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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Adduct NIP346658

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Huntsman Advanced Materials (Australia) Pty Ltd
Gate 3, Ballarat Road
Deer Park
Victoria 3023
ABN: 93091627879

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:
Chemical name
Other names
CAS Number
Molecular formula
Structural formula
Spectral data
Purity
Monomer identity and composition
Residual monomers
Import volume
Details of use
Identity of manufacturers/recipients

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

Vapour Pressure
Hydrolysis as a Function of pH
Partition Coefficient (n-octanol/water)
Adsorption/Desorption
Dissociation Constant
Flammability Limits
Autoignition Temperature
Explosive Properties
Human tox data (analogue data used)
Ecotoxicity of Daphnida and Fish (analogue data used)

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Adduct NIP346658

METHODS OF DETECTION AND DETERMINATION

METHOD	GPC-RI, MALDI-TOF analyses and infra-red spectroscopy (IR) data were provided by the notifier
Remarks	Reference spectrum provided.
TEST FACILITY	Huntsman (2004) Huntsman (2005) Witco GmbH (2004)

3. COMPOSITION

DEGREE OF PURITY
>90%

DEGRADATION PRODUCTS
Hazardous decomposition products are carbon oxides and nitrogen oxides.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Can occur while product is in liquid form. Once hardened no loss is expected.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported from Europe in 200 L drums as a component of a formulated product. The notified polymer will be present at < 70% concentration in the imported product.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<10	<20	<20	<20	<20

USE
The notified polymer will be used as a hardener in a two-part epoxy resin industrial coating system.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
The finished product containing the notified polymer Adduct NIP 346658 will be sold to 2 main industrial customers who may repack the product into smaller containers. End use sites will be generally large construction projects.

TRANSPORTATION AND PACKAGING
The 200L steel drums of imported formulated product containing the notified polymer will be transported by road from the wharf to a bunded warehouse for storage prior to distribution as needed by road to customer sites. The repacked product will be stored and transported from the customer sites to industrial end-use sites by road in 200L steel drums and 20L steel pails.

5.2. Operation description

The notified polymer will not be manufactured or formulated in Australia.

Importation
The finished product containing the notified polymer at <70% will be imported in 200L steel drums and stored in a bunded warehouse prior to distribution Australia-wide to coating manufacturers as needed.

Re-packaging by coating manufacturers
The customers will usually be coating manufacturers with large plants and extensive experience in the use of two-part epoxy resin coating products of a similar type.

At their plants, the product containing the notified polymer will be transferred from the 200 L drums to smaller pack sizes (e.g. 20L pails) and the containers re-labelled before on-forwarding to the professional market place. At the plants, transfer/decanting operations are typically undertaken by means of pumps and filling machines in dedicated areas that are well ventilated and bunded to minimise potential inhalation exposure and prevent release of any spills, respectively. It is anticipated that some plants will merely re-label the imported 200L steel drums containing the formulated product prior to on-forwarding to industrial end-users.

Applicators
The specific identity of the end-use applicators is not known however such applicators are expected by the notifier to be tradespersons skilled in the use of two-part epoxy resin coating products.

At the end-use sites, the applicators will open the drums/pails/cans and manually pour the required amount of formulated product containing the notified polymer into a bucket and subsequently add the second component of the two-part epoxy resin coating. The two-part epoxy resin components are manually added, in proportions as recommended by the manufacturer, to a mixing pail, mixed with a paddle mixture attached to an electric drill, and subsequently diluted with water using the same mixing procedure. For large application jobs, the customers may use mix/metering equipment that mechanically measures out the two components of the two-part epoxy resin coating in the correct ratio.

The two components of the two-part epoxy resin coating must be thoroughly mixed. The mixing ratio of epoxy resin to the notified polymer depends on the epoxy resin used. The following recommended mix ratios apply:

1. Araldite GY 776: Hardener containing Adduct NIP 346658 is 100:80 parts by weight
2. Araldite PZ 756/67: Hardener containing Adduct NIP 346658 is 100:53 parts by weight
3. Araldite PZ 3961: Hardener containing Adduct NIP 346658 is 100:15 parts by weight
4. Araldite PZ 3962: Hardener containing Adduct NIP 346658 is 100:16.5 parts by weight

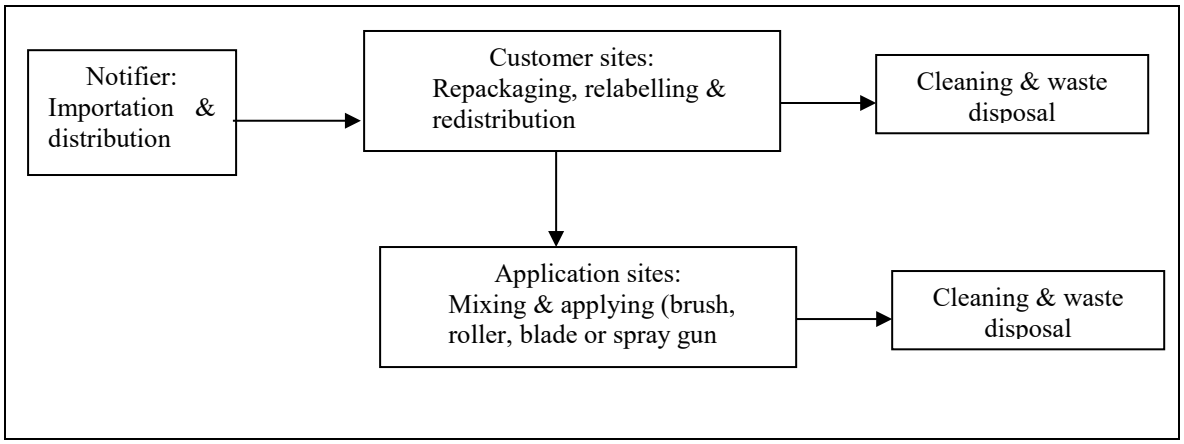
Deviations from this of up to 5-10% can be tolerated with the diluent being water, preferably deionised, directly before application. Usually the dilution is carried out on the resin / hardener mixture rather than diluting them individually and then mixing them.

From the above recommended mixing ratios the final concentration of notified polymer in the dispersion coating will range from 26.2% to 8.5% approximately.

The two-component dispersion mixture may be applied to surfaces by fine or coarse brush, a roller, doctor blade or a spray gun. Brush application is recommended for application to damp surfaces. The degree of waste generated will depend on the method of application. In general from previous experience with similar products most of the product is applied by brushing or rolling.

The two-part coating will cure within 1 to 3 hours of mixing.

Application equipment will be cleaned with slightly acidic water containing surface-active agents, followed by final rinsing with a water compatible solvent.



5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Importation			
Transport, storage and distribution	6-8	1-2 hours/week	50 days/year
Quality Assurance			
Re-packaging by Coating manufacturers			
Repackaging and relabelling Transport and distribution	30-50	4-8 hours/week	50 days/year
Application			
Application workers	>1000	8 hours/day	200 days/year

Exposure Details

Importation

Truck drivers, forklift operators and warehouse personnel will only come into contact with the notified polymer in the event of an accidental breach of the 200L steel import drums containing the finished product (50-70% notified polymer). Workers will wear overalls, safety boots and safety glasses and have access to the Material Safety Data Sheet (MSDS).

Re-packaging by Coating manufacturers

The notifier advises that repackaging will be carried out by plant operators with extensive experience in the use of two-part epoxy resin. The sites will have in place sufficient measures such as engineering controls and occupational health and safety measures and training to minimise potential exposure to such products. The relevant measures include:

- All operators required to wear overalls, gloves (complying to AS 2161) and safety glasses (complying to AS 1336).
- While the use of respiratory protection is not normally required due to the plants extraction systems, respiratory protection complying to AS 1715, 1716 available as required, e.g., in the event of failure of the extraction system or during clean up of spills.
- Site-specific Safety Procedures in place for the safe handling and disposal of chemicals.
- A full risk assessment (a Standard Operating Procedure) undertaken by the Site Safety Committee prior to the introduction to the plant of any new chemical product.
- An Emergency Response Team to provide all necessary information required for the clean up of any spill and to carry out the clean-up operation.
- Good house-keeping measures in place which include the requirement that until the product is required in the plant, the product is stored in a chemical store that complies with all local regulations. No containers containing the notified polymer are stored/left in the transfer/re-packing area.

Dermal contact, and limited ocular and inhalation exposure to the notified polymer is possible during handling bulk containers and repackaging of the product containing the notified polymer into smaller containers.

Minor spills may occur during the transferring to smaller containers. Major spills would only be expected to occur in the event of an accident. Skin contact from spillages of the product containing the notified polymer at <70%is also possible.

Skin, eye and limited inhalation exposure may also occur during cleaning and repair of the equipment may also occur.

Application workers
Dermal exposure is likely for application workers during mixing and application. However, this will be minimized by the PPE equipment used and the training provided. In the event of a new chemical being introduced into a particular manufacturing area, the workers in that area are "taken-through" the MSDS to make them familiar with the hazards presented by the new chemical.

- Only personnel who have had training in the use of chemical products such as the finished product containing Adduct NIP 346658 are allowed to handle them.
- Training is provided in–house on an "on the job" basis under the supervision of the Safety Committee.
- If any significant changes in the manufacturing process or products used in the process occur, then a re-fresher training course is run for the operators.
- Generic chemical training is provided to all personnel likely to come into contact with chemical products such as this. This includes general chemical safety and the use of all types of Personal Protective Equipment that is appropriate for their activities.
- MSDS for all chemicals brought on customer site are demanded from suppliers and are kept on site in the First Aid Room

Dermal contact, and limited ocular and inhalation exposure to the notified polymer is possible during handling and mixing of the product containing the notified polymer at < 70% into the coating mixtures.

During the application process the level of dermal, eye and inhalation exposure will vary depending on the mode of application, with maximal dermal exposure during application with brush, roller and blade and maximal inhalation, eye and skin exposure during spray gun application.

Skin, eye and limited inhalation exposure may also occur during cleaning and repair of the equipment may also occur.

Gloves, safety glasses and respirator will be worn by applicators.

5.4. Release

At Huntsman Advanced Materials
Transport and Storage
Release is not expected during transport or storage before distribution to the repacking sites. However, should the finished product containing < 70% of the notified polymer stored in the ABX warehouse in Tullamarine, Victoria, be released to the environment due to accidental spill or damaged drum, this would not be expected to be significant. The quantities likely to be stored at any one time will be relatively small (typically <5 tonnes). The ABX warehouse is fully compliant with all current government regulations relevant to the storage of hazardous chemicals.

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

1. In the case of a spill or damage to the container in which the notified polymer (Adduct NIP 346658) is supplied. It is envisaged that supply will be in 200 L drums. In this scenario, the amount of finished product containing Adduct NIP 346658 that would be spilt would be ca 129 kg per annum of the notified polymer. The notified polymer will never be released in isolation at

customer site.

2. Spillage during transfer from the containers in which the product is supplied into smaller containers. This process is conducted in a well controlled environment, hence spillage would be expected to be minimal. It is expected to be less than 20 kg/annum.
3. Residual material in the containers. This product is of relatively low viscosity, hence it is reasonable to assume that >98% of the contents of each container will be consumed. For the 200 L drums, only 4.3 kg of product will remain or 2.5 kg notified polymer. This would be cured prior to disposal to licensed solid waste sites.
4. The release of the finished product containing Adduct NIP 346658 and notified polymer to the atmosphere is not likely to be of any significance due to the adduct having a high molecular weight hence a low vapour pressure. It is used at ambient temperatures only.

End-use

The notified polymer is a reactive species that will react with the epoxy resin component to form an inert polymeric material. The most significant opportunities for release to the environment will occur during the mixing phase. A typical mix of epoxy resin and hardener typically would be of the order of 20 kg, which translates to 13 kg of the resin and 7 kg of hardener. However, once the resin and hardener have been mixed, the curing reaction occurs which results in the formation of an inert polymeric material. It is usual for waste cured material or residue in the 5 L and 10 L cans and 20 L pails, to be disposed of as industrial waste at an approved land-fill site.

Environmental release of the notified polymer is summarised in the following table.

Source of release	% Annual Volume	Released to
Residual notified polymer within 200 L Import Containers	<2%	Landfill
Accidental Spills	<1%	Incinerator
Residual notified polymer within 5, 10, 20, and 200 L consumer containers	<2%	Landfill
Rinsate from the cleaning of application equipment	<5%	Domestic Sewer
Overspray	<30%	Landfill
Applied notified polymer.	≥60%	Landfill

5.5. Disposal

Waste material resulting from the use of the product containing the notified polymer on site is usually disposed of as industrial waste. The finished product containing Adduct NIP 346658 is mixed with epoxy resin and any remaining mixture at the end of the day is allowed to solidify prior to disposal. Wastage by the applicators is usually <5% due to the nature of the work done and the high cost of the products, which dictates maximum utilisation of the products.

Notified polymer that is disposed of by incineration is expected to be thermally decomposed to form simple oxides of carbon, nitrogen and hydrogen.

Notified polymer that is disposed to sewer is expected to remain within the aquatic compartment. Overtime the notified polymer should breakdown via biotic and abiotic means to form simple organic compounds.

Notified polymer that is disposed to landfill is expected to be cured prior to disposal, and should therefore be immobile. Overtime the notified polymer should breakdown via biotic and abiotic means to form simple organic compounds.

5.6. Public exposure

The notified polymer or products containing it will not be sold to the public. It will only be used for industrial applications. Products containing this adduct will only be sold to professional users. This will be made available to them through professional building supply/trade outlets. Members of the public will not come into contact with finished product containing Adduct NIP 346658, nor will they come into contact with the surfaces freshly coated with the dispersion coatings in the ordinary course of events. Once the coating has cured the polymer will be bound in the coating and will not be bioavailable.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Yellow brown liquid

Melting Point/Freezing Point -38 ºC

METHOD ISO 9001 - DSC
Remarks Results only provided
TEST FACILITY Solvias AG Basel, 2005

Boiling Point 102.8ºC

METHOD ISO 9001 – Pinhole with DSC
Remarks Results only provided
TEST FACILITY Solvias AG Basel, 2005

Density 1081 kg/m^3 at 25ºC

METHOD ISO 9001
Remarks Results only provided
TEST FACILITY Solvias AG Basel, 2005

Vapour Pressure Not determined.

Remarks Based on the results for one of the major residual monomers the vapour pressure is $2x10^{-3}$ kPa at 20 ºC.

Water Solubility >4.5 g/L

Remarks A semi-qualitative water solubility test was conducted. 0.9 g of the notified polymer was found to be completely dispersed in 200 mL of water forming a very light hazy solution. Note, the algae test found the formulation containing the notified polymer to be insoluble in water.
TEST FACILITY University of Sydney (2005)

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer does not contain any functional groups that are hydrolysable.

Partition Coefficient (n-octanol/water) Not determined

Remarks The water solubility of the notified polymer is expected to be relatively high and therefore the partition coefficient is expected to be relatively low.

Adsorption/Desorption Not determined

Remarks Expected to be low based on water solubility, but much higher based on cationic potential.

Dissociation Constant Not determined

Remarks Typical range for primary and secondary amines is pKa = 9 to 11.

Particle Size Not applicable. Liquid.

Flash Point >165ºC

METHOD In house PMANP2FL

TEST FACILITY Huntsman (2005a)

Flammability Limits Not determined

Remarks

Autoignition Temperature Not determined.

Remarks Not expected to auto ignite

Explosive Properties Not determined

Remarks Not expected to be explosive

Reactivity

Remarks The notified polymer will react with strong acids and strong bases. It will also react with strong oxidising agents.

7. TOXICOLOGICAL INVESTIGATIONS

Toxicological data for the notified polymer was not submitted.
In order to provide a general toxicological profile for the notified polymer, the notifier provided toxicological information on analogues containing primary and secondary amine functionalities similar to those present in the notified polymer. The following information on analogues was used for toxicological effects assessment:

- OECD SIDS Initial Assessment Report on a monomer of the notified polymer (OECD, 2004)
- IUCLID data set on the monomer. ECB (2000)
- IUCLID data set on 1,3-Benzenedimethanamine (m-XDA) ECB (2000a)
- HSDB data sets for Diethylentriamine-DETA and Triethylenetetramine-TETA HSDB (1997 and 1997a)
- Subchronic toxicity of triethylenetetramine dihydrochloride in B6C3F1 mice and F344 rats (Greenman, 1996)
- Case study on occupational airborne allergic contact dermatitis due to the monomer (Case study, 1995)
- Evaluation of genotoxic potential of alkyleneamines (Leung, 1994)

The information from the sources outlined above can be summarized as follows:

Endpoint and Result	*Result and relevant chemical*	*Assessment Conclusion*
Acute Oral Toxicity	LD_{50}: Residual monomer - 1030 mg/kg bw (rat) DETA - 1080 mg/kg bw (rat) TETA - 1600, 4300 & 5500 mg/kgbw (for mice, rats & rabbits, respectively) m-XDA – 930 mg/kg bw (rat)	Harmful
Rabbit, Acute Dermal Toxicity	LD_{50} for m-XDA: 2000 mg/kg bw	Harmful
Rat, acute inhalation	LC_{50}: m-XDA - 2.4 mg/L /4 hours DETA – no mortalities in rats exposed to saturated vapour for 4h	Harmful
Human Case Study on airborne allergic contact dermatitis	One worker demonstrated occupational airborne allergic contact dermatitis due to exposure to mixture containing the residual monomer	Potentially a Respiratory Sensitiser
Rabbit and Rat, skin irritation	Undiluted residual monomer caused irritation and inflammation more intense in rabbits than in rats.	Irritating

Rabbit, eye irritation	Undiluted residual monomer caused serious injury almost immediately after application and showed necrosis by 24 hours.	Corrosive
Guinea pig, skin sensitisation-Maximization test	Residual monomer showed evidence of sensitisation	Evidence of sensitisation
Rat, inhalation repeat dose toxicity - 14 days	Residual monomer two studies: First study: $LOAEL_1$ = 2.2 mg/m³ (reversible minimal to mild degeneration of respiratory nasal mucosa); Second study: $LOEL_2$ = 18 mg/m³ (degeneration/necrosis in the olfactory epithelium)	May cause adverse affects on olfactory and respiratory mucosa after subchronic exposure
Rat, oral repeat dose toxicity - 90 days	Residual monomer NOAEL = 60mg/kg bw/day	NOAEL ≤ 60mg/kg bw/day
Rat and Mice oral repeat dose toxicity – 92 days	TETA dihydrochloride in the drinking water of animals and two different diets. Toxicity occurred only in mice in the highest dose (3000 mg/L) group fed a special purified diet.	No conclusion about NOAEL can be deduced
Genotoxicity - bacterial reverse mutation	Residual monomer - negative results reported in three Ames tests with and without metabolic activation TETA was found to be mutagenic in the *Salmonella typhimurium*	May be mutagenic
Genotoxicity – in vitro CHO Cells	Residual monomer - negative results reported with and without metabolic activation For TETA and other two other alkyleneamines sister-chromatid exchanges were reported.	May be genotoxic
Genotoxicity – in vitro hepatocytes	DETA – negative results reported TETA – positive results reported	May be genotoxic
Genotoxicity – in vivo Micronucleus assay	Residual monomer and TETA - negative results reported	Non-mutagenic

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

Only one ecotoxicological test was provided for a formulation containing the notified polymer, as reported below. Other analogues submitted were not considered suitable.

8.2.1. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	USEPA Method 1003.0 (1994)
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	Nominal: 6.25, 12.5, 25, 50, 100 mg/L Actual: Not measured
Auxiliary Solvent	HPLC Grade Acetone
Analytical Monitoring	conductivity, pH and dissolved oxygen saturation
Remarks - Method	In preliminary trials, the test material proved to be insoluble in water and of poor solubility in methanol, but dissolved well in HPLC grade acetone. A 100 mL stock solution of 20 g/L was prepared, which was milky white

in colour. As the toxicity tests can only accept up to 0.1% vol/vol acetone without causing adverse effects, a maximum of 100 mg/L in dilution water could be tested. The test material in the acetone carrier solvent dispersed well at the maximum rate of 0.1%.

The test concentrations plus control and solvent control (0.1% vol/vol acetone) and a positive (toxic) control test was conducted using copper chloride were prepared in 250 mL beakers. After homogenising, the conductivity, pH and dissolved oxygen saturation of the test treatments were measured.

The IC50 estimates (with 95% confidence limits) were determined using the linear interpolation method. Data analyses were performed using ToxCalc v5.0.23 (Tidepool Scientific Software).

RESULTS

Biomass	
E_bC50	*NOEC*
mg/L at 72 h	
23.0 (19.4-29.0)	6.25

Remarks - Results

None of the test solutions exhibited any opaqueness, and therefore were unlikely to have affected light availability to the algal cells. The solvent control treatment was not significantly different to the control treatment, and the solvent control treatment was used for statistical comparison against the test treatments. All test criteria were met, thus validating the test.

CONCLUSION

The test material was found to be harmful to aquatic algae under the strict conditions of the test.

TEST FACILITY

Ecotox (2006)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

It is anticipated that at least 90% of the total annual volume of notified polymer will be disposed of to landfill mostly in cured form. In landfill, the notified polymer should be immobile and it is expected that it will eventually degrade via biotic and abiotic process to form simple carbon and nitrogen based compounds. Up to 5% of the total annual volume of notified polymer may be disposed of to the domestic sewer in rinsate from the cleaning of application equipment. A Predicted Environmental Concentration was calculated, as described in the following table.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	3.85	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Daily effluent production:	4,099	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC - River:	0.94	µg/L
PEC - Ocean:	0.09	µg/L

9.1.2. Environment – effects assessment

Only one test report was submitted for freshwater algae. Based on the structure of the notified polymer, this should be the most sensitive trophic level. However, a conservative assessment factor of 1000 was applied as described in the following table.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
IC50 (Alga), (60% notified polymer in formulation)	13.80	mg/L
Assessment Factor	1,000.00	
PNEC:	13.80	µg/L

9.1.3. Environment – risk characterisation

The risk quotient was determined, as described in the following table.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.94	13.8	0.068
Q - Ocean:	0.09	13.8	0.007

As the PEC/PNEC ratio is less than 1 for both river and ocean, there should be an acceptable risk to aquatic organisms.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Categories of workers likely to be exposed to the notified polymer are those involved in transport and storage, coating formulation and application and cleaning up spills and equipment.

Dermal and inhalation exposures are the most likely routes. Ocular exposure may occur from accidental splashes.

Workers involved in transport and storage would only be exposed to product containing 50-70% of notified polymer, in the event of an accident.

Workers involved in re-packaging at the coating manufacturers sites may be exposed to the notified polymer during handling bulk containers containing product with 70% of notified polymer and repackaging it into smaller containers. The exposure could be dermal, ocular and by inhalation, however it would be minimized by applying appropriate engineering controls and safety procedures, including training of workers and usage of PPE. Skin, eye and limited inhalation exposure may also occur during cleaning and repair of the equipment.

Dermal and inhalation exposure to product containing the notified polymer is also likely for the application workers during mixing of the coating mixtures (up to 70% of notified polymer) and application (up to 30% of notified polymer). The exposure would be minimized by the PPE equipment used by the workers and the training provided to them in handling similar substances. The level of dermal, eye and inhalation exposure will vary depending on the mode of application, with potential dermal exposure during application with brush, roller and blade and maximal inhalation, eye and skin exposure during spray gun application. In addition, skin, eye and limited inhalation exposure may also occur during cleaning and repair of the equipment may also occur.
Once the resin has been applied and cures, there will be no further exposure to the notified polymer.
Overall, there is significant risk of exposure to the notified polymer with the worst-case scenario being a dermal, ocular and inhalation exposure to <30% of notified polymer during the spray application under conditions that engineering controls are not provided and personal protective equipment is not worn. Potential exposure would be minimized by training of workers, safe work practices and worker use of overalls, gloves, industrial safety glasses and respiratory

protection when necessary.

9.2.2. Public health – exposure assessment

The notified polymer or products containing it will not be sold to the public. Products containing this adduct will only be sold to professional users. Members of the general public will not come into contact with finished product containing the notified polymer, nor will they come into contact with the surfaces freshly coated with the dispersion coatings in the ordinary course of events. Once the coating has cured the polymer will be bound in the coating and will not be bioavailable. Public exposure is considered to be very low.

9.2.3. Human health – effects assessment

Toxicokinetics, metabolism and distribution.

There is no information available on toxicokinetics and metabolism of the notified polymer nor any of the analogues.

Acute toxicity.

The LD50 after oral application in rats for the residual monomer is 1,030 mg/kg bw with the kidney appearing to be the potential target organ. The LD50 for the other two alkyleneamines varies from 1080 to 5500 mg/kg bw in the three animal systems tested. LD50 for m-XDA is 930 mg/kg bw in rat. Based on this data and the proposed analogy, it may be extrapolated that the notified polymer may be harmful if ingested.

The LD50 reported for m-XDA after dermal application is about. 2000 mg/kg bw. Based on this data and the limited analogy of m-XDA and the notified polymer, it may be extrapolated that the notified polymer may be harmful after contact with skin. Based on the data for homologues and the relatively high molecular weight of the notified polymer it is not expected to be harmful if inhaled. However, due to the presence of low molecular weight species in the notified polymer resin, adverse effects on the respiratory pathways are possible in the case of spray application.

Irritation and Sensitisation.

The results reported for the residual monomer in rabbits indicate that it is a strong irritant and corrosive after repeated application to the skin. It is also corrosive to the eyes of rabbits.
The residual monomer was found to induce dermal sensitisation when tested in guinea pigs. In addition, evidence is reported that frequent occupational exposure to the residual monomer may lead to the development of allergic contact dermatitis in humans. Considering the chemical analogy of the residual monomer and the notified polymer and the presence of a significant quantity of the monomer in the polymer, it can be concluded that the notified polymer may cause corrosive effects and sensitization by skin contact.

Repeated Dose Toxicity (sub acute, sub chronic, chronic).

From two 14-day inhalation studies it can be concluded that the residual monomer may cause minimal to mild degeneration of respiratory nasal mucosa. Therefore subchronic exposure to the notified polymer may cause adverse affects on the olfactory and respiratory mucosa.

A 90 day oral repeat dose toxicity study (drinking water), established a NOAEL of 59 mg/kg bw/day (males) and 62 mg/kg bw/day (females). Administration of 150 mg/kg bw/day led to reduced absolute and relative kidney weights with histopathology being indicative for tubular necrosis.

Mutagenicity.

The residual monomer was not mutagenic in bacteria and mammalian cell systems *in vitro* and *in vivo.* However, some of the alkyleneamines showed positive results in bacteria and in mammalian tests in vitro. Based on these results the possibility for the notified polymer or its metabolic products to induce mutations in case of exposure in humans, can not be excluded.

Carcinogenicity.

No data for carcinogenicity is available on any of the analogues of the notified polymer.

Toxicity for reproduction.

No studies have been performed on the reproductive toxicity of the residual monomer. However, the data from an oral 90-day study in rats did not reveal any adverse effects on the male and female reproductive organs.

Observations on Human Exposure.

There is evidence that frequent occupational exposure to the residual monomer may lead to the development of allergic contact dermatitis in humans (OECD, 2004). In addition, there is one case study describing a serious attack of bronchial obstruction in a man after working with resins and hardeners, releasing fumes of a mixture of trimethyl-1,6-hexanediamine and the residual monomer.

Hazard classification for health effects.

Based on the on the limited toxicological data for the notified polymer it is not possible to classify the notified chemical as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However, based on data for analogues the notified polymer the following classification and labelling details should apply:
R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed
R43 - May cause sensitisation by skin contact
R34 - Causes burns

9.2.4. Occupational health and safety – risk characterisation

Considering the intended use of the notified polymer and the data for the health effects of several analogue molecules including a hazardous residual monomer, the main risks for the health and safety of workers likely to be exposed the notified polymer are related to the corrosive and skin sensitising properties. In addition the products containing the notified polymer may also be harmful if inhaled. Even though harmful by the oral route, there is no significant risk of systemic exposure to the notified polymer by this route except in the case of an accident.

Systemic exposure through the dermal route may also be harmful but would be minimal under the standard condition of use with PPE and safe operational procedures.

Dermal and inhalation exposure may occur during the formulation, repackaging and coating processes, and this poses a risk of adverse health effects, particularly skin irritation and skin sensitisation, in the case that engineering controls are not in place.

The most significant risk for adverse health effects including skin and eye irritation, eye irritation, skin sensitisation and harmful effects to the olfactory and respiratory pathways will occur during spray application of the mixtures containing <30% of notified polymer.

The risk of adverse effects will be reduced by employment of engineering controls including enclosure and local exhaust ventilation during formulation, safe work practices and the appropriate use of personal protective equipment including respiratory equipment especially in confined spaces.

Since the notified polymer is classified as harmful by inhalation, in contact with skin and if swallowed, it is corrosive and is a skin sensitiser, any products containing equal and more than 1% notified polymer are classified as hazardous. Workers who become sensitised should avoid direct handling of the polymer and solutions containing the polymer and all workers that are likely to come into contact with the notified polymer should wear appropriate personal protection equipment.

Overall, risk of adverse effects to the health and safety for workers handling the products containing the notified polymer is significant, especially where spray application occurs. The risk can be reduced by appropriate operational safety procedures and PPE.

9.2.5. Public health – risk characterisation

The public will not have access to the notified polymer. Contact with the notified polymer may only occur if there is a spill during transport of the product containing < 70% notified polymer. The public will contact treated areas after the chemical has completely cured. The risk to public health upon contact with treated surfaces that has completely dried is low.

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

10.1. Hazard classification

Based on the on the limited toxicological data for the notified polymer it is not possible to classify the notified chemical as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However, based on data for analogues the notified polymer the following classification and labelling details should apply:
R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed
R43 - May cause sensitisation by skin contact
R34 - Causes burns

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the notified polymer 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, due to the risk of sensitisation and irritation. This risk will be reduced by the implementation of appropriate controls at the coating application sites.

10.3.2. Public health

There is Negligible Concern to public health under the proposed conditions of use.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 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 product containing the notified 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

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Conc ≥ 25%: R20/21/22; R34; R43;
  - 25%> Conc ≥ 10%: R34; R43
  - 10%> Conc ≥ 5%: R36/37/38; R43
  - 5%> Conc ≥ 1%: R43

- Products containing more than 1% notified chemical and available to the public must carry the following safety directions on the label:
  - S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
  - S36 Wear suitable protective clothing
  - S37 Wear suitable gloves
  - S42 During spraying wear suitable respiratory equipment (appropriate wording to be specified by the manufacturer)

- S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.
- S64 If swallowed, rinse mouth with water, (only if the person is conscious)

Health Surveillance

- As the notified chemical is a 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 sensitisation.
- Sensitised workers should be advised not to further handle the notified polymer

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical as mixed for use:
  - enclosure of pumps and filling machines during repackaging to prevent exposure to aerosols;
  - isolation of spray working areas where possible;
  - local exhaust ventilation during transfer of notified polymer from drum to mixing tank;
  - good ventilation during preparation and application of coating solutions.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical
  - avoid skin and eye contact;
  - avoid breathing spray;
  - avoid spills and splashes, and clean up any spilt material promptly;
  - collect and dispose of over-spray waste without exposing workers to dust;
  - avoid skin contact with uncured coating when removing personal protective equipment; and
  - 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 chemical as mixed for use, and as used in the mixed products:
  - protective gloves
  - long-sleeved overalls
  - eye protection
  - appropriate respiratory protection where there is potential exposure to spray or dust during end-use (for vapour or for dust). This should meet the requirements set out under the NOHSC National Guidance for Spray Painting (1999) for epoxy resins.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of by incineration or to landfill.

Emergency procedures

- Spills/release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

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 Section 64(1) of the Act; if

– the notified polymer is made available to the public.

or

(2) Under Section 64(2) of the Act; if

– if any additional information in relation to the notified polymer becomes available
– if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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