24 hours was observed when 0.5 mL of the chemical was applied to the skin for 24 hours under occlusive dressing and when 0.1 mL of the chemical was introduced into the conjunctival sac of one eye.

A repeated dose feeding study was conducted in rats at dose levels of 0, 93 and 239 mg.kg⁻¹.dy⁻¹ for 31 days. There were no deaths during the test period, the overall appearance and behaviour of the treated and control animals were good, and no relevant gross pathology was noted at autopsy.

9.1.3 Acute toxicity of the amine (full reports)

Full reports were provided for studies on skin irritation. In addition, a single summary page from a report which was stated to be lost indicated that the amine was not a skin sensitiser in guinea pigs.

9.1.3.1 Skin Irritation (5)

<i>Species/strain:</i>	rabbit/NZW
<i>Number/sex of animals:</i>	6/unknown
<i>Observation period:</i>	72 hours
<i>Method of administration:</i>	0.5 mL of undiluted amine under occlusive dressing for 1 hour
<i>Test method:</i>	similar to Draize (6)
<i>Result:</i>	the notified chemical was corrosive to the skin of rabbits; second degree chemical burns were seen in all rabbits at 72 hours and in 5/6 rabbits at 24 hours; the remaining rabbit exhibited slight irritation; at one hour 5/6 rabbits exhibited moderate and one rabbit slight erythema; oedema at one hour was not observed in 2 rabbits and was slight in 4 rabbits

9.1.3.2 Corrosivity study (7) *Species/strain:*

rabbit/NZW	<i>Number/sex of</i>
<i>animals:</i>	6/3 per sex

<i>Observation period:</i>	48 hours
<i>Method of administration:</i>	0.5 mL under occlusive dressing for 4 hours
<i>Test method:</i>	in house protocol
<i>Result:</i>	the notified chemical was corrosive to the skin of rabbits as judged by signs of necrosis in two out of six rabbits at 4 hours and 5 out of six rabbits at 44 hours after treatment

9.2 Repeated Dose Toxicity - 90-day Dermal Administration (8)

<i>Species/strain:</i>	Rat/Sprague-Dawley
<i>Number/sex of animals:</i>	15/sex/dose group and 10/sex control and high dose animals given a 28 day recovery period
<i>Method of administration:</i>	dilutions in deionised water under occlusive dressing for 6 hours per day, 5 days per week
<i>Dose/Study duration::</i>	0, 50, 80, 250 mg.kg ⁻¹ (control, low, mid or high dose, respectively)/ 90 days with a 28 day recovery period; 5 animals per group were killed at day 30
<i>Clinical observations:</i>	no significant observations; dermal irritation was observed in several mid-dose females toward the end of the study; dermal irritation was observed in both sexes at the high dose and included some or all of erythema, oedema, scattered areas of necrosis, 25-50% necrosis at the application site, scab formation, fissuring and/or sloughing of skin and alopecia; severity and incidence of effects generally increased with treatment duration
<i>Clinical chemistry:</i>	a number of changes were observed which had no histopathological correlates and were considered not to be biologically relevant; they were either not dose related and/or were within normal limits
<i>Haematology:</i>	no dose-related changes in haematological parameters were observed

<i>Organ weights:</i>	the sole observation was a decrease in relative liver to body weight ratios for the male high dose group on day 30 compared to the control group
<i>Histopathology:</i>	no changes related to treatment
<i>Test method:</i>	similar to OECD guidelines (9)
<i>Result:</i>	dermal application of the amine to rats did not result in systemic toxicity when administered five days out of 7 for 30 and 90 days at doses of 50, 80 or 250 mg.kg.dy ⁻¹

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (10)

<i>Strains:</i>	TA 1535, TA 1537, TA 1538, TA 98, TA 100
<i>Concentration range:</i>	100 - 10 000 µg.plate ⁻¹
<i>Test method:</i>	similar to OECD guidelines (9)
<i>Result:</i>	the amine did not induce back mutation to prototrophy in either the presence or absence of metabolic activation (provided by rat liver S9 fraction) in <i>S. typhimurium</i> by either base change or frameshift

9.3.2 Mouse Lymphoma Forward Mutation Assay (11)

<i>Species/strain:</i>	mouse lymphoma cell line, L5178Y TK+/-
<i>Doses:</i>	0.5 - 6.0 µL of the test material (a clear liquid) per mL (equates to approximately 0.48 - 5.8 mg.mL ⁻¹) for 4 hours
<i>Test method:</i>	similar to OECD guidelines (9)
<i>Result:</i>	the amine was not mutagenic in mouse lymphoma cells in either the presence or absence of metabolic activation (provided by rat liver S9 fraction)

9.3.3 *In vitro* Transformation of BALB/3T3 Cells (12)

<i>Species/strain:</i>	mouse BALB/3T3 cell line
<i>Doses:</i>	0.075 - 0.450 $\mu\text{L/mL}$ (equates to approximately 72.5 - 435 $\mu\text{g.mL}^{-1}$) for 24 hours
<i>Test method:</i>	similar to OECD guidelines (9)
<i>Result:</i>	the amine was inactive in the BALB/3T3 transformation assay

9.4 Overall Assessment of Toxicological Data

Toxicological data on the breakdown products of the notified chemical, an aldehyde and an amine were submitted. It was considered that summation of the individual hazards for the breakdown products would adequately reflect the worst case for the notified chemical.

The aldehyde was of moderate to low acute oral and dermal toxicity in rats and rabbits, respectively. The LC_{50} in rats exposed for 10 minutes was greater than 7 000 mg.m^{-3} . The chemical was a moderate skin irritant in rabbits and a 0.2% solution was irritating to the eyes of rabbits and dogs. Skin sensitisation in response to a 5% solution of the chemical in petrolatum has been observed in dermatitis patients previously shown to be sensitised to Balsam Peru. Balsam Peru contains esters of the related carboxylic acid as major components. Other evidence of urticarial reactions has been observed. However, an attempt to induce sensitisation with a 4% solution of the chemical in petrolatum in human volunteers using a maximisation protocol was unsuccessful. In animal studies, sensitisation was not induced by repeated topical application but was induced by a regime involving intradermal administration.

Repeated doses of 200, 400 and 800 mg.kg.dy^{-1} for 5 days per week for 13 weeks resulted in several deaths at the highest dose. Histopathological examination revealed damage to the brain and kidneys at this dose and mild injury to the forestomach at this dose and the mid dose of 400 mg.kg.dy^{-1} . The NOAEL was 200 mg.kg.dy^{-1} in this study.

A report on reproductive toxicity showed that there were fewer pregnancies in rats given 5 mg.kg^{-1} by gavage on alternate days for 32 weeks when mated with untreated males 75 and 108 days after the initial dose. No changes were observed in the number of pups born, their weight or their viability.

Genotoxicity studies showed increases in sister chromatid exchange in mammalian cells in culture, including human lymphocytes in the presence or absence of metabolic activation. Both positive and negative studies on chromosomal damage in Chinese Hamster cells were presented.

Mutagenicity was not evident in either *Salmonella typhimurium*, *Drosophila melanogaster* or *Neurospora crassa*.

Preliminary reports from long term feeding studies noted benign tumours of the forestomach in mice, but no evidence of carcinogenicity in rats.

The amine was of low acute oral and dermal toxicity in rats and rabbits, respectively. No deaths in rats were recorded in an atmosphere near saturation for 7 hours. The amine was found to be corrosive to skin and eyes of rabbits. Repeat dose studies found no organ toxicity in rats dosed orally with 239 mg.kg⁻¹.dy⁻¹ for 30 days and treated dermally for 5 days per week with doses up to 250 mg.kg⁻¹.dy⁻¹ for up to 90 days. No evidence of genotoxicity was observed in mutagenicity tests in bacteria or mouse cells and no evidence of transformation was observed in mouse cells.

On the basis of the toxicity data for the breakdown products of the notified chemical, it would be classified as hazardous according to the Approved Criteria in terms of skin sensitisation, corrosivity to skin and eye and acute toxicity.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. These data relate to the amine hydrolytic breakdown product. In normal use this chemical is a transitory species resulting from reaction of the notified polymer with atmospheric moisture, and should exist in appreciable quantities only during the hardening phase of the sealant, or within the walls to which the sealant has been applied. However, in the event of release of the notified polymer to water, this amine would be produced in significant quantities. The test methodologies employed in deriving the toxicity data was not described by the notifier.

Test	Species	Results
Acute Toxicity	Rainbow Trout	LC ₅₀ (96 hour) > 100 mg.L ⁻¹
	<i>Oncorhynchus mykiss</i>	NOEC (96 hour) > 100 mg.L ⁻¹
Acute Immobilisation	Fresh water invertebrates <i>Daphnia magna</i>	EC ₅₀ (24 hour) = 48 mg.L ⁻¹
		NOEC (24 hour) = 32 mg.L ⁻¹
		EC ₅₀ (48 hour) = 15 mg.L ⁻¹
		NOEC (48 hour) = 5.6 mg.L ⁻¹
Growth Inhibition	Algae	E _b C ₅₀ (72 hour) = 135 mg.L ⁻¹
	(species not defined)	E _b C ₅₀ (96 hour) = 135 mg.L ⁻¹

No test reports or summary of experimental conditions or test methods were provided with the notification, and consequently the data tabulated above should be considered a guide only, and may significantly underestimate the ecotoxicological potential for the parent chemical. Amine compounds are well

known to be at least moderately toxic to aquatic life forms - particularly to algae (13) -, and without details of the test conditions including physico-chemical data on water quality, pH, dissolved oxygen levels etc, the results above give no clear indication of the potential toxicity.

However, it is unlikely that significant quantities of the amine breakdown product of the notified chemical would be released into water compartment from normal usage of the SIKA HARDENER BJ in the sealant, since it would quickly react with free isocyanate containing compounds in the sealant and become part of a solid matrix.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified polymer appears to be low after it has been used in the intended manner, since it would only be exposed to the environment as part of a crosslinked polymer mass with little potential for leaching or escape of fugitive vapours. At the end of their serviceable lives, structures containing the notified material would be demolished and the residues of sealant would most likely be placed into landfill with other rubble. Here the sealant mass containing the notified polymer would undergo slow decomposition to water and gases which may include oxides of carbon and nitrogen, or - under anaerobic conditions - methane and ammonia.

However, prior to being incorporated into sealant masses the chemical could pose a hazard as a consequence of its ability to hydrolyse to an amine which, if released to the water compartment could pose an environmental hazard to aquatic organisms.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

No toxicological data were available for the notified chemical. However, it breaks down to an aldehyde and an amine on exposure to moisture in the presence of an organic acid. This is the basis for its use as a curing agent in adhesives and sealants. The toxicological profiles of the breakdown products were accepted as an appropriate substitute for that of the notified chemical and the fact that the chemical is to be introduced in products at a concentration of approximately 2% means that the risk of adverse health effects is reduced. On this basis the notified chemical should be considered of moderate acute toxicity, corrosive to skin and eyes and a possible skin sensitiser. The chemical is not likely to be harmful on repeated or prolonged exposure solely in terms of systemic toxicity and is not likely to be genotoxic. According to the Approved Criteria, the notified chemical would be classified as hazardous due to sensitising effects and corrosivity. As a result the chemical is a Type I hazard. However, the products in which the notified chemical is to be imported would not be classified as hazardous with regard to skin or eye irritant effects. The potential for the aldehyde to induce skin sensitisation suggests that the products should be considered Type I hazards, as the concentration of the notified chemical in the products is above the concentration cutoff of 1%. However, the fact that a 4% solution of the aldehyde did not induce sensitisation in human volunteers suggests that the products also may not induce sensitisation.

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The notified chemical is to be imported in formulations in relatively small cartridges or “sausages” which fit into application guns. Thus, exposure of transport or storage workers is unlikely. Exposure to the notified chemical is most likely when the products containing it are applied when partitions, window frames or cladding are installed and the excess removed. The notified chemical will be bioavailable for up to 4 hours until curing of the product occurs. If exposure of the skin occurs during removal of excess material, such exposure could be prolonged due to the tacky nature of the products to be imported. Thus, there is a risk (albeit low) of skin sensitisation in some individuals during use of the products to be imported and gloves as described below should be worn.

The notified chemical contains hazardous impurities but the levels in the products to be imported would not result in their being classified as hazardous according to the Approved Criteria.

Although the notified chemical has significant toxicological hazards, public exposure will be minimal. Contact with cured sealant is unlikely to lead to exposure to the notified chemical and where contact does occur, the low concentration of the notified chemical in the sealant and its crosslinking into the matrix will lead to negligible exposure. The risk to the public from use of the notified chemical in the manner described by the notifier is negligible.

13. RECOMMENDATIONS

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

- During application of sealants or adhesives spillages or excess should be removed using rags or similar materials which should then be placed in containers for at least 4 hours to allow the spillage or excess to cure;
- Industrial clothing should conform to the specifications detailed in AS 2919 (14);
- Impermeable gloves or mittens should conform to AS 2161 (15);
- All occupational footwear should conform to AS/NZS 2210 (16);
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for products containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (17).

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 and if the chemical is to be imported at a concentration of greater than 5% in formulations. No other specific conditions are prescribed.

16. REFERENCES

1. National Occupational Health and Safety Commission 1994, *Control of Workplace Hazardous Substances [NOHSC:1005(1994), 2007(1994)]*, Australian Government Publishing Service, Canberra.
2. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra.
3. Bibra International 1989, *Toxicity Profile*, Surrey, U.K.
4. Brett, B.e.a. 1968, , Project no., 68-20, American Cyanamid Company, NJ, USA.
5. Scibor, G.e.a. 1977, *Primary Skin Irritation with Four Samples in Albino Rabbits*, Project no., 8530-10563, Industrial Bio-test Laboratories Inc, IL, USA.
6. Draize, J.H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, vol. 49, pp. 2-56.
7. Mallory, V.T.e.a. 1982, *DOT Corrosivity Study in Rabbits 5601-9-1 Order #J-154*, Project no., PH 419-TX-004-82, Pharmakon Research International Inc, PA, USA.
8. Margitich, D.J. 1990, *Subchronic 90 Day Dermal Toxicity Study - Rat 6398-9-20*, Project no., PH 470-TX-001-89, Pharmakon Research International Inc, PA, USA.

9. Organisation for Economic Co-operation and Development 1995-1996, *OECD Guidelines for the Testing of Chemicals on CD-Rom*, OECD, Paris.
10. Godek, E.G. 1982, *Ames Salmonella/Microsome Plate Test*, Project no., PH 301-TX-016-81, Pharmakon Research International Inc, PA, USA.
11. Cifone, M.A. & Brusik, D.J. 1982, *Mutagenicity Evaluation of 4236-44-15 in the Mouse Lymphoma Forward Mutation Assay*, Project no., 20989, Litton Bionetics Inc, MA, USA.
12. Rundell, J.O. & Brusik, D.J. 1982, *Evaluation of 4236-44-15 #J128 in the in vitro Transformation of BALB/3T3 Cells Assay*, Project no., 20992, Litton Bionetics Inc, MA, USA.
13. Nabholz, J.V., Miller, P. & Zeeman, M. 1993, 'Environmental Risk Assessment of New Substances under the Toxic Substances Control Act Section Five', in *Environmental Toxicology and Risk Assessment*, American Society for Testing and Materials, ASTM STP 1179, Philadelphia, pp. 40-55.
14. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing*, Standards Association of Australia, Sydney.
15. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves)*, Standards Association of Australia, Sydney.
Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.
17. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, Australian Government Publishing Service, Canberra.