

File No LTD/1133

August 2004

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Adduct LSU 935

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FULL PUBLIC REPORT

Adduct LSU 935

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Huntsman Advanced Materials (Vantico Pty Limited) (ABN 93091627879) of 235 Settlement Road THOMASTOWN VIC 3074.

NOTIFICATION CATEGORY

Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, other name, molecular weight, molecular and structural formulae and spectral data, CAS Number, monomer identity and composition, identity of customer(s).

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: all physical and chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Commercial Evaluation Permit for Adduct LSU 935 (Permit Number: 548), December 2002.

NOTIFICATION IN OTHER COUNTRIES

USEPA in 1994 (PMN 81-497, EPA Accession No. 49720).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Adduct LSU 935,
TK 12888 (solid form of the notified polymer),
Component of Aradur 265-1.

MOLECULAR WEIGHT

Number-average molecular weight and weight-average molecular weight are taken to be >1000 (calculated). Gel-permeation chromatography traces were provided, however, these were unreliable due to probable binding of the polymer onto the column.

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL IR
METHOD

3. COMPOSITION

Data are claimed exempt from publication.

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer, Adduct LSU 935, will be manufactured overseas and imported into Australia as a component of Aradur 265-1.

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

| <i>Year</i> | <i>1</i> | <i>2</i> | <i>3</i> | <i>4</i> | <i>5</i> |
|---------------|----------|----------|----------|----------|----------|
| <i>Tonnes</i> | 10-30 | 10-30 | 10-30 | 10-30 | 10-30 |

USE

Curing agent for a two-part epoxy resin system.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Melbourne, Victoria

IDENTITY OF MANUFACTURER/RECIPIENTS

Huntsman Advanced Materials (Vantico Pty Limited).

TRANSPORTATION AND PACKAGING

The product Aradur 265-1 containing the notified polymer LSU 935 at 30-60% will be imported in 200 kg steel drums. The drums will be transported directly to the formulation site. However, in the future some stock may be retained in the notifier's site.

Formulated products will be packaged and supplied to industry in 2.4 L and 5 L cans/pails.

5.2. Operation description

The operations which will take place in Australia are transport, storage, blending, quality control, packaging and application of the products containing the notified polymer.

One epoxy hardener will be produced by repackaging Aradur 265-1, the other will be produced by formulation of Aradur 265-1 into a hardener containing 5-20% notified polymer.

At the formulation site, production operators transfer the Aradur 265-1 from the drums into a mixing vessel. Aradur 265-1 is blended with other raw materials (mainly solvents and pigments) in a sealed vessel. Blending is achieved by use of both a high speed disperser and an anchor stirrer. The normal batch size is 1200 L. After passing quality control testing, the formulated product is packed off into cans or pails for supply to customers.

At the application sites, workers will mix the resin system and load the mixture into an airless spray equipment. The final concentration of the notified polymer in the mixture is <10%. These workers then enter the tank and apply the coating containing the notified polymer onto the surface of the tank. The coating can also be applied by a roller or a brush.

5.3. Occupational Exposure

Number and Category of Workers

| <i>Category of Worker</i> | <i>Number</i> | <i>Exposure Duration</i> | <i>Exposure Frequency</i> |
|---------------------------|---------------|--------------------------|---------------------------|
| Formulation site: | | | |
| Incoming goods personnel | 2 | 1-2 hours/week | 10 weeks/year |
| Production Operators | 4 | 35 hours/week | 48 weeks/year |
| Quality Control Chemists | 4 | 38 hours/week | 48 weeks/year |
| Despatch personnel | 4 | 35 hours/week | 48 weeks/year |
| End-user sites: | | | |
| Applicators | 6-8* | 35 hours/week | 48 weeks/year |

*Depending on size of contractor

Exposure Details

Transportation

Two incoming goods receiving personnel will unload the drums of Aradur 265-1 and store them in designated storage areas. They may also transfer the drums from the storage area to the production area. The only possibility of exposure to these people will be in the case of a spillage. Warehouse personnel wears overalls, gloves, appropriated footwear and safety glasses.

Formulation and repackaging

The production operators typically work 35 hours per week, and 48 weeks per year. However, if a tender is successful, and the timeframe for supply of product is short, the production operators may work some overtime.

Aradur 265-1 containing the notified polymer will be transferred from the drum into the blending vessel by pumping under local exhaust ventilation. Other than during the filling of the mixing vessel, Aradur 265-1 is handled in closed system. After blending, packaging of the formulated products is automated and carried out under local exhaust ventilation. Occupational exposure, mainly dermal contamination, may occur during the formulation and repackaging processes. Operators carrying out these tasks wear overalls, gloves and safety glasses. The use of respiratory protection is not normally required due to the use of extraction systems in the factory. Respirators are available in the factory should it be required due to a failure of the extraction system or to clean up any spillage that may occur.

Quality control personnel will handle the notified polymer when testing batches of product containing it. Quality control chemists wear overalls, gloves, and safety glasses.

The despatch personnel will be exposed to the notified polymer only in the event of a spill. Given the pack size of 20 L for a resin kit, the hardener component makes up 2.4 L. Any spill of the hardener containing the notified polymer would be relatively small and be easily contained.

End-use

The applicators who use the mixture prepared from the formulated products to coat the steel storage tanks are expected to apply the coatings by airless spray, roller or brush.

Applicators wear overalls, gloves and industrial safety glasses when applying the epoxy coatings to the tanks. If necessary, respiratory protection is worn, especially if working in enclosed areas.

After application, the epoxy resin/amine-based hardener cures to form an inert polymeric material, which is non-bioavailable.

5.4. Release

RELEASE OF CHEMICAL AT SITE

At importer

Release to the environment of Aradur 265-1 during storage, accidental spills or from damaged drums or pails is not expected to be significant. The quantities likely to be stored will be relatively small (typically <3 tonnes). The storage warehouse is fully compliant with all current government regulations relevant to the storage of hazardous chemicals.

At formulation site

Release of the adduct to the environment is expected to be minimal. The release points to the environment are:

1. In the case of a spill or damage to the container in which Aradur 265-1 is supplied, the amount spilt would be ca 200 kg, which translates to 90-120 kg of the notified polymer. The notified polymer will never be released in isolation at the formulation site.
2. Spillage during transfer from the drums in which the product is supplied into the mixing vessel will be contained within the factory area. This process is well controlled, hence spillage would be expected to be minimal and difficult to quantify. The spilt material is

absorbed into an inert material (sand/vermiculite) and subsequently disposed of by incineration by an approved waste disposal company. The residue in the 200L containers are expected to account for up to 5% of the import volume, that is, $0.05 \times 30 \text{ tonnes} = 1.5 \text{ tonnes}$. The empty containers are cleaned with solvents and will be collected by licensed waste contractors for disposal to landfill. The waste solvent material will be collected by licensed waste contractors.

3. Spillage during transfer from the mixing vessel to the cans/pails is well controlled and spillage would be expected to be minimal. It is estimated that the spillage will account for 1% of the import volume per year. This is approximately 300 kg/year, based on 30 tonnes per year import volume.
4. The formulated product after mixing is of relatively low viscosity, hence it is reasonable to assume that >97% of the contents in the mixing vessel will be transferred to cans/pails. The residual material in the mixing vessels will be washed out using solvents which are subsequently drummed off and sent to a licensed waste disposal company.
5. It is highly unlikely that any of the notified polymer will enter the waterways due to it being used under well controlled conditions and the site is fully bunded. There is no discharge to sewer.
6. The release of the notified polymer to the atmosphere is not likely to be of any significance due to the polymer's high molecular weight and expected low vapour pressure. The notified polymer is used at ambient temperatures only. However, it is a reactive species that will react with the epoxy resin component to form an inert polymeric material.

RELEASE OF CHEMICAL FROM USE

The formulated products may be applied by airless spray and/or by brushing or rollers to large steel tanks. However, since the coating is usually applied to the inside of the tanks, any released material will be trapped within the tank. Once the hardener is mixed with the epoxy resin, it will react to form an inert polymeric material.

Assuming a minimum of 97% of the contents of a (5 L or 2.4 L) can/pail is used by the applicators, then for each can approximately 0.72 kg of the formulated product will remain in the can. Based on the percentage of the notified polymer presented in the formulated product at end-use, the level of the notified polymer remains in the can will be up to a maximum of $0.07 \times 0.72 \text{ kg} = 50 \text{ g}$. The residue is mixed with epoxy resin and allowed to cure. Licensed waste contractors collect the waste. Cans/pails are usually disposed of as industrial waste by the applicators.

5.5. Disposal

Most waste material resulting from the use of the formulated products on site is usually disposed of as industrial waste.

The majority of the notified polymer will be disposed of to landfill or incinerated at the end of the products' useful lifetimes bound within the cured polymer matrix.

5.6. Public exposure

The public will not come into contact with the notified polymer. The only scenario where the public would have any direct exposure to the adduct would be in the event of a spill from a drum of Aradur 265-1 or cans/pails of the formulated products.

Aradur 265-1 itself will be restricted to two sites, namely the formulation site and the notifier's site. It is not envisaged that it will be available to the general public in any form, as it has been developed specifically for the heavy industrial protective coating application.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notifier applied for a variation of schedule requirements for all physical and chemical properties. The information below is for Aradur 265-1, which contains 30-60% of the notified polymer. Some physical and chemical properties are based on the presence of residual 1,2-diaminocyclohexane (DACH).

| | |
|--|--|
| Appearance at 20°C and 101.3 kPa | Viscous liquid with amine-like strong odour. |
| Melting Point/Freezing Point | Not determined. |
| Remarks | The polymer is a liquid at room temperature. |
| Boiling Point | Not determined. |
| Remarks | Expected to be > 100°C based on presence of DACH which has a boiling point of 188-192°C. |
| Density | 1080 kg/m ³ at 25°C |
| Remarks | from Vantico Data Sheet |
| Vapour Pressure | Not determined. |
| Remarks | The relatively high molecular weight of the polymer suggests that it would have a low vapour pressure. Residual DACH has vapour pressure of 1.5x10 ⁻⁴ kPa at 20°C. |
| Water Solubility | 46 g/L (temperature not reported) |
| METHOD | A ground sample of Adduct LSU 935 was tumbled with water adjusted to pH 4 with concentrated HCl. After centrifugation the water was decanted off. This extraction step was repeated. The remaining washed sample and the washings were evaporated to dryness, and the dried residues weighed. The percentage water soluble component was calculated from both the weight loss of the original sample, and (as confirmation) from the weight of the residue obtained from water washings. |
| Remarks | The water-soluble portion is likely to be due to the presence of residual 1,2-cyclohexanediamine. The notified polymer itself is expected to be insoluble in water, based on the presence of the highly hydrophobic portion of the polymer molecule. However, it also contains amines and hydroxy groups that could confer some water solubility to the polymer itself. |
| TEST FACILITY | Probe Analytical (2004) |
| Hydrolysis as a Function of pH | Not determined |
| Remarks | Based on the chemical structure, the test material does not contain any functional groups that are expected to be readily hydrolysable. |
| Partition Coefficient (n-octanol/water) | Not determined |
| Remarks | Given the likely hydrophobicity of the notified polymer, it is likely that the notified polymer would be expected to partition to the organic phase. |
| Adsorption/Desorption | Not determined |
| Remarks | Given the mainly hydrophobic nature of the notified polymer, it is likely that the notified polymer will adsorb to, or associate with soils and sediments. |
| Dissociation Constant | Not determined |
| Remarks | The notified chemical contains primary and secondary amines. A typical pKa range is expected to be 9.0-11.0. However the polymer is expected to be water |

insoluble.

Particle Size Not applicable.

Remarks Liquid at room temperature.

Flash Point Not determined.

Remarks Expected to be >75°C based on characteristics of DACH.

Flammability Limits Not expected to be flammable.

Autoignition Temperature Not determined. .

Remarks Not expected to undergo autoignition.

Explosive Properties Not determined.

Remarks Not expected to be explosive.

Reactivity Conditions to avoid: Take necessary action to avoid static electricity discharge. Avoid strong acids, strong bases and strong oxidising agents. Product will not decompose explosively.

Remarks From the MSDS.

7. TOXICOLOGICAL INVESTIGATIONS

| <i>Endpoint and Result</i> | <i>Assessment Conclusion</i> |
|--|--|
| Rat, acute oral | LD50 2439 mg/kg bw, Low to moderate toxicity |
| Rat, acute dermal | LD50 > 3000 mg/kg bw, Low toxicity |
| Rabbit, skin irritation | Moderately irritating |
| Rabbit, eye irritation | Irritating |
| Guinea pig, skin sensitisation - adjuvant test | Evidence of sensitisation. |

7.1. Acute toxicity – oral

TEST SUBSTANCE TK 12855

METHOD Similar to OECD TG 401 Acute Oral Toxicity.
Species/Strain Rat/Tif:Raif (SPF)
Vehicle Distilled water containing 0.5% carboxymethylcellulose and 0.1% Tween 80

RESULTS

| <i>Group</i> | <i>Number and Sex of Animals</i> | <i>Dose mg/kg bw</i> | <i>Mortality</i> |
|--------------|----------------------------------|----------------------|------------------|
| 1 | 5 males | 500 | 0 |
| 2 | 5 males | 2000 | 1 |
| 3 | 5 males | 2500 | 2 |
| 4 | 5 males | 5000 | 4 |
| 5 | 5 females | 500 | 0 |
| 6 | 5 females | 2000 | 2 |
| 7 | 5 females | 2500 | 2 |

| | | | |
|-------------------|--|------|---|
| 8 | 5 females | 5000 | 4 |
| LD50 | 2439 mg/kg bw | | |
| Signs of Toxicity | Some systemic toxicity was observed. | | |
| Effects in Organs | No treatment-related gross organ changes were observed. | | |
| Remarks - Results | The acute oral LD50 of TK 12855 in rats of both sexes observed over a period of 14 days is 2439 (1479-5492) mg/kg. | | |
| CONCLUSION | The notified polymer is of low to moderate toxicity via the oral route. | | |
| TEST FACILITY | Ciba-Geigy Limited (1981a). | | |

7.2. Acute toxicity - dermal

| | |
|------------------|---|
| TEST SUBSTANCE | TK 12855 |
| Not specified | |
| METHOD | Similar to OECD TG 402 Acute Dermal Toxicity. |
| Species/Strain | Rat/ Tif: RAIF (SPF) |
| Vehicle | Polyethylene glycol 400 (PEG 400) |
| Type of dressing | Occlusive |

RESULTS

| Group | Number and Sex of Animals | Dose mg/kg bw | Mortality |
|-------|------------------------------|------------------|-----------|
| 1 | 5 males | 3000 | 0 |
| 2 | 5 females | 3000 | 0 |

| | |
|------------------------------|--|
| LD50 | > 3000 mg/kg bw |
| Signs of Toxicity - Local | Erythema was observed. |
| Signs of Toxicity - Systemic | Some systemic toxicity was observed. The animals recovered from these systemic symptoms within 9 days. |
| Effects in Organs | No treatment-related gross organ changes were observed. |
| CONCLUSION | The notified polymer is of low toxicity via the dermal route. |
| TEST FACILITY | Ciba-Geigy Limited (1981b). |

7.3. Irritation – skin

| | |
|--------------------|--|
| TEST SUBSTANCE | TK 12855 |
| METHOD | Proposed Guidelines of the USEPA “Primary dermal irritation study” |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 male and 3 female |
| Vehicle | A mixture of 70 parts PEG 400 and 30 parts physiological saline. |
| Observation Period | 7 days |
| Type of Dressing | Occlusive |
| Remarks - Method | 24 hours exposure. |

RESULTS

| Lesion | Mean Score* | | Maximum Value | | Maximum Duration of Any Effect | | Maximum Value at End of Observation Period | |
|--------|----------------|-----------------|----------------|-----------------|-----------------------------------|-----------------|--|-----------------|
| | Intact skin | Abraded skin | Intact skin | Abraded skin | Intact Skin | Abraded skin | Intact skin | Abraded skin |

| | | | | | | | | |
|------------------------|-----|-----|---|---|--------|--------|---|---|
| <i>Erythema/Eschar</i> | 1.8 | 1.7 | 2 | 2 | 7 days | 7 days | 2 | 2 |
| <i>Oedema</i> | 0.6 | 0.8 | 2 | 2 | 7 days | 7 days | 1 | 1 |

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

| | |
|-------------------|--|
| Remarks - Results | One female died after 48 hours. No gross lesion was observed. The primary irritating index (PII) for the intact skin and abraded skin is 2.0 and 2.1, respectively. These scores are calculated based on this 24-hour exposure study. If the exposure time were 4 hours, less severe dermal irritation would be expected. |
| CONCLUSION | The notified polymer is moderately irritating to skin. |
| TEST FACILITY | Ciba-Geigy Limited (1981c). |

7.4. Irritation - eye

| | |
|--------------------|---|
| TEST SUBSTANCE | TK 12855 |
| METHOD | Proposed guidelines of the USEPA "Primary eye irritation study" |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 males and 3 female |
| Observation Period | 7 days |
| Remarks - Method | Approximately 30 seconds after treatment, the treated eyes of 3 animals were flushed with 10 ml of the physiological saline. The eye irritation was scored for each rabbit on day 1, 2, 3, 4, and 7. |

RESULTS

Not rinsed eyes

| <i>Lesion</i> | <i>Mean Score*</i> <i>Animal No.</i> | | | <i>Maximum</i> <i>Value</i> | <i>Maximum</i> <i>Duration of Any</i> <i>Effect</i> | <i>Maximum Value at</i> <i>End of Observation</i> <i>Period</i> |
|-------------------------------|---|-----|-----|--------------------------------|---|---|
| | 1 | 2 | 3 | | | |
| <i>Conjunctiva: redness</i> | 3 | 0.3 | 3 | 3 | 7 days | 3 |
| <i>Conjunctiva: chemosis</i> | 2.7 | 0 | 3 | 4 | 7 days | 3 |
| <i>Conjunctiva: discharge</i> | 1.7 | 0 | 2 | 3 | 7 days | 1 |
| <i>Corneal opacity</i> | 2.7 | 0 | 1.7 | 3 | 7 days | 3 |
| <i>Iridial inflammation</i> | 2 | 0 | 1 | 2 | 7 days | 2 |

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

Rinsed eyes

| <i>Lesion</i> | <i>Mean Score*</i> <i>Animal No.</i> | | | <i>Maximum</i> <i>Value</i> | <i>Maximum</i> <i>Duration of Any</i> <i>Effect</i> | <i>Maximum Value at</i> <i>End of Observation</i> <i>Period</i> |
|-------------------------------|---|-----|-----|--------------------------------|---|---|
| | 1 | 2 | 3 | | | |
| <i>Conjunctiva: redness</i> | 3 | 3 | 0.3 | 3 | 7 days | 2 |
| <i>Conjunctiva: chemosis</i> | 1.3 | 1.3 | 0 | 2 | 7 days | 1 |
| <i>Conjunctiva: discharge</i> | 0.7 | 1.3 | 0 | 2 | 4 days | 0 |
| <i>Corneal opacity</i> | 0.3 | 1 | 0 | 1 | 7 days | 1 |
| <i>Iridial inflammation</i> | 0 | 1 | 0 | 1 | 7 days | 1 |

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

| | |
|-------------------|---|
| Remarks - Results | Data from the rinsed eyes showed a slight low level of irritation when comparing to that from the un-rinsed eyes. |
| CONCLUSION | The notified polymer is irritating to the eyes. |

TEST FACILITY Ciba-Geigy Limited (1981d).

7.5. Skin sensitisation

TEST SUBSTANCE TK 12855

METHOD According to the maximization test of Magnusson and Kligman.
Species/Strain Guinea pig/Pirbright White
PRELIMINARY STUDY Not reported.
MAIN STUDY
Number of Animals Test Group: 10/sex Control Group: 10/sex
INDUCTION PHASE Induction Concentration:
intradermal injection 0.5% (in propylene glycol mixture)
topical application 25% (in Vaseline)
Signs of Irritation Not reported.
CHALLENGE PHASE
1st challenge topical: 10% (in Vaseline)
Remarks - Method

RESULTS A preliminary study was carried out, but not reported.

| <i>Animal</i> | <i>Challenge Concentration</i> | <i>Number of Animals Showing Skin Reactions after challenge 24 h</i> |
|----------------------|--------------------------------|--|
| <i>Test Group</i> | | |
| 10 male | 10% TK 12855 | 10 (3 of Draize score 1 and 7 of Draize score 2) |
| 10 female | 10% TK 12855 | 10 (6 of Draize score 1 and 4 of Draize score 2) |
| <i>Control Group</i> | | |
| 10 male | Vehicles alone | 0 |
| 10 female | Vehicles alone | 0 |

Remarks - Results Since the notified polymer was determined as a skin irritant, some irritation effects were expected to occur during topical induction and challenge.

At the challenge phase, the control animals did not receive the notified polymer but the vehicle only. Therefore, the control data could not be used for any comparison.

No data of the 48 hours observation after the challenge were reported.

CONCLUSION

TEST FACILITY Ciba-Geigy Limited (1981e).

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer will be imported as a component of Aradur 265-1 and subsequently be incorporated into two formulated products. These will be used as curing agents for epoxy resins which are applied as protective coatings to steel tanks. As such the majority of the notified polymer will be bound within the polymer matrix of the cured articles. Since the coating is usually applied to the inside of the tanks, any released material will be trapped within the tank. Some release of the notified polymer into the environment may occur during formulation and during cleaning of mixing equipment.

The notifier estimates approximately 1.8 tonnes per year of the notified polymer will be wasted during manufacture, either as waste in import containers or as washings of mixing equipment. Wastes in import containers and washings from the cleaning of mixing equipment will be collected by licensed waste contractors.

Once the hardener is mixed with the epoxy resin, it will react to form an inert polymeric material. The majority of the notified polymer will be disposed of in landfill bound within the polymer matrix in the articles into which it has been coated at the end of their useful lifetime. In landfill, it is anticipated that the cured polymer will not be mobile and will degrade slowly to give water and oxides of carbon and nitrogen.

9.1.2. Environment – effects assessment

No data were provided for the notified polymer. Groups anticipated to become cationic in water include, but are not limited to, aliphatic primary, secondary and tertiary amines. Polycationics of concern have to be either water-soluble or dispersible in water (Boethling and Nabholz 1997). Based on the presence of the multiple amine groups which are potentially cationic, significant toxicity to aquatic species would be expected, however, based on the expected low water solubility and the relatively high molecular weight, it is anticipated that the notified polymer would have low aquatic exposure.

9.1.3. Environment – risk characterisation

As the notified polymer is used as a curing agent for epoxy resins which are applied as protective coatings inside oil tanks, most of the polymer will be incorporated into the inert plastic matrix and trapped within the tanks, posing little risk to the environment. It is highly unlikely that the notified polymer will enter the waterways as the factory is fully bunded during the formulation process and no release to sewer will occur.

Most wastes generated during manufacture and washings of equipments will be collected by licensed waste contractors who will reclaim the solvent and dispose of solid residues to approved landfill. Residues in small containers containing the formulated products are mixed with hardener, allowed to cure and solidify and then dispose of to landfill. Thus, given the low environmental exposure, there is unlikely to be a significant environmental risk under the reported use pattern.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During transport and storage, workers are unlikely to be exposed to the notified polymer except when the packaging is accidentally breached.

At the formulation site, Aradur 265-1 containing the notified polymer is transferred by pumping, and blending is carried out in a sealed vessel under local exhaust ventilation. Packaging of the formulated products is automated and also carried out under local exhaust ventilation. Except during the filling of the mixing vessel, Aradur 265-1 is handled in closed systems. Therefore, worker exposure is expected to be low, although incidental exposure may occur during spillage, for example, overfilling during packaging.

Similarly, incidental exposure may occur during repackaging of the imported product Aradur 265-1.

Dermal and inhalation exposure to the formulated coating product containing the notified polymer may occur during filling of containers at the formulation site or during preparation and mixing of the coating solutions prior to application. Exposure during preparation may be significant if controls such as local exhaust ventilation are not employed.

The coating solutions containing the notified polymer at < 7% will be applied by airless spray, roller or brushes. As engineering controls may not be provided during these processes, inhalation and dermal exposure is likely during application unless personal protective equipment is worn. Workers are expected to wear overalls, gloves and industrial safety glasses when applying the epoxy coatings to the tanks and, if necessary, respiratory protection in enclosed areas.

Once the resin has been applied and cures, there will be no further exposure to the notified polymer.

9.2.2. Public health – exposure assessment

The public are not expected to come into contact with the notified polymer, or the products containing the polymer in the ordinary course of events. Therefore exposure to the public is considered to be negligible.

9.2.3. Human health - effects assessment

Toxicological data on the product containing the notified polymer (TK 12855 - LSU 935 Solids) were provided for acute oral and dermal toxicity, eye irritation, skin irritation and skin sensitisation. The notified polymer is of low to moderate by the oral route and of low toxicity by the dermal route. It is irritating to skin and eyes in rabbits. Test results for skin sensitisation using the maximisation test method showed the notified polymer to be a skin sensitizer in guinea pigs.

The notified polymer is therefore classified as Irritant (Xi) with risk phrase R36 (Irritating to eyes) and R38 (Irritating to skin), and Sensitisation (Xn) with R43 (May cause sensitisation by skin contact) according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

The imported product Aradur 265-1 contains 28-36% benzyl alcohol (risk phrases R20/22) and 10-16% 1,2-cyclohexanediamine, which is harmful by inhalation, causes burns and is a skin sensitizer (R20, R34 and R43). Therefore, Aradur 265-1 is as a hazardous substance with the risk phrases R20/22, R34 and R43. In addition, Aradur 265-1 is a Class 8 (Corrosive substances) Dangerous Good.

The repackaged product has the same hazard status as the imported product. The classification of the formulated coating product containing the notified polymer will depend on the other additives in the coating formulation, however, the product will be classified as an irritant and skin sensitizer as a minimum.

As the coating solutions used during application contain at least 1% notified polymer, they will be sensitising to the skin as a minimum.

9.2.4. Occupational health and safety – risk characterisation

The main health concerns of the notified polymer are its corrosive and skin sensitising properties. The imported product containing the notified polymer is also harmful by inhalation. As dermal and inhalation exposure may occur during the formulation, repackaging and coating processes, there is a risk of adverse health effects, particularly irritation and skin sensitisation. In particular, engineering controls may not be in place during the preparation and use of the final coating solutions so, as these coating solutions will still be hazardous substances, there is a risk of irritation and sensitisation unless protective measures are taken.

The risk of adverse effects will be reduced by employment of engineering controls, for example, enclosure and local exhaust ventilation during formulation, and the appropriate use of personal protective equipment. Respiratory equipment may be required in confined spaces.

Since the notified polymer is a skin sensitiser, any products containing equal and more than 1% notified polymer are classified as hazardous, and workers who become sensitised should avoid further handling of the polymer and solutions containing the polymer.

9.2.5. Public health – risk characterisation

Since no exposure to the public will occur with the notified polymer, or the products containing the notified polymer in the ordinary course of events, the adverse health risk for the public is negligible.

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

10.1. Hazard classification

Based on the available data the notified polymer is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

Irritant (Xi) with R36/38 (Irritating to eyes and skin).
Sensitisation (Xn) with R43 (May cause sensitisation by skin contact).

As a comparison only, the classification of notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

Skin corrosion/irritation for the notified polymer is not included in the following table of GHS classification due to the exposure duration was 24 hours in the study report rather than up to 4 hours as described in the GHS documents.

| | <i>Hazard category</i> | <i>Hazard statement</i> |
|--------------------------------------|------------------------|-------------------------------------|
| Severe eye damage/ eye irritation | 2A (irritant) | Causes serious eye irritation |
| Skin sensitisation | 1 | May cause an allergic skin reaction |

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Moderate Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health based on its reported use pattern.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the products containing the polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

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

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC should consider the following health hazard classification for the notified polymer:
 - R36/38: Irritating to eyes and skin
 - R43: May cause sensitisation by skin contact.
- Use the following risk phrases for products/mixtures containing the notified polymer:
 - $\geq 20\%$, R36/38
 - $\geq 1\%$, R43
- Use the following special provisions for dangerous preparations containing $\geq 0.1\%$ notified polymer:
 - “May produce an allergic reaction.”
- The imported product Aradur 265-1 containing the notified polymer should be classified as follows under the ADG Code:
 - Class 8 (Corrosive Substances)
 - Packaging group III
- Suppliers should label Aradur 265-1 as a Class 8 dangerous good with the signal word ‘Corrosive Substances’ and the risk and safety phrases R20/22, R34, R43, S26, S36/37/39 and S45.

Health Surveillance

- As the notified polymer is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of the health effect.
- Sensitised workers should be advised not to further handling the notified polymer.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - enclosure of mixing tanks during formulation to prevent exposure to aerosols
 - local exhaust ventilation during transfer of notified polymer from drum to mixing tank.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - good ventilation during preparation and application of coating solutions;
 - workers who became sensitised should stop handling the notified polymer;
 - workers using spray technique to apply products containing the notified polymer should follow the NOHSC National Guidance Material for Spray Painting.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:

- protective gloves
- long-sleeved overalls
- eye protection
- respirator during spray application (if identified as a risk in the workplace risk assessment).

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- Do not allow material or contaminated containers to enter drain, sewers or water courses.

Disposal

- The notified polymer should be disposed of by mixing with hardener and allowed to solidify prior to disposal in an approved landfill or by incineration.

Emergency procedures

- Absorb with sand, sawdust or earth. Collect in drums and arrange for disposal by licensed contractor.

12.1. Secondary notification

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Boethling RS and Nabholz JV (1997) Environmental assessment of polymers under the U.S. Toxic Substances Control Act In: Hamilton JD and Sutcliffe R ed. Ecological assessment of polymers. First edition, A Division of International Thomson Publishing Inc., pp 187-234.

CIBA-GEIGY Limited (1981a) Report on acute oral LD50 in the rat of TK 12855. Project No: 810123. CIBA-GEIGY Limited, Basle, Switzerland (unpublished report, provided by the notifier).

CIBA-GEIGY Limited (1981b) Report on acute dermal LD50 in the rat of TK 12855. Project No: 810126. CIBA-GEIGY Limited, Basle, Switzerland (unpublished report, provided by the notifier).

CIBA-GEIGY Limited (1981c) Report on skin irritation in the rabbit after single application of TK 12855. Project No: 810125. CIBA-GEIGY Limited, Basle, Switzerland (unpublished report, provided by the notifier).

CIBA-GEIGY Limited (1981d) Report on eye irritation in the rabbit after single application of TK 12855. Project No: 810124. CIBA-GEIGY Limited, Basle, Switzerland (unpublished report, provided by the notifier).

CIBA-GEIGY Limited (1981e) Report on skin sensitizing (contact allergenic) effect in Guinea pigs of TK 12855. Project No: 810127. CIBA-GEIGY Limited, Basle, Switzerland (unpublished report, provided by the notifier).

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1999a) List of Designated Hazardous Substances [NOHSC:10005(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (1999b) National Guidance Material for Spray Painting. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (2002) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

Probe Analytical (2004) Analysis of Water Solubility: Analytical Report 890-A6687/04-004. 6/4/2004. Probe Analytical, Division of Interek Testing Services (Australia) P/L, West Footscray, Victoria (Unpublished report provided by notifier).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.