File No: NA/804

June 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

HARDENER ALD-1

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

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Director
Chemicals Notification and Assessment

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HARDENER ALD-1

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 'HARDENER ALD-1'.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, purity of the notified chemical and the hazardous impurities have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name: HARDENER ALD-1

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical will only be imported as a finished product, Sikaflex PRO 2HP. The physical and chemical properties provided below relate to the final product unless otherwise stated.

Appearance at 20°C & 101.3 kPa:	thixotropic tacky material existing in many colours (product) pale yellow clear viscous liquid (notified chemical)
Boiling Point:	not determined; the product cures over a range of temperatures in the presence of moisture
Specific Gravity:	1.26 at 20°C
Vapour Pressure:	< 0.8 kPa at 25°C
Water Solubility:	product insoluble in water 2.4 mg/L at 25°C (notified chemical, estimation)
Partition Co-efficient (n-octanol/water):	not determined for the notified chemical calculated log P_{ow} 4.93± 0.4
Hydrolysis as a Function of pH:	the product undergoes slow hydrolysis in water; a

	reaction catalysed by acidic and basic conditions (see comments below)
Adsorption/Desorption:	K_{oc} 11 454; log K_{oc} = 4.1
Dissociation Constant:	the notified chemical lacks dissociable groups; therefore is unlikely to be anionic or cationic at pH 4 – 9.
Particle size:	not relevant as the notified chemical is in liquid form
Flash Point:	247°C (notified chemical) 63.5 °C (final product)
Flammability Limits:	product is not flammable
Autoignition Temperature:	not determined
Explosive Properties:	not expected to be explosive (notified chemical)
Reactivity/Stability:	decomposition on contact with water will yield benzaldehyde and diamine; thermal decomposition will produce carbon monoxide, carbon dioxide and nitrogen oxides

Comments on Physico-Chemical Properties

The notifier used the Advanced Chemistry Development (ACD) Laboratory software to estimate the partition coefficient, which was subsequently used to estimate the water solubility and adsorption coefficient. The use of this software is acceptable, since determination of the partition coefficient, adsorption/desorption behaviour and the dissociation constant for the notified chemical via laboratory testing would be difficult due to the moisture sensitive nature of the chemical.

The notifier has indicated that the chemical will undergo hydrolysis in water to give a substituted diamine and an aromatic aldehyde. The reaction rate will be increased under acidic or basic conditions.

No test reports for specific gravity or vapour pressure were provided.

4. PURITY OF THE CHEMICAL

Degree of Purity:	<100%
Hazardous Impurities:	none above concentration cut-offs listed in the NOHSC *List of Designated Hazardous Substances* (NOHSC, 1999a)

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

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical is an adduct that crosslinks polyurethane prepolymers (polyisocyanates) in the finished product, Sikaflex PRO 2HP. The finished product, containing up to 1% of the notified chemical, will be used as a joint sealant within expansion joints, pre-cast concrete elements, panels, window and door-frames and retaining walls. Therefore, its use will be predominantly in the building industry (estimated to be 80% of sales) with a small percentage of use (approximately 20%) by the general public.

The finished product will be imported in sealed 310 mL aluminium cartridges or 600 mL aluminium polyester laminated "sausages" designed to fit into special applicator guns. Each carton will contain 12 cartridges or 20 "sausages".

The notifier estimates that 4 300 kg of the notified chemical (corresponding to 500 000 kg of the finished product), will be imported per annum over the next five years.

6. OCCUPATIONAL EXPOSURE

Transport and storage
The notified chemical will be imported as finished product in custom designed cartridges or "sausages" that fit into applicator guns. The palletised cartons containing the cartridges/"sausages" will be transported by road from the docks to relevant warehouses throughout Australia. Warehouse workers will unload cartons and store them in purpose built storage areas.

Transport and warehouse workers are not likely to be exposed to the notified chemical except in the case of an accident involving damage to packaging. Recommendations for the clean up of accidental spills are included in the material safety data sheet (MSDS). The notifiers estimates that 2-4 waterside workers and 5-10 transport workers will handle the packed product for 5-10 hours per day, 10-20 days per year. Ten to 20 warehouse workers are expected to handle cartons for 2 hours per day, 75 days per year.

Distributors
Workers at distributor sites will unpack cartons and place the cartridges/"sausages" on shelves. No worker exposure is expected except in the case of an accident. The notifier indicates that 20 distribution workers will handle cartridges/"sausages" for 2 hours per day, 75 days per year.

Applicators
The notifier estimates that 80% of product sales will be for use within the building industry. Workers will apply the product into the joint either using an applicator gun or nozzle. When using cartridges, the inner seal is broken at the nozzle end, the nozzle fixed and cut to the desired size. "Sausages" are placed in the applicator gun, the wrapper nicked at the extrusion

end or cut off at the very end of the ”sausage” (if it contains partially cured lumpy product). Excess material will be removed using a spatula, rag, paper or detergent/water solution.

Skin contamination may occur particularly when applying the product using a nozzle and removing excess material. Spillage is unlikely given the tacky nature of the product. Considering the packaging of the end use product, its consistency and application method, significant ocular exposure is not expected. The notifier recommends that workers wear overalls, rubber or PVC gloves and eye/face protection when applying the product. The vapour pressure of the product is low (<0.8 kPa) and the product will most often be used in well ventilated areas. When used in poorly ventilated areas and confined spaces, additional protection, namely a half face respirator with an organic vapour filter is recommended.

Two thousand applicators are expected to use Sikaflex PRO 2HP daily for 4-8 hours.

7. PUBLIC EXPOSURE

The potential for widespread public exposure to the notified chemical is low. Exposure of the general public as a result of transport and disposal of the product containing the notified chemical is low. Although a majority of the product containing the notified chemical will be used in the construction industry, it will also be used infrequently by the general public in domestic situations. Dermal contact with the products containing the notified chemical is likely during use. Ocular contact may occur to a lesser extent than dermal contact.

8. ENVIRONMENTAL EXPOSURE

Release

The possibility of release due to spills or leaks is low since the product is contained in sealed individual units. The notifier estimates that the contents of two 600 mL containers may be lost annually, which equates to approximately 0.016 kg of notified chemical. Once applied, any excess sealant is removed with a spatula or cloth, accounting for to 0.5% of imported volumes (21.5 kg of waste notified chemical annually). It is likely that these scrapings and rags would be disposed of to landfill.

Residual sealant will be left in the empty container. The notifier estimates this accounts for up to 0.7% of imported volumes, i.e. 31.5 kg, annually. The amount of residual sealant in the container will depend on whether it has been used by an industrial user or by the general public. For industrial applications, container residues are expected to be sent to licensed waste contractors for disposal, while the containers used by the public are likely to be disposed of with household garbage. In both cases the residual sealant in the containers is expected to have cured prior to disposal.

Therefore, the total release from application and the disposal of cartridges and foils will amount to less than 1.5% of the total import volume of the notified chemical, approximately 54 kg per annum.

It should be noted that 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 atmospheric moisture.

Fate

The majority of the notified chemical is not likely to be released to the environment until it has been fully cured into a solid matrix. The sealant will remain with the jointed surfaces until it is removed or disposed of with the articles to which it is bound. Therefore most of notified chemical will be incorporated in a polymer matrix, most of which will eventually be disposed of to landfill.

The small amount of waste generated during application is expected to eventually go to landfill or be incinerated.

The resultant matrix structure should limit hydrolysis or biodegradation potential. Leaching from landfill sites is not expected, since the estimated water solubility of the notified chemical is low.

No biodegradation data for the notified chemical was provided. In 5 day Biological Oxygen Demand (BOD) tests non-cyclic byfunctional amines are persistent, and benzaldehyde has a BOD 50% over 10 days (National Library of Medicine, 1997).

The bioconcentration factor for the notified chemical has been estimated to be 3287 (ACD Estimation), so the chemical may bioaccumulate in aquatic organisms. However, the uncured notified chemical is unlikely to reach the aquatic environment. In an aquatic environment the chemical may degrade but the rate is unknown.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicology data were not provided for the notified chemical. The notifier sought variation to the Schedule requirements on the basis that the chemical is unlikely to exist in the manufactured state in biological systems. Hardener Ald-1 is manufactured by the reaction of a substituted diamine with an aromatic aldehyde to form a schiff base. The schiff base will readily hydrolyse in water, and consequently in biological systems.

Toxicity data on benzaldehyde were provided in the form of a BIBRA International Review (BIBRA International, 1989) and Hazardous Substances Data Bank (HSDB) record (National Library of Medicine, 1997).

Toxicity data on the substituted diamine were not provided. Instead, data were provided for several related organic amine compounds. The data was in the form of readily available compilations of hazardous properties, from ACGIH (American Conference of Governmental Industrial Hygienists, 1991), RTECS (National Institute of Occupational Safety and Health, 1997) and HSDB (National Library of Medicine, 1997). The analogue chemicals were isophorone diamine (IPD), m-xylylene diamine (m-XDA), diethylenetriamine (DETA) and triethylenetetramine (TETA).

The analogue data are accepted in this report as a suitable surrogate for the notified chemical. Consequently, the findings are taken as representing the toxicity of the notified chemical.

Information on study protocols and compliance with good laboratory practice was unavailable in the peer-reviewed summaries provided. Hence, the quality of the studies could not be evaluated against contemporary standards of toxicity testing.

9.1 Acute Toxicity

Summary of the acute toxicity of benzaldehyde and reference alkylamines

Test substance	Species	*Outcome*	*Reference*
Acute oral toxicity			
benzaldehyde	rat	LD_{50} 1 300 mg/kg	BIBRA
IPD		no data	-
m-XDA		LD_{50} 660 mg/kg	ACGIH
DETA		LD_{50} 1 080 mg/kg	ACGIH
TETA		LD_{50} 2 500 mg/kg	ACGIH
Acute dermal toxicity			
benzaldehyde	rabbit	LD_{50} >1 250 mg/kg	BIBRA
IPD		no data	-
m-XDA		LD_{50} 2 000 mg/kg	ACGIH
DETA		LD_{50} 1 090 mg/kg	ACGIH, RTECS
TETA		LD_{50} 805 mg/kg	RTECS
Acute inhalation toxicity			
benzaldehyde	rat	LC_{50} >7 000 mg/m^3	BIBRA
IPD		no data	-
m-XDA		LC_{50} 3750 mg/m^3 (I hour) equivalent to 1900 mg/m^3 (4 hour)	ACGIH
DETA		no deaths following 300 ppm exposure for 8 hours	ACGIH
TETA		LC_{50} 805 mg/m^3	RTECS
Skin irritation			
benzaldehyde	rabbit	moderate irritant	BIBRA
	human	non irritant (4% in petrolatum, 48 hour occlusive application	
IPD		no data	
m-XDA	guinea pig	corrosive	ACGIH
DETA	rabbit	moderate to severe irritation	RTECS
TETA		severe irritation	RTECS
Eye irritation			

benzaldehyde	rabbit	irritant at 0.2%	BIBRA
IPD	-	no data	-
m-XDA	rat	exposure to aerosol produced ocular irritation and lacrimation	ACGIH
DETA	rabbit	severe irritant	RTECS
	human	severe corneal injury after application of a 15 % solution; minor corneal injury with 5%	ACGIH
TETA	rabbit	solution moderate to severe irritant	RTECS
Skin sensitisation			
benzaldehyde	guinea pig	sensitiser (maximisation test); non-sensitiser (Bueler test)	BIBRA
	human	sensitising to persons sensitised to Balsum peru*	
m-XDA	human	potent sensitiser	ACGIH
IPD	human	sensitiser[a]	(Patussi et al., 1995) (Guerra et al., 1992)
DETA	human	respiratory and skin sensitiser	ACGIH
TETA	human	marked sensitisation in 6 out of 20 workers in one factory	HSDB
m-XDA	guinea pig	mild sensitiser	RTECS

* Balsum Peru consists predominantly of esters of benzoic acid

[a] A 53 year old male with a four year history laying impermeable floors coated with epoxy resins including IPD showed an erythematous eruption of the face which disappeared on spending two weeks away from work. The eruption recurred 2 months later, and disappeared with treatment with oral corticosteroids and time away from work. He tried four more times to recommence work after this, with dermatitis reappearing each time. Patch testing with the chemicals used in the epoxy mixtures gave a positive result for IPD (Patussi et al., 1995).
A 36 year old male with a ten year history as a wine vat varnisher, with dermatitis of the hands and face, a 44 year old male with an eruption of the face following use of and adhesive, and a 37 year old female worker in a car factory with dermatitis on the hands and a history of exposure to plastics, rubbers and adhesives, all tested positive to IPD in patch testing (Guerra et al., 1992).

9.2 Repeated Dose Toxicity

Benzaldehyde
In a 90 day oral (gavage) rodent study, rats were treated at 0, 50, 100, 200, 400 and 800 mg/kg/day and mice at 0, 75, 150, 300, 600 and 1200 mg/kg/day. Deaths were noted at 800 mg/kg/day (male and female rats) and 1200 mg/kg/day (male mice only). Necrotic and degenerative lesions of the brain, renal tubular necrosis and epithelial hyperplasia and hyperkeratosis of the fore-stomach were observed in rats of both sexes at 800 mg/kg/day. It is reasonable to assume that the fore-stomach lesions were caused by the irritant nature of benzaldehyde, hence its relevance for humans is limited. Renal tubular necrosis (only) was also demonstrated in male mice at 1200 mg/kg/day. Decreased body weight gain was seen in

rats and mice at 800 mg/kg/day and 600 mg/kg/day, respectively. The No Observed Adverse Effect Levels (NOAELs) established in this study were; 400 mg/kg/day in rats based on central nervous system effects and renal effects and 600 mg/kg/day in mice for renal lesions (Kluwe et al., 1983, cited in BIBRA International, 1989 and National Library of Medicine, 1997).

Rats fed benzaldehyde at 50 mg/kg/day for 27-28 weeks and 500 mg/kg/day for 16 weeks did not demonstrate treatment related macroscopic or microscopic lesions (Hagan et al., 1967, cited in BIBRA International, 1989).

In a 4 month inhalation study, rats exposed to 6 mg/m^3 did not display any treatment related effects, while 26 mg/m^3 caused reversible changes in body weight gain and haematology (Peresedov, 1974, cited in BIBRA International, 1989).

A lifetime feeding study (vehicle corn oil) on B6C3F1 mice comprised 50 animals per sex per group. Dosage depended on sex; males treated at 0, 200 and 400 mg/kg/day and females at 0, 300 and 600 mg/kg/day. Squamous cell papillomas and epithelial hyperplasia of the fore-stomach was observed in all treatment groups. These lesions are of limited relevance to humans. As part of the same experiment, male and female F344/N rats were treated with benzaldehyde in corn oil at 0, 200 and 400 mg/kg/day. The only adverse effect noted was a lower survival rate in males treated at 400 mg/kg/day (DHHS, National Toxicology Program Report, cited in HSDB 1997).

9.2.1 Clinical observations in humans

Clinical observations of workers at an m-XDA production site indicated that the chemical may be a gastrointestinal irritant (ACGIH, 1998).

9.3 Genotoxicity

Benzaldehyde
Benzaldehyde did not demonstrate mutagenic activity in several *Salmonella typhimurium* Reverse Mutation Assays, in the presence and absence of exogenous metabolic activation (BIBRA International, 1989).

Mammalian cell culture assays, including human lymphocytes, indicated an increase in sister chromatid exchanges in the absence and presence of metabolic activation. Equivocal results were obtained from Chinese hamster ovary cell cultures (BIBRA International, 1989).

Analogue alkylamines
The notifier provided a published study on the genotoxicity of a number of alkylamines, ethylenediamine (EDA), aminoethylethanolamine (AEEA), aminoethyl-piperazine (AEP), DETA, TETA and tetraethylenepentamine (TEPA). Among the compounds tested, only triethylenetetramine (TETA) was considered to be mutagenic (Leung, 1994).

Test	Result					
	EDA	AEEA	AEP	DETA	TETA	TEPA
S*almonella typhimurium* reverse mutation	N	N	N	N	Y	N

CHO gene mutation	N	N	I	N	N	N
sister chromatid exchange	N	N	Y	N	Y	Y
unscheduled DNA synthesis	N	N	N	N	Y	Y
in vivo micronucleus	no test	no test	I	N	N	N
gene mutation assay	N	N	I	N	N	N

N = negative result Y = positive result I = inconclusive result

The clearest genotoxicity results, for TETA, corresponded to a positive *Salmonella typhimurium* reverse mutation assay. In the absence of metabolic activation, TETA produced a significant number of revertant colonies in all test strains and concentration related increase in revertant colonies in two of the four test strains. In the presence of S9, TETA produced concentration related increase in revertants in 3 of the 4 test strains. Overall, the Chinese hamster ovary gene mutation assay and unscheduled DNA synthesis assay were negative. Despite some positive findings in *in vitro* assays, the lack of positive findings in *in vivo* studies suggests that the class of chemicals is at most weakly mutagenic.

9.4 Reproductive toxicity

Benzaldehyde
Female rats fed 5 mg/kg/day every other day for 32 weeks were mated with untreated males. The reproductive index affected was a lower number of pregnancies. Foetal parameters appeared to be unaffected by treatment (Sporn et al., 1967, cited in BIBRA International, 1989).

9.5 Overall Assessment of Toxicological Data

Based on the toxicity profiles of benzaldehyde and the reference alkylamines, the notified chemical is likely to be of low acute oral toxicity and at worst of moderate acute dermal toxicity. Available acute inhalation toxicity data, albeit scanty, suggests that the notified chemical may be of moderate acute inhalation toxicity. The NOHSC exposure standards for m-XDA and DETA have skin notations, indicating potential for skin absorption. As the notified chemical contains similar functional groups, the lower molecular weight components of the notified chemical may also be absorbed through the skin. The higher molecular weight components would be too large for skin absorption. The LD_{50} values for oral and dermal toxicity of the benzaldehyde and the reference alkylamines and the LC_{50} value for inhalation of TETA and m-XDA (by extrapolation), indicate that the risk phrase R20/21/22 'Harmful by inhalation, in contact with skin and if swallowed' should be applied (NOHSC, 1999).

Overall, the reference alkylamines ranged from moderately irritating to corrosive to the skin of experimental species. A 4% solution of benzaldehyde was non-irritant to human skin whilst the pure compound was moderately irritating to the rabbit skin. The lack of full study reports precluded the scoring of skin irritant effects. On balance, the notified chemical is likely to be corrosive, with the risk phrase R34 'Causes burns' (NOHSC, 1999b).

Benzaldehyde and the alkylamines appear to be moderate to severe eye irritants in animals. Available human data on DETA indicates that it causes corneal injury in a dose related manner (15% solution caused severe corneal injury). By extrapolation, the notified chemical is expected to cause severe ocular lesions in humans and should be assigned the risk phrase R41 'Risk of serious damage to eyes' (NOHSC, 1999b).

The organic amine class of chemicals to which the notified chemical belongs are known skin sensitisers. All of the analogue chemicals for which data was provided by the notifier were subject to reports of occupational skin sensitisation. The notified chemical should therefore also be considered a skin sensitiser with the risk phrase R43 'May cause sensitisation by skin contact' (NOHSC, 1999b).

The analogue data provided for repeat dose toxicity is insufficient to predict the likely repeat-dose toxicity of the notified chemical. In biological systems, the notified chemical is expected to readily hydrolyse into a substituted diamine and an aromatic aldehyde. Limited repeat-dose toxicity data were provided for benzaldehyde but not the diamine. Therefore, on the available analogue data, the effects of prolonged or repeated exposure to the notified chemical can be regarded as unknown. The potential for repeated exposure is limited by the serious effects of acute exposure to the chemical.

All reference chemicals, bar TETA, gave a negative result in a *Salmonella typhimurium* reverse mutation assay. A report on the mutagenic potential of a number of organic amines showed that the class of chemicals is likely to be at most weakly mutagenic. Therefore, it is unlikely that the notified chemical will be a strong mutagen.

The notified chemical is determined to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b), on the basis of its (predicted) acute toxic effects by the oral, dermal and inhalation routes, its skin and eye irritant properties and its skin sensitisation potential. The following risk phrases are required:
R20/21/22 'Harmful by inhalation, in contact with skin and if swallowed';
R34 'Causes burns'; and
R43 'May cause sensitisation by skin contact'.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. These results were generated using the US EPA ECOSAR model.

Species	Test	Result (mg/L)
Fish	96 h acute (ClogP)	LC50 = 0.04
Fish	96 h acute (SRC)	LC50 = 0.073
Daphnid	48 h acute (ClogP)	EC50 = 0.130
Daphnid	48 h acute (SRC)	EC50 = 0.093

These estimations indicate that the notified chemical is very highly toxic to fish and highly to very highly toxic to daphnids.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will be imported in sealed ready-to-use containers of 310 mL or 600 mL, so the possibility of release due to spill/accident is considered low. From the model results presented by the notifier the chemical is highly toxic to aquatic organisms. However within the sealant product the chemical will be in contact with isocyanates and other reactive components. If the sealant was spilt, the chemical would react with the other sealant components as soon as it came into contact with the atmospheric moisture.

It is estimated that up to 54 kg of the waste notified chemical would be generated by the use of the sealant. This waste is likely to be disposed of to landfill where it is unlikely to leach out.

The environmental hazard from the intended use of the notified chemical is expected to be low, since it would be exposed to the environment as part of a crosslinked inert solid 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 on building rubble would most likely be placed into landfill.

In landfill, the notified chemical is not expected to leach. The environmental hazard from the disposal of construction material, containing the cured notified chemical, to landfill is expected to be low.

The overall environmental hazard is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is determined to be a hazardous substance according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b). The following risk phrases are required:R20/21/22 ‘Harmful by inhalation, in contact with skin and if swallowed’; R34 ‘Causes burns’; and R43 ‘May cause sensitisation by skin contact’.

Based on analogue data, the notified chemical is likely to be of low acute oral toxicity and at worst of moderate acute dermal and inhalation toxicity. The lower molecular weight components of the notified chemical may be absorbed through the skin, however the higher molecular weight components would be too large for skin absorption. The notified chemical is likely to be corrosive and sensitising to skin and a severe ocular irritant.

Available toxicological data were inadequate to predict the effects of prolonged or repeated exposure to the notified chemical. However, it is reasonable to assume that the potential for repeated exposure would be limited by the serious effects of acute exposure to the chemical. The notified chemical is unlikely to be a strong mutagen.

The final product, Sikaflex PRO 2HP, contains hazardous ingredients in addition to the notified chemical, ie. xylene and white spirits. Accordingly, the product MSDS indicates that it is a hazardous substance and that skin and eye irritation and skin sensitisation are possible on contact.

Occupational health and safety
The notified chemical is imported as a finished joint sealant. Transport and storage workers and distributors will handle packaged product infrequently. The likelihood of exposure and therefore the risk of adverse health effects in these workers is low.

Within the building industry, workers may become contaminated during application of the product to joints and removing excess material. The product Sikaflex PRO 2HP has the potential to be used on a daily basis by several thousand workers. Given the consistency of the product (thixotropic), its low vapour pressure (<0.8 kPa) and application method (applicator gun or nozzle), the predominant route of occupational exposure is dermal and to a lesser extent ocular. The major hazards of the notified chemical are acute dermal toxicity, skin irritation, skin sensitisation and eye irritation. Skin and eye contact with Sikaflex PRO 2HP will be minimised by the wearing of overalls, gloves and eye/face protection. In the presence of organic solvents, PVC and natural rubber gloves may not provide adequate protection, particularly on prolonged or extensive contact. The product MSDS recommends the use of neoprene or nitrile rubber gloves in these instances.

The product contains ingredients with NOHSC exposure standards (NOHSC, 1995). Inhalation exposure will be minimised by the low vapour pressure of the product and use in a well ventilated area. The use of a half-face respirator is recommended when working in areas where ventilation is poor. Overall, the risk of adverse health effects is low when the product is used in the proposed manner and suitable protective equipment worn.

Public health
The potential for widespread public exposure to the notified chemical is low and its use infrequent. Dermal contact with the product containing the notified chemical is likely during domestic use. Ocular contact may occur, but less frequently than dermal contact. The notified chemical is likely to present a toxicological hazard to the members of the public exposed to it. However, the relatively low (up to 1%) concentration of the notified chemical in the product is likely to reduce the potential hazard. Exposure of the general public as a result of transport and disposal of the product containing the notified chemical is low. Consequently, the potential for public exposure during all phases of the life cycle of the notified chemical is low.

13. RECOMMENDATIONS

The following regulatory action is recommended:

. Nomination of the notified chemical to the National Occupational Health and Safety Commission for consideration for inclusion in the NOHSC List of Designated Hazardous Substances.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b), then workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

. Nomination of the notified chemical to the National Drugs and Poisons Scheduling Committee for consideration of an appropriate poisons schedule in the Standard for the Uniform Scheduling of Drugs and Poisons.

To minimise occupational exposure to HARDENER ALD-1 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

- Spillages should be allowed to cure, removed mechanically and put into containers for disposal;

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

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the product containing the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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 may be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

Secondary notification may also be required if the method of use changes in such a way as to greatly increase the environmental exposure of the notified chemical, particularly to natural waters, or if additional information becomes available on adverse environmental effects of the chemical. This should include information on the hydrolysis rate in water, which would clarify whether degradation and aquatic toxicity results are relevant.

16. REFERENCES

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