File No: NA/826

November 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Hardener HY 283 I/A

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Hardener HY 283 I/A

1. APPLICANT

Vantico Pty Ltd of 235 Settlement Road, THOMASTOWN VIC 3074, (ACN No. 091 627 879) has submitted a standard notification statement in support of their application for an assessment certificate for Hardener HY 283 I/A.

2. IDENTITY OF THE CHEMICAL

The chemical name, other name(s), CAS number, molecular and structural formula, spectral data, information of the composition e.g. identity of certain hazardous impurities, non-hazardous impurities and identity of additives/adjuvants have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name: Hardener HY 283 I/A.
Hardener HY 283 (Product containing 25.3% notified chemical).

3. PHYSICAL AND CHEMICAL PROPERTIES

As indicated, some of the data presented below was determined for Hardener HY 283, which contains 25.3% of the notified chemical.

Appearance at 20°C & 101.3 kPa:	Amber coloured, viscous liquid.
Boiling Point:	>200°C (Hardener HY 283).
Density:	1000-1050 kg/m^3 at 25°C (Hardener HY 283).
Vapour Pressure:	4.9×10^{-2} kPa at 20°C (for DETA – see comments below).
Water Solubility:	Not measured (see comments below).
Partition Co-efficient (n-octanol/water):	Log Pow = 9.2 (see comments below).
Hydrolysis as a Function of pH:	The notified chemical has an amide group, which may undergo hydrolysis under extreme conditions (see comments below).

Adsorption/Desorption:	Log Koc = 6.4 (see comments below).
Dissociation Constant:	The notified chemical contains secondary/tertiary amine groups, which will have pK_a between 9-11.
Particle size:	Not applicable for a liquid.
Flash Point:	Greater than 93° C.
Flammability Limits:	Not flammable. Combustible.
Autoignition Temperature:	Not determined.
Explosive Properties:	Not explosive.
Reactivity/Stability:	Stable under normal conditions of use.

Comments on Physico-Chemical Properties

The vapour pressure of the notified chemical is expected to be lower than that tabulated for diethylenetriamine (DETA), the major low molecular weight impurity.

No measured data for water solubility were provided. Based on a Quantitative Structure Activity Relationship (QSAR) that relates the water solubility to the partition coefficient (also calculated using ACD software), the notifier indicated that the new chemical is insoluble. This conclusion is not accepted because the probable amphoteric nature of the material was not considered. Compounds with amphoteric structural features form colloidal aggregates in water which can affect significant solubility through self-aggregation and formation of colloidal sized aggregates (Tanford, 1960). Consequently, the chemical is likely to have appreciable water solubility. The material safety data sheet (MSDS) indicates that Hardener HY 283 is miscible in water, and while the new compound comprises only 25.3% of the notified chemical, the statement supports high water solubility.

The new compound contains amide groups, which may undergo hydrolysis under extreme pH, although significant hydrolytic cleavage of these bonds is unlikely in the environmental region with pH 4-9.

The notifier calculated log Pow, estimated from the structure of a representative congener molecule containing four ethylenediamine units using ACD software. The calculated log Pow of 9.2±0.5 indicates no affinity for water. However, this calculation is based on the overall chemical structure (probably derived via a computer generated molecular fragmentation algorithm) and ignores the potential protonation of the amino groups and gain of positive ionic charges. Molecules containing significant hydrocarbon portions and ionic groups are usually surface active and form colloidal aggregates which are highly dispersible (if not truly soluble) in water. Consequently, while the estimated log Pow indicates no affinity for the aqueous phase, the probable surfactant properties may confer significant compatibility with water.

The ACD software was used to estimate log Koc from the estimated value of log Pow using QSAR. The derived estimate of log Koc was 6.4, indicating high affinity for the organic

component of soils and sediments. Again, these estimates ignore the protonation of the amine groups and the probable surface-active nature of the material, and cannot be used with confidence. Nevertheless, while the hydrocarbon portion of the molecule will have true affinity for organic material in soil, the probable appreciable water solubility indicates that the compound may be mobile in soils and sediments.

The chemical contains secondary/tertiary amine groups, which are appreciably basic with typical pKa values between 9 and 11, and which would become protonated in contact with water.

4. PURITY OF THE CHEMICAL

Degree of Purity: >90%.

Hazardous Impurities:

Chemical name:	(2-aminoethyl)-1,2-ethanediamine
Synonyms:	Diethylenetriamine (DETA).
CAS No.:	111-40-0
Weight percentage:	Concentration in adducted polyamide is not stated.
Hazardous properties:	Causes burns; harmful in contact with skin and if swallowed; may cause sensitisation by inhalation and skin contact (NOHSC, 1999a).

Chemical name:	N,N'-bis(2-aminoethyl)-1,2-ethanediamine.
Synonyms:	Triethylenetetramine (TETA).
CAS No.:	112-24-3.
Weight percentage:	Not stated.
Hazardous properties:	Causes burns; may cause sensitisation by skin contact; harmful in contact with skin (NOHSC, 1999a).

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

Additives/Adjuvants in the final product, Hardener HY 283:

Chemical name:	Benzyl alcohol
Synonyms:	Benzenemethanol
CAS No.:	100-51-6
Weight percentage:	30% (approximately)
Hazardous properties:	Harmful by inhalation and if swallowed (NOHSC, 1999a).

5. USE, VOLUME AND FORMULATION

The notified chemical is an epoxy-curing agent, and used as an ingredient at 25.3% in a liquid modified polyamido-amine hardener product, Hardener HY 283. The product is generally used in a two-part epoxy resin coating (eg. Hardener HY 283/Araldite GY6010 mix or other combination with Araldite epoxy resins) for industrial applications such as for maintenance, marine coatings, floor coatings, equipment coatings and various other applications in electrical and civil engineering. The notified chemical and the product are for industrial use only. The imported product may also be reformulated by other industrial users to produce coating products containing up to 3% notified chemical.

The notified chemical will be imported into Australia in Hardener HY 283 in 200L metal drums. However, the notifier envisages that, if local manufacturing becomes a feasible option, the notified chemical will be manufactured in Australia when local sales reach a level that warrants it.

The notifier estimates the following maximum annual import quantities of the notified chemical for the first five years:

Year I: 12.5 tonnes adducted polyamide
Year 2: 25 tonnes adducted polyamide
Year 3 to year 5: 50 tonnes adducted polyamide.

6. OCCUPATIONAL EXPOSURE

The notifier states that initially the hardener product containing 25.3% of the notified chemical will be imported into Australia. Local customers (coating manufacturers) may reformulate the final product and sell it directly to industrial applicators. In future, the notified chemical and the hardener may be manufactured in Australia and sold to coating manufacturers to sell to applicators.

Transport and storage
The hardener, contained in 200 L metal drums, will be unloaded at the docks and transferred to trucks for delivery to the notifier's warehouse. Warehouse staff will unload the pallets of drums and store them in purpose built storage areas. Later, the hardener will be delivered to customer sites via road transport.

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 notifier estimates that 5-10 dockside and transport workers will handle the chemical for 1-10 hours per day, 20 days per year. Fifteen to 30 warehouse workers (at the notifier's and customer sites) are expected to handle the drums for 2 hours per day, 75 days per year.

Customer sites
The hardener will be delivered to 2-3 industrial suppliers' sites, where the 200L drums of chemical will be stored in a warehouse until required for use. These specialist-coating manufacturers may use the hardener as an ingredient for other industrial coating products or re-sell it as is under the customer's trade name. When used as an ingredient for other coating

products, the hardener will be blended with other ingredients such as extenders, fillers, pigments and solvents, to form a coating product. The resulting mixture contains at up to 3% with other coating ingredients. Blending will be carried out in an enclosed mixing vessel. Heating of the mixing vessel may be required depending upon the coating formulation and process requirement. Workers blending the chemical with other ingredients may be exposed to the chemical during weighing and while pouring it in the mixing vessels. Two to three workers will handle the hardener for up to 8 hours per day, 200 days per year.

The blended formulation will be dispensed into containers or drums, which will then be transferred to pallets and stored in the warehouse until orders are placed. Dispensing is mostly automated using filling machines, however, skin contact may result if spillage occurs.

The MSDS mentions that, where possible, the workplace must be ventilated sufficiently to ensure that exposure standards are met. Airflow, where this product is being used, must be directed away from the workers. Use of long impervious gloves (rubber, neoprene or PVC complying to AS 2161) and industrial safety glasses as well as organic vapour respirator is recommended when using the hardener containing the notified chemical.

Local manufacture – in future

The manufacturing procedure for the notified chemical consists of blending the ingredients in a sealed mixing vessel (2 500 L capacity). The resulting notified chemical will then be blended with other chemicals to produce the final hardener product. At times, the notified chemical may be produced separately and stored in 200 L drums for use in the manufacture of the hardener at a later date.

A typical batch of the hardener would be about 2 000 – 2 500 kg. The contents of the mixing vessel are then transferred into the specified containers via outlets located at the bottom of the vessels. Hence the drums are located directly underneath the outlets, allowing easy transfer of the liquid through a filter into the containers. Containers are usually 20 L pails or 200 L drums. The drums are then transferred to pallets and stored in the warehouse.

Samples are normally taken for quality control (QC) testing by filling a container via the opening in the vessel. Samples are also taken from a tap situated at the bottom of the vessel.

Manufacturing operators may be exposed to the notified chemical when taking samples for QC testing, transferring the chemical to the filling machine and cleaning the mixing vessels. The manufacture of a batch of chemical takes approximately 22 hours. It is estimated that 6-10 manufacturing operators and 2-4 packaging operators will work 8 hours per day, 80-160 days per year. Six to 8 warehouse staff will be involved for 4-8 hours per day, 80-160 days per year.

Applicators

The hardener containing the notified chemical, in combination with the second part of the epoxy resin coating component will be used at 70:100 for structure and surface coatings. Both components are degassed before application to remove air bubbles, decanted and mixed manually, then degassed again. The mixture, containing approximately 10% notified chemical, is applied to the surface to be coated using either a brush, roller or spray equipment.

The spray painters who will be exposed to the notified chemical will be trained in use of such chemicals. For spray applications, the mixture will be diluted with solvents to reduce viscosity and loaded manually into a hopper, which feeds automatically into a spray gun. The notifier states that the dilution and loading will be carried out within a spray booth or undercover and appropriate respiratory protection is recommended. Application to marine structures, such as boats, will be done in dry docks. No underwater application of the coating will occur.

After spraying, the spray equipment will be washed with solvents. The waste solvent will be collected into a container and disposed of by a waste contractor or as appropriated depending upon State legislation. Applicators can also be exposed to the notified chemical when cleaning the spraying equipment.

Around 500 applicators are expected to use the product, 6-8 hours per day, 300 days per year. The main exposure routes will be dermal and inhalation. Eye and skin contamination may occur when pouring the chemical for blending, mixing, degassing and applying, particularly when spraying. The vapour pressure of the chemical is low, however, inhalation exposure may occur during manual mixing and spray coating. Workers will wear long impervious gloves, protective overalls and safety glasses/face shields. If risk of inhalation exists, especially when spraying the product, organic vapour respirator is recommended by the notifier. Spray painters will wear personal protective equipment at all times; gloves and overalls while mixing the chemical, and, in addition, a full face shield and respirator while inside the spray booth.

The drying time for the mixture is around 6 hours. Workers are not likely to be exposed to the notified chemical after this time, as the chemical will be bound within the coating matrix.

7. PUBLIC EXPOSURE

Exposure of the general public as a result of manufacture, transport and disposal of the notified chemical and products containing the notified chemical is assessed as being negligible. Coating products containing the notified chemical are to be used in a variety of industrial applications. The notified chemical and products containing the notified chemical will not be available to the public. The general public may make contact with cured coatings on floors or items such as automobile components.

8. ENVIRONMENTAL EXPOSURE

Release

Manufacture

The notifier anticipates that around 600 kg/annum of the notified chemical will be released annually as a result of manufacturing activities. Of this 100 kg is expected from spills and leaks, while the remaining 500 kg will result from cleaning of equipment. Spillages and leaks will be contained by bunding and cleaned up using absorbent material, which will be disposed of, by incineration or landfill. The mixing vessel and lines are cleaned using a solvent. This solvent will be collected and disposed of by a licensed waste contractor.

Reformulation

The notifier has not estimated the losses expected when the hardener product is reformulated into the floor coatings products. However, it can be estimated that the releases of the notified chemical during these processes will be similar to that from the manufacturing process, ie. 500 kg/annum from cleaning and 100 kg/annum from spill and leaks. Additionally it would be expected that up to 250 kg/annum of the hardener product containing the notified chemical would be left as residues in the drums after emptying. This waste will cure and solidify in the drums and will be destroyed when the drums are incinerated.

Application

The notifier has estimated that approximately 15% of the notified chemical will be lost due to overspray during application of the coatings products, which would equate to 7.5 tonnes/annum (at the maximum import/manufacture volume of 50 tonnes/annum). This waste will be collected on protective sheeting where possible and disposed of via approved methods, likely incineration or landfill.

Leaks and spills would account for 200 kg/annum waste, which will be disposed to landfill. Residues remaining in the drums after emptying will be approximately 250 kg/annum and will solidify and remain in the drums when they are disposed of by licensed waste contractors by incineration or landfill. The application equipment will be cleaned using solvents, which should be collected and disposed of by waste contractors by recycling or incineration. Approximately 50 kg/annum of notified chemical would be released in this way.

Therefore, the total release from manufacture, reformulation and application of the notified chemical will be approximately 9450 kg/annum (18.9% of the import volume).

Fate

The majority of the notified chemical is not expected to be released to the environment until it has been mixed into the coatings products and fully cured into a solid matrix. The coating will remain with the articles to which it has been applied until it is removed or disposed of with these articles. Therefore most of notified chemical will be incorporated in a polymer matrix, most of which will eventually be disposed of to landfill. Abrasion and wear-and-tear may result in some of solid coating being dislodged as flakes or small particles into the environment but this is expected to be minor and the chemical will be cured and bound into an inert solid matrix.

The waste generated during manufacture, reformulation and some of the application processes will be disposed to landfill after it cures and solidifies. The waste from the equipment cleaning will be in solvent but the solids will be separated out by the waste contractors and disposed to landfill or incinerated.

The overspray waste from the spray application of the coatings will be collected where possible and disposed of by approved methods, most likely to landfill. However, some overspray may be released to the environment and care should be taken, particularly with the marine applications that this release is kept to an absolute minimum, as this chemical is likely to be mobile in the environment and toxic to aquatic organisms when in an uncured state.

The resultant matrix structure should limit hydrolysis or biodegradation potential. Leaching from landfill sites is not expected, since the chemical will not be soluble when cured and bound within the polymer matrix of the coating products. However, the chemical is miscible with water when uncured and will be mobile in the environment, so users should cure and solidify the chemical before disposal.

The MSDS for the hardener product indicates that it is not expected to be readily biodegradable. No other data specific to the chemical was supplied by the notifier but it was indicated that non-cyclic bi-functional amines are not readily biodegradable and persist in the environment (HSDB, 1997). However, as most organic material is degraded eventually through biological and abiotic processes, the chemical would be expected to degrade under aerobic conditions to water and oxides of carbon and nitrogen and under anaerobic conditions to water, methane and ammonia.

Based on the QSAR estimate for log Pow, the notified chemical has potential to bioaccumulate in aquatic organisms with an estimated Bioconcentration Factor (BCF) $>10^6$. However, the computer estimated log P_{ow} and resultant parameters (including BCF) are unlikely to reflect true physical behaviour in the environment and the expected significant water solubility would mitigate bioaccumulation (Connell, 1990). In any case direct (ie. unpolymerised) exposure of the new chemical to the aquatic compartment is very unlikely.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicology data were not available for the notified chemical or for Hardener HY 283. The notified chemical contains residual impurities (<10%) comprising mostly of DETA and TETA. The notifier has sought variation to the Schedule requirements by providing toxicity data for DETA and TETA.

Full toxicology study reports on DETA and TETA were not provided. The notifier provided toxicity data on these two chemicals prepared 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 data are accepted in this notification as a suitable surrogate for the notified chemical, given that the stoichiometry of the chemical reaction and molecular weight measurements indicate a low degree of amine substitution.

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 DETA and TETA

Test substance	*Species*	*Outcome*	*Reference*
Acute oral toxicity			
DETA	Rat	LD_{50}=1 080 mg/kg	ACGIH, 1991
TETA	Rat	LD_{50}=2 500 mg/kg	RTECS, 1997
Acute dermal toxicity			
DETA	Rabbit	LD_{50}=1 090 mg/kg	ACGIH, 1991
TETA	Rabbit	LD_{50}=805 mg/kg	RTECS, 1997
Acute inhalation toxicity			
DETA	Rat	LC_{50}>2500 mg/m^3	ACGIH, 1991
TETA	Rat	No data	RTECS, 1997
Skin irritation			
DETA	Rabbit	Moderate to severe irritant	RTECS, 1997
TETA	Rabbit	Severe irritant	RTECS, 1997
Eye irritation			
DETA	Rabbit	Severe irritant	RTECS, 1997
TETA	Rabbit	Moderate to severe irritant	RTECS, 1997
Skin sensitisation			
DETA	Human	Respiratory and skin sensitiser	ACGIH, 1991
TETA	Human	Marked skin sensitisation in 6 out of 20 workers in one factory	HSDB, 1997

9.2 Repeated Dose Toxicity

The notifier provided a published study on the repeat dose toxicity of triethylenetetramine dihydrochloride (TETA-2HCl) in rats and mice (Greenman et al, 1996).

In the 92-day oral study, 18 rats (F344) and 20 mice (B6C3F1) of each sex were given 0, 120, 600 or 3000 ppm/day TETA-2HCl in drinking water. Animals were fed either a cereal based diet (NIH-31) or a purified (AIN-76A) diet, both containing adequate levels of copper. An additional control group of rats and mice received Cu-deficient AIN-76A diet. The Cu-

deficient diet was used as a positive control to distinguish between Cu-deficiency effects and other biological properties of TETA-2HCl, because TETA-2HCl is known to chelate Cu ions leading to Cu deficiency in animals.

Rats

The Cu-deficient diet resulted in Cu deficiency symptoms, such as anaemia, liver periportal cytomegaly, pancreatic atrophy and multifocal necrosis, spleen hematopoietic cell proliferation and increased heart weight together with undetectable levels of plasma copper in rats of positive control group.

No deaths occurred in rats from test groups and no clinical symptoms were attributable to dosing with TETA-2HCl. Body or organ weights were not affected. TETA-2HCl treatment induced no signs of anaemia or other hematologic effects in rats fed either purified or cereal-based diet. A few significant differences were observed in plasma enzymes but they were not of any biological importance. No differences in plasma cholesterol or protein concentrations were found that could be attributed to TETA-2HCl exposure or copper deficiency.

TETA-2HCl lowered plasma and liver copper levels at higher dose levels (600 and 3000 ppm). Liver copper levels were more sensitive with a significant decrease at all doses in females and at 600 ppm (purified diet) or 3000 ppm (cereal diet) in males. It caused an increase frequency in uterine dilatation at the highest dose in rats fed normal diet but not in rats fed Cu-deficient diet. No changes in the histopathology of rats were observed.

Mice

TETA-2HCl toxicity occurred in mice in the highest dose group. It did not have any effect on body weight of mice fed cereal-based diet and clearly suppressed weight gain only in males fed the purified diet, exposed to 3000 ppm TETA-2HCl. No clinical symptoms were attributable to TETA-2HCl. Increased frequencies of inflammation of lung interstitium and liver periportal fatty infiltration were seen in both sexes, and hematopoietic cell proliferation was seen in the spleen of males given 3000 ppm TETA-2HCl. Incidence of renal cytoplasmic vacuolisation and kidney and body weights were reduced in male mice of high dose groups.

Analysis of haematology results revealed few significant differences between TETA-2HCl-treated and control mice.

This study also confirmed that the effects of TETA-2HCl in rats and mice were not related to copper deficiency since most of the usual signs of copper deficiency were not observed. A no observed effect level (NOEL) for TETA-2HCl was not established in the study. However, all significant toxicological changes in rats and mice were noted at or above 600 ppm TETA-2HCl.

9.3 Genotoxicity

The notifier provided a published study (Leung, 1994) on the genotoxicity of a number of alkylamines, such as, ethylenediamine (EDA), aminoethylethanolamine (AEEA), aminoethyl-piperazine (AEP), DETA, TETA and tetraethylenepentamine (TEPA). The following table gives the summary conclusion of the genotoxic potential of alkyleneamines.

Test		Result					
		EDA	**AEEA**	**AEP**	**DETA**	**TETA**	**TEPA**
S*almonella typhimurium* reverse mutation	-S9	N	N	N	N	Y	N
	+S9	N	N	N	N	Y	N
CHO gene mutation	-S9	N	N	I	N	N	N
	+S9	N	N	I	N	N	N
Sister chromatid exchange	-S9	N	N	Y	N	Y	Y
	+S9	N	N	Y	N	I	Y
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

Among the compounds tested, only triethylenetetramine (TETA) was considered to be mutagenic. 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 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 Overall Assessment of Toxicological Data

The two alkylamines, DETA and TETA have low acute oral toxicity, moderate acute dermal toxicity and low acute inhalation toxicity. They are moderate to severe skin irritants, severe eye irritants and may be corrosive to both skin and eye. The alkylamines appear to be both skin and respiratory sensitisers.

In a 90-day repeat dose oral study using TETA-2HCl, a medical chelating agent used to treat the effects of excess copper in humans, different effects were observed in rats and mice. Lung and liver inflammation were observed in mice and increased frequency in uterine dilatation was noted in rats. These effects were not related to copper deficiency. Although liver copper levels were reduced in rats, this did not lead to signs of copper deficiency. A NOEL could not be established from the study.

The genotoxicity of alkylamines appears to be variable. TETA gave a positive result in a *Salmonella typhimurium* reverse mutation assay and DNA synthesis assay. DETA was not

mutagenic in any of the tests.

The dermal oncogenic activity of DETA was evaluated with both the high purity and commercial grade product. No treatment-related skin tumours were observed, nor was there any evidence of increased incidence of internal tumours (HSDB, 1997). Carcinogenicity studies on TETA are not available. One study revealed no evidence of teratogenicity either in six patients or in animals that became pregnant during TETA treatment. All infants born during the study had normal development (Walshe, 1982).

Based on the toxicity profiles of the alkylamines provided by the notifier, the notified chemical is likely to be of low acute oral toxicity, moderate acute dermal toxicity and low acute inhalation toxicity, corrosive and a skin and respiratory sensitiser.

No substantial predictions on the sub-chronic toxicity of the notified chemical could be made from the published study provided by the notifier.

DETA and TETA are on the NOHSC *List of Designated Hazardous Substances* (NOHSC, 1999a), on the basis of their corrosivity, sensitising effects and acute toxicity. The following risk phrases have been assigned to the two chemicals:

DETA:	R21/22	Harmful in contact with skin and if swallowed
	R34	Causes burns
	R43	May cause sensitisation by skin contact
TETA:	R21	Harmful in contact with skin
	R34	Causes burns
	R43	May cause sensitisation by skin contact

Hardener HY 283 I/A 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 corrosive properties and skin and respiratory 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
R42/43 'May cause sensitisation by inhalation and skin contact'.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No experimental data on toxicity of the compound to aquatic organisms was provided although organic compounds containing amino groups are well known to be toxic (Nabholz et al, 1993) as acknowledged by the notifier in providing literature data (Van Wijk *et al*, 1994) for the toxicity of DETA and TETA. This paper reported the LC_{50} of DETA and TETA to daphnia were 53.5 and 5.3 mg/L respectively, while the corresponding EC50 values against *Selenastrum* were 345.6 and 3.7 mg/L. However, the relevance of this data to the notified chemical is questionable since the presence of the substantial hydrocarbon portion of these molecules may modify the intrinsic toxicity of the amine groups.

The notifier provided QSAR estimates for the toxicity of the notified chemical. The ECOSAR program was used (with a QSAR appropriate for aliphatic amines) to generate data for the analogue congener containing the DETA moiety (log Pow estimated as 9.88), and indicates extremely high toxicity. The ECOSAR prediction for LC_{50} for fish (species not specified) was 1.4 μg/L, the LC_{50} against daphnia was 0.3 μg/L and EC50 for green algae (species not given) was 8 μg/L.

These QSAR derived data suggest the notified chemical will be extremely toxic to aquatic life, and since the ECOSAR program depends on the estimated value of log Pow, the estimates should be treated cautiously. However, very high experimental toxicity of relatively low molecular weight polymers containing polyamine moieties have been measured, and the values are well accepted in the ecotoxicological literature (Nabholz and Boethling, 1997).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The estimated 9450 kg of the waste notified chemical generated by the use of the coatings product is likely to be disposed of to landfill or be incinerated. Also, at the end of their serviceable lives, equipment, structures and other items coated with the notified material would be disposed to landfill or recycled. Since the waste will be in the form of a cured cross-linked polymer mass, leaching from a landfill is considered to be unlikely and the material is expected to be slowly mineralised to carbon dioxide and nitrogen compounds.

The compound is likely to be appreciably water-soluble and, since it contains a high proportion of secondary and tertiary amine groups, which are known to be toxic to aquatic species, direct release to receiving waters is a potential environmental hazard. Although no experimental data was provided, the QSAR data suggests the compound may be extremely toxic to aquatic species, with the 48 hour LC_{50} against daphnia estimated as 0.3 μg/L. However, except in the case of transport accident, direct release to the water compartment is very unlikely since most release will entail prior cross-linking the chemical into a polymer matrix.

Despite the potentially very high toxicity to aquatic organisms, the use of the notified chemical as a hardener for epoxy reins is assessed as presenting a low environmental hazard since release should only be as part of an inert polymer matrix.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on toxicological data of the residues (DETA and TETA used as surrogate data), the notified chemical is likely to be of low acute oral toxicity and at worst of moderate acute dermal and inhalation toxicity. It is likely to be corrosive to skin and eyes and a skin and respiratory sensitiser.

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 R42/43 ‘May cause sensitisation by inhalation and skin contact’.

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 control mechanisms in place to prevent the serious effects of acute exposure to the chemical. The notified chemical is unlikely to be a strong mutagen.

The final product, Hardener HY 823, contains hazardous ingredients in addition to the notified chemical, ie. Benzyl alcohol and TETA. 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
Initially, the notified chemical will be imported as an ingredient of a hardener product at 25.3%. In future, the notified chemical and the product may be manufactured in Australia. 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.

The hardener containing the notified chemical will be formulated into coating products containing up to 3% notified chemical or used directly in spray painting. Coating products may also be applied by brush and roller.

Workers involved in reformulating the hardener into coating products may be exposed to the notified chemical in its most concentrated form (25.3% in hardener) while weighing the hardener and pouring it into the mixing vessel. Skin and eye contact may occur; therefore there is a risk of skin and eye irritation during these operations. Allergic dermatitis may result in sensitive workers if skin contamination is regular. The mixing and filling operations are enclosed, however, workers on the filling line may be exposed dermally to the notified chemical in dilute form (3%) if spillage or overfilling occurs. In these circumstances, there remains some risk of skin irritant and sensitising effects. As the mixing process is enclosed, the risk of respiratory sensitisation in formulation workers is low unless aerosols are generated during handling of the hardener.

If local manufacture of the notified chemical is to occur in the future, the risk of irritant and allergic effects may be greater due to possible worker exposure to the notified chemical in pure form. During manufacture and formulation, sufficient workplace ventilation is required to eliminate exposure to vapours.

Application of the hardener and coating products will be mostly by spray painting. In direct application, the hardener containing the notified chemical will be manually mixed with the other epoxy resin component, diluted with solvent and loaded into the spray gun for application. Skin contact and inhalation of the notified chemical may occur during these operations, particularly during mixing and spray application. Therefore, there is a risk of skin and respiratory disease and associated irritant effects in these spray painters. The risk of irritant effects in workers applying only the formulated coating product would be less due to potential exposure to the notified chemical at a lower concentration. For application by brush or roller, there remains a risk of dermal effects, however, the risk of respiratory effects would be reduced.

Due to the risk of adverse health effects described above, skin and eye contact with Hardener HY 283 will need to be prevented by the wearing of overalls, gloves and eye/face protection. Chemical impervious gloves sufficient to guarantee protection on prolonged or extensive contact with the hardener and solvents must be used. Spray application should be in accordance with the NOHSC *National Guidance Material for Spray Painting* (NOHSC, 1999c) and a respirator with organic vapour cartridge should be used for other tasks where aerosols or vapours might be generated, for example, during pouring or mixing.

Workers who become sensitised to the notified chemical or the impurities in the workplace should no longer continue to handle the chemical or products containing it.

The product contains ingredients with NOHSC exposure standards (NOHSC, 1995), for example, DETA (1 ppm TWA, skin notation). Employers are responsible for ensuring that exposure standards are not exceeded in the workplace.

The occupational health risk associated with exposure to the final surface coating is negligible as the notified chemical is reacted and bound within the matrix upon curing.

Public health
The public may make dermal contact with items such as floors and automobile components coated with products containing the notified chemical. However, the risk to public health from the notified chemical will be negligible as it is bound within a cured film, from which it is unlikely to be bioavailable.

Based on this information, it is considered that the notified chemical will not pose a significant hazard to public health when used in the proposed manner.

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.

To minimise occupational exposure to Hardener HY 283 I/A the following guidelines and precautions should be observed:

- Spray use of the hardener and coating products containing the notified chemical should be in accordance with the NOHSC *National Guidance Material for Spray Painting* (NOHSC, 1999c);

- Workplaces handling the notified chemical should be sufficiently ventilated to ensure that respiratory exposure to workers does not occur;

- Eye/face protection, chemical resistant industrial clothing and footwear and impermeable gloves should be used during occupational use of the notified chemical and products containing the notified chemical; where engineering controls and work

practices do not prevent the generation of aerosols and vapours, a respirator with organic vapour cartridge or an air-fed respirator should be worn;

- Spillages of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

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

Due to the risk of skin and respiratory sensitisation, workers potentially exposed to the notified chemical should be subject to health surveillance in accordance with State and Territory hazardous substances regulations.

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. Employers should ensure that NOHSC exposure standards for all of the components of the final spray mix are not exceeded in the workplace;

Guidance in selection of goggles may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994a); for respirators, in AS/NZS 1715 (Standards Australia/ Standards New Zealand, 1994b) and AS/NZS 1716 (Standards Australia/ Standards New Zealand, 1994c).

14. MATERIAL SAFETY DATA SHEET

The MSDS for the hardener 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 subsection 64(1) of the Act, secondary notification is required:

1. When production of the new material is to take place in Australia, details of the production process including descriptions of engineering controls to contain releases should be provided, plus experimental physico-chemical and ecotoxicity data of the new material against fish, daphnia and algae; and

2. 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.

Information on the hydrolysis rate in water, to clarify whether degradation and aquatic toxicity results are relevant would be needed.

Secondary notification of the notified chemical may also be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

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Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

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

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

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

CONJUNCTIVAE

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

IRIS

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