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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

ANQUAMINE 701 / EPILINK 701

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Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL: + 61 2 8577 8800
FAX + 61 2 8577 8888.
Website: www.nicnas.gov.au

Director
Chemicals Notification and Assessment

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ANQUAMINE 701 / EPILINK 701

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Air Products Australia Pty Limited
2/20 Hunter Street Parramatta, NSW 2124

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
CAS number
Molecular formula, structural formula
Molecular weight
Spectral data
Composition
Exact import volume
Identity and composition of the polymer

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Partition coefficient
Adsorption/desorption coefficient
Dissociation constant
Flammability limits
Auto-ignition temperature
Explosive properties
The above parameters were not measured as they are not applicable for water dispersions.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US EPA 1999; Environment Canada 2000.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Anquamine 701
Epilink 701

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	IR Spectroscopy
TEST FACILITY	Air Products and Chemicals Inc. (2001)

3. COMPOSITION

DEGREE OF PURITY
>90%

DEGRADATION PRODUCTS
The product is not expected to degrade or decompose under normal conditions

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
All the un-reacted monomers are expected to fully react with epoxy resin or be incorporated into the final product matrix

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a 60% aqueous dispersion.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-100	10-100	10-100	10-100	10-100

USE
The notified polymer will be reformulated in paint products for application as a coating to concrete or steel structures, eg. Industrial, hospital and parking garage floors, bridge coatings and maintenance applications.

Anquamine 701 is one component of a two-part coating mixture. The paint is made by mixing the formulated product containing Anquamine 701 with a liquid epoxy resin. When the final paint is mixed, it is applied by roller, brush or spray depending on the end-use application. Approximately 40% of the notified polymer is applied by roller, a similar percentage by brush and approximately 20% by spray.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not known

IDENTITY OF RECIPIENTS
The imported notified polymer will be stored at Anchor Chemicals Warehouse. It is expected to be sold to about 10 customers. However, initially only one customer will incorporate it into an epoxy flooring formulation.

TRANSPORTATION AND PACKAGING
The notified polymer is imported in 200 L steel drums. The formulated paints will be supplied to customers in 200 L drums as well as 5 gal (18.4 L) containers.

5.2. Operation Description

Anquamine 701 is formulated by paint/flooring manufacturers. The formulated product will be used by professional industrial painters and/or coating applicators.

Paint formulation:
The notified polymer (60% in imported product) will be transferred via drum pumps from the imported drums into enclosed stirred, formulating tanks for manufacture of the paint hardener. The customer will add pigments and other ingredients. Normally, the paint formulating tanks are

enclosed to contain any spills of raw materials or finished product that might occur. The final paint product (hardener) is drained from the formulating vessel and packaged. The filling line is usually automated. The notified polymer in the formulated product is present at 25-50%.

Paint application:
The product containing notified polymer may be used by 100-120 professional brush, roller and spray applicators.

The epoxy coating mixture is prepared by emptying the 18.4 L cans of hardener (containing the notified polymer) in a mixing station, adding the second component, and stirring. The final paint mixture contains 20-40% of the hardener. Once combined the epoxy resin and the notified polymer will irreversibly react to form a cross linked polymer network of high molecular weight (MW) within 10 minutes.

The coating mixture is applied to a concrete surface by pouring the mixture onto a floor and then spreading with a brush or roller or dipping the brush or roller in the container containing the coating mixture and applying to the surface.

For spray applications (up to 40 % notified polymer), the coating mixture is applied to steel surface by pumping the mixture from a pail to the spray gun.

The paint normally cures about three hours after application.

5.3. Occupational exposure

Exposure Details
Transport and storage:
10-20 workers will be involved in transport and handling of the material from wharf to the warehouse and another 10-15 from the warehouse to industry.

Paint Manufacturers
About 4 process operators will transfer the notified polymer via drum pumps from the imported drums into enclosed stirred, formulating tanks. Exposure during these operations is expected to be of short duration. The process steps are nearly completely enclosed and require little worker attention.

End-use
It is estimated that 100 to 120 applicators will apply the coatings to concrete or steel structures. Potential worker exposure exists during the following activities:

- emptying the container of hardener
- mixing and stirring the hardener with another component
- during application when pouring the mixture onto a floor and then spreading with a brush or roller or when dipping the roller or brush into the mixture and applying on a surface, and when applying as spray
- cleaning up spills and equipment

5.4. Release

RELEASE OF CHEMICAL AT SITE
The water-based epoxy curing agent, Anquamine 701 / Epilink 701, containing the notified polymer, will be reformulated into paint and coating formulations at paint manufacturing facilities. No release to the environment is anticipated during the formulation process because the product is transferred directly from the import containers via pumps to enclosed mixing vessels in bunded areas. A small amount of solid waste may be generated during equipment cleaning following formulation. The mixing equipment will be cleaned with an organic solvent, and the solvent reclaimed, while the solid residues are either incinerated or sent to landfill.

The empty import drums are expected to contain 0.25% (0.5 kg) of residues when sent to drum recyclers, who will remove the residues using a high temperature, high pressure caustic (pH~13) washing process. The wash water arising from this procedure is disposed of through a licensed waste

disposal company and the agglomerated solid from the settling tank is disposed of in an approved landfill. The notifier estimates about 62.5 kg per year of notified polymer (taking into account 25% water solubility) could enter waterways via on site waste water treatment facilities each year.

RELEASE OF CHEMICAL FROM USE

The end users (approximately 100-120 applicators) will apply the coating by brush, roller, or spray to floors or other structures exposed to corrosive environments. The notifier anticipates that brush and roller applications will account for 80% and spray will account for the remaining 20% of applications.

The notifier estimated that 10-15% of paint will be wasted to overspray during spray applications, equating to 1.2 tonnes of notified polymer. It is anticipated that 80% of the oversprayed paint will be captured on protective sheets, allowed to cure, and disposed of in landfill. The remaining 20% (240 kg) is likely to drift during the application process and be deposited on nearby ground surfaces. It is expected that paint residues remaining on brushes and rollers after painting will be cleaned with an organic solvent, while the solid residues are either incinerated or sent to landfill. Alternatively, brushes will be washed with water and the washings containing the hardened polymer released into the sewer.

The notifier estimates about 0.5% of paint residues may remain in the paint containers, equating to 200 kg of notified polymer. The residues are expected to harden and be disposed of in landfill along with the paint containers.

5.5. Disposal

The Material Safety Data Sheet (MSDS) indicates that the preferred disposal method of the notified polymer is by incineration.

5.6. Public exposure

The public will not have access to the coating formulation containing notified polymer. Public exposure may occur from accidental spills during transport and upon contact with treated areas.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer will be imported as a 60% aqueous dispersion. Where indicated, the physicochemical properties are for the dispersion.

For some physico-chemical properties, the notifier provided data on a claimed structural analogue, ethylenediamine ($NH_2C_2H_4NH_2$). The analogue represents the component amine in the polymer, comprising repeating units of NC_2H_4, which is the strongest base in the polymer, and comprises about 25% of the polymer by weight. However, this approach should be treated with extreme caution, as this is entirely bound within a polymer of MW >1000; hence, the polymer is likely to exhibit different properties from the low MW monomer.

Appearance at 20°C and 101.3 kPa	Opaque yellow emulsion with an ammoniacal odour (Technical Bulletin, 1999)
Boiling Point	>100° C (aqueous dispersion)
Density	1096.4 kg/m^3 at 25°C (aqueous dispersion)
Vapour Pressure	2 kPa at 25°C (aqueous dispersion)
Remarks	The vapour pressure indicates the notified polymer is highly volatile (Mensink *et al* 1995). However, the volatility is likely due to the presence of water as the polymer is a high molecular weight salt.
Water Solubility	25%

Remarks The notified polymer is sold as a stable dispersion of up to 60% solid polymer in water. The water solubility could not be determined because the notified polymer is a polymeric mixture, occurring in the form of a micro gel, which cannot be filtered or centrifuged. However, the chemist who developed the notified polymer estimates the water solubility to be about 25%. The water solubility is due to the presence of about 25% bound 1,2-ethanediamine in the polymeric mixture, and to the presence of some protonated nitrogen from this mixture. The US EPA PMN notification has the water solubility listed as <10%.

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer is not expected to hydrolyse under normal environmental pH ranges and temperatures as it does not contain groups generally considered as hydrolysable.

Partition Coefficient (n-octanol/water) Not relevant as the notified polymer is introduced as an aqueous solution.

Remarks The notified polymer is an ionic polymer and hence the partition coefficient could not be measured.

Adsorption/Desorption Not determined

Remarks The notifier estimates a log Koc of 3.6 (Hazardous Substances Data Bank), based on the structural analogue, ethylenediamine, which suggests the amine groups in the polymer will be slightly mobile in soils (McCall *et al.* 1980).

Dissociation Constant Not determined

Remarks The notified polymer contains some amine groups, which are expected to be partially protonated in environmental pH ranges. A worst case scenario dissociation constant is pKa = 10.6 based on the claimed structural analogue, ethylenediamine.

Particle Size Not applicable as the notified polymer is imported as aqueous dispersion

Flash Point Not available

Flammability Limits Not measured

Autoignition Temperature Not measured

Explosive Properties Not measured

Reactivity

Remarks The polymer is predicted not to have oxidising properties.
Compatibility with other substances: Mineral acids, organic acids, oxidising agents, sodium or calcium hypochlorite.

Reaction with peroxides may result in violent decomposition of peroxide possibly creating an explosion. A reaction accompanied by large heat release occurs when the product is mixed with acids. Heat generated may be sufficient to cause vigorous boiling creating a hazard due to splashing or splattering of hot material.

Viscosity 5-10 Pa.S at 25°C (Technical Bulletin, 1999)

7. TOXICOLOGICAL INVESTIGATIONS

The notifier submitted the following toxicity studies on Anquamine 701: Acute oral, dermal and ocular toxicity and 3 eye irritation studies. Inhalation toxicity studies (acute and repeat dose studies) and skin irritation study (summary only) were provided on a similar chemical, Anquamine 700 (Epilink 700). Anquamine 701 is a modified chemical structure developed to replace Anquamine 700 (Epilink 700).

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	harmful LD_{50} 1890 mg/kg bw
Rat, acute dermal	low toxicity LD_{50} > 2000 mg/kg bw
Rat, acute inhalation	toxic LC_{50} 0.251 mg/L/4 hour
Rat, Acute Inhalation (neurotoxicity)	Neurobehavioural changes
Rabbit, acute ocular	Corrosive to the eyes
Rabbit, skin irritation (summary only provided)	Mildly irritating to rabbit skin
Rabbit, eye irritation (3 studies)	Corrosive to the eyes
Rat, Inhalation repeat dose toxicity – 28 days.	LOAEL* 0.003 mg/L
Rat, 5-day inhalation study	LOAEL* 0.0194 mg/L

* Low Observed Adverse Effect Level (LOAEL)

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified polymer

METHOD — OECD TG 401 Acute Oral Toxicity.

Species/Strain — Rat/Wistar albino

Remarks - Method — Initially 5 males and 5 females were dosed with 2000 mg/kg bw/day. At this level mortality occurred.

Rats were observed at 1, 2 and 4 hours after administration and once daily for 14 days.

The dose was administered orally by syringe and dosing needle at a dose level of 2000 mg/kg bw.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 males and 5 females	2000	1 female and 3 males died
II	5 males and 5 females	1500	1 male died
III	5 males and 5 females	1000	None

LD50 and 95% confidence limit — Males 1890 (1498-2385) mg/kg bw
Females >2000 mg/kg bw

Signs of Toxicity — The body weight changes of all group III and surviving group II animals were normal. In group 2 animals, body weight changes were normal in five out of six treated animals.

Animals that died showed signs of tremors and lethargy.

Systemic observations were noted in all treated groups. The main physical signs were brown staining of the nose/mouth area and diarrhea.

Necropsy results of surviving animals were normal, except for one male in group III that had a yellow mass attached to fat associated with testes. Necropsy results of animals that died showed excess fluid in the pleural

cavity and abnormalities of the lungs, stomach and intestine.

Remarks - Results

CONCLUSION The notified polymer is harmful via the oral route (LD50 1890 mg/kg bw/day)

TEST FACILITY MB Research Laboratories (1999a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified polymer

METHOD OECD TG 402 Acute Dermal Toxicity.
Species/Strain Rabbits/New Zealand White
Type of dressing Occlusive (the notified polymer was applied under a four layered surgical gauze patch, and remained intact with the skin for 24 hours))
Remarks – Method Dermal responses were recorded at 24 hrs post dose and on days 7 and 14.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
	3 males	2000	One male

LD50 > 2000 mg/kg bw
Signs of Toxicity – Local Dermal reactions were absent to well defined at 24 hrs, absent to moderate on day 7 and absent on day 14.

Body weight changes were normal in all surviving animals.
Signs of Toxicity – Systemic One female showed kidney abnormalities.
Remarks – Results One male died on day 2 showing signs of yellow nasal discharge, dyspnea, reduced faecal output and sagging eyelids. Necropsy showed abnormalities to the liver, lung, spleen and treated skin of the animal that died.

CONCLUSION The notified chemical is of low toxicity via the dermal route (Dermal LD50 >2000 mg/kg bw/day).

TEST FACILITY MB Research laboratories (1999b)

7.3. Acute toxicity – Ocular

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion
Species/Strain Rabbits/New Zealand White
Number of animals 3 males
Remarks – Method 0.1 mL was instilled into one eye of each of 3 rabbits
The animals were tested for 3 batches of the notified polymer
The irritation scores were recorded at 1 hr after administration.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*
Conjunctiva: redness	2	2	1 hr
Conjunctiva: chemosis	2.6	3	1 hr

Conjunctiva:discharge	2.4	3	1 hr
Corneal opacity	3	3	1 hr
*Iridial inflammation***	2	2	1 hr

*Calculated on the basis of the scores at 1 hr for ALL animals.

Signs of Toxicity – No mortality occurred. Remnants of the test chemical were present in the eyes and/or the outside of the lids of all animals.

Lethargy and tilting of the head was seen in all animals.

Remarks – Results Severe effects on the cornea, iris and conjunctivae were observed.

CONCLUSION The notified chemical is corrosive to the eye.

TEST FACILITY NOTOX B.V. (2000)

7.4. Acute toxicity – inhalation

TEST SUBSTANCE Epilink 700 (analogue)

METHOD Acute (4-hour) inhalation toxicity study with an aerosol of Epilink 700 in rats[#]
OECD 403: Acute inhalation toxicity study

Species/Strain Rats/Wistar outbred

Method of Exposure
- Three exposure groups A, B and C started one day apart (5 males and 5 females in each group). No air controls were included in the study.
- The target concentrations were 1.2 (A), 0.35 (B) and 0.2 (C) mg/L
- Nose-only inhalation chamber:
  The animal was securely placed in a chamber so that the animal's nose was exposed only to the test material aerosol directed downward through the mixing chamber. At the bottom of the unit, the test atmosphere was exhausted.
  Rats were exposed to a continuous supply of fresh test atmosphere diluted with measured amounts of humidified clean air.
- The test atmosphere was generated by nebulising the test material into small droplets.
- The test material was diluted with demineralised water and was continuously stirred to prevent stabilising and flocculating.
- Airflow, through the exposure chamber was 44.8, 49.6 and 44.8 L/min during exposures A, B and C respectively.
- Observation period was 14 days

One protocol deviation was noted related to the second particle size determination. This deviation is not considered compromising to the study.

Exposure Period 4 hours

Physical Form liquid aerosol

Particle Size Distribution Particle size measurement at the animal's breathing zone:
Aerodynamic diameter equal to or less than 4.2 μm (99% of the particles)
Mass Median Aerodynamic Diameter (MMAD) (geometric standard deviation) :
Exposure A 3.1 μm (1.5)
Exposure B 2.8 μm (1.7) for 2 measurements
Exposure C 2.8 μm (1.6) and 2.9 μm (1.5)

Remarks – Method During exposure, the animals had no access to feed and water and were housed individually in the holders
There was one protocol deviation related to the measurement of the

[#] The design of the exposure unit and generation of the test chemical were similar in the submitted inhalation studies

second particle size determination. The deviation is not considered compromising to the study.

RESULTS

Group	*Number and Sex of Animals*	*Measured Concentration mg/L*	*Mortality*
A	5 males and 5 females	1.235	100%
B	5 males and 5 females	0.346	80%
C	5 males and 5 females	0.205	30%

Analytical results: The temperature readings in all groups were 20°C. Relative humidity was 31-44% during exposures A, B and C. The oxygen content for A, B and C was 22.1-22.2%.

Signs of toxicity: Group A: All animals died in the third hour of exposure. Laboured breathing was observed after the first hour of exposure.

Group B and C: Breathing abnormalities were seen. Eight animals (3 males and 5 females) died in group B and 3 (2 males and one female) in group C. Surviving animals displayed piloerection and blepharospasm. During the observation period, no abnormalities were noted.

Clinical signs of toxicity were apparent including a decreased weight gain and weight loss in the first week of exposure. Moderate weight gain was seen in the second week of the observation period.

Necropsy studies showed discoloration of the lungs and thymus in dead animals. In some surviving animals, some minor macroscopic changes of the lungs were observed.

Remarks - Results: 4 hour LC50 0.251 mg/L with a 95% reliability interval from 0.133 to 0.362 mg/L. There was no significant difference seen between male and female animals.

CONCLUSION: The notified polymer is toxic via inhalation.

TEST FACILITY: TNO Nutrition and Food Research Institute (1998a)

7.5. Acute inhalation neurotoxicity study

TEST SUBSTANCE: Epilink 700 (analogue)

METHOD: Acute neurotoxicity study with inhalatory exposure of rats to Epilink 700#
OECD 203, Acute Inhalation Toxicity

Species/Strain: Rats/Wistar outbred

Method of Exposure:
- Two groups: A- receiving Epilink 700 at 0.1 mg/L (target concentration)
  B- controls exposed to clean air
- Nose-only inhalation chamber:
  The animals were secured using animal holders and positioned radially through the outer cylinder around the central column. Only the nose of the rat protruded into the interior of the column.
- Rats were exposed to a continuous supply of fresh test atmosphere diluted with measured amounts of humidified clean air.
- The test atmosphere was generated by nebulising the test material

into small droplets.
- The test material was diluted with demineralised water and was continuously stirred to prevent stabilising and flocculating.
- Total airflow through the exposure chamber (group A) was 49.3 L/min. Air flow through the control chamber was 25.0 L/min.
- Observation period was 14 days
- Control animals were exposed on the same days to clean air
- Animals were observed 15 minutes after the end of the exposure period and 7 and 14 days after exposure
- Neurobehavioural observations were performed using a standardised functional observational battery (FOB[1]) and automated motor activity assessment, and neuropathological examination of nervous tissue. The assessment was made within one week prior to testing, 15 minutes after the end of the exposure period and 7 days and 14 days following exposure.
- Deviations from the protocol were noted on body weight records and histopathological examinations. These deviations are not considered to have compromised the study.

Exposure Period	6 hours
Physical Form	Aerosol liquid
Particle Size Distribution	Equal to or less than 4.2 μm (99% of particles measured at the animal's breathing zone): MMAD (geometric standard deviation): 2.1 μm (1.9) both measurements for male exposure 2.3 μm (1.9) and 2.1 μm (2.0) during the female exposure
Remarks – Method	During exposure and FOB and motor activity assessment, the animals had no access to feed and water and were housed individually in the holders

RESULTS

Group	*Number and Sex of Animals*	*Measured Concentration mg/L*	*Mortality*
A (Exposed)	10 males and 10 females	0.0924 (males) 0.0895 (females)	None
B (Control)	10 males and 10 females	- -	None

* based on gravimetric analysis

Analytical results	Temperature, relative humidity and oxygen content: 21ºC, 40% and 21.7-22.3% respectively for female exposure; for male exposure the respective values were 21.2, 38% and 21.6-22%.
Signs of Toxicity	Because of the effects seen on body weights of control animals, group differences could not be seen. Changes in FOB measures from different functional domains were observed. Neuromuscular function: significant decrease in foot splay 15 minutes after treatment, 7 days after treatment and 14 days after treatment in treated male and female groups. In males, 2 animals showed ataxia 15 minutes after treatment. Convulsive activity comprising body tremor and repetitive movement was seen in males and females at 15 minutes after exposure. Only 1 treated female showed convulsions after 7 days of treatment. Tonic convulsions were not observed.

[1] FOB- a series of non invasive observational and interactive measures designed to assess the neurobehavioural and functional integrity of the rat.

	Motor activity domain: in males and females, the total number of movements, and the total distance travelled were significantly decreased. Arousal levels were also reduced in both sexes. In males, changes in autonomic function was indicated by impaired palpebral closure 15 minutes after treatment. Sensimotor reactivity domain: significant changes were observed in responses to a click stimulus in both exposed females and males. Body temperature (severe) of treated animals were significantly decreased 15 minutes after treatment.
Neuropathology	Animals selected for neuropathology were those that showed most severe behavioural measures. The only effect noted was incidental degeneration of axons in control and treated animals.
Remarks - Results	Overall, the behavioural changes observed were not persistent, based on observations at 7 and 14 days after exposure.
CONCLUSION	The single 6 hr inhalatory exposure of rats to 0.1 mg/L Epilink 700 induced a number of changes in behavioural patterns from different functional domains, however neuropathological changes were not seen.
TEST FACILITY	TNO Nutrition and Food Research Institute (1999)

7.6. Irritation – skin

TEST SUBSTANCE	Epilink R2009 (identical to Epilink 700 (analogue))
SUMMARY	This study was conducted as per OECD Guideline 404. Three healthy rabbits were dosed with the test chemical at 0.5 mL (placed on the intact shaved skin of the back). The test chemical was kept in contact with the skin with a semi-occlusive dressing for four hours and was scored for erythema and oedema at 1, 24, 48, and 72 hours following patch removal. Erythema was very slight in all three animals one hour after bandage removal. Erythema persisted in two animals at the 24 hour observation and in one animal at the 48 hour observation. All irritation resolved by the 72 hour examination. Epilink R2009 was not corrosive to the skin and was only mildly irritating.
REFERENCE	Rees (year not stated)

7.7. Irritation – eye (a)

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	2 males and 1 female
Observation Period	Signs of toxicity and mortality were observed for the first hour post dose and at 1 and 24 hrs following administration
Remarks – Method	One eye of each rabbit was dosed The animals were observed continuously for 24 hours

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*
Conjunctiva: redness	2	2	24 hrs
Conjunctiva: chemosis	4	4	24 hrs
Conjunctiva:discharge	2.7	3	24 hrs
Corneal opacity	3	3	24hrs
Iridial inflammation	2	2	24hrs

*Calculated on the basis of the scores at 24 hours for ALL animals.

Remarks - Results	One instance of lethargy was noted at one hour after dosing. Corneal opacity, iritis and conjunctival irritation persisted through 24 hrs.
CONCLUSION	The notified polymer is corrosive to the eye.
TEST FACILITY	MB Research laboratories (2000a)

7.8. Irritation – eye (b)

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	2 males and 1 female
Observation Period	Signs of toxicity and mortality were observed for the first hour post dose and at 1 and 24 hrs following administration
Remarks - Method	One eye of each rabbit was dosed The Rats were observed 1 and 24 hrs.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*
Conjunctiva: redness	3	3	24 hrs
Conjunctiva: chemosis	4	4	24 hrs
Conjunctiva:discharge	2	2	24 hrs
Corneal opacity	4	4	24hrs
*Iridial inflammation***	2	2	(see comment below)

*Calculated on the basis of the scores at 24 hours for ALL animals.
** Iris inflammation could not be read at 24 hrs due to the extent of chemosis. The value shown was scored at 1 hr

Remarks - Results	There were no abnormal physical signs noted within one hr of dosing and at 24 hrs. An abnormal attitude of the head was noted. No systemic toxicity was reported following ocular administration.
CONCLUSION	The notified polymer is corrosive to the eye.
TEST FACILITY	MB Research laboratories (2000b and 2000c)

7.9. Irritation – eye (c)

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	5 male and 5 females

Observation Period	Signs of toxicity and mortality were observed for the first hour post dose and at 1 and 24 hrs following administration
Remarks - Method	One eye of each rabbit was dosed Due to the severity of the responses, the study was terminated following the 24 hr observation period.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	3.1	4	24 hrs	4
Conjunctiva: chemosis	3.9	4	24 hrs	4
Conjunctiva:discharge	2.1	3	24 hrs	3
Corneal opacity	3.9	4	24hrs	4
*Iridial inflammation***	2	2	(see comment below)	

*Calculated on the basis of the scores at 24 hours for ALL animals.
** Iris inflammation could not be read at 24 hrs in most animals due to the extent of corneal opacity. The value shown was read at 1 hr

Remarks - Results	There were no abnormal systemic signs noted in any animal during the one-hour post dose observation period or at 24 hours post dose.

CONCLUSION The notified polymer is corrosive to the eye.

TEST FACILITY MB Research laboratories (2000d)

7.10. Repeat dose inhalation toxicity

TEST SUBSTANCE EPILINK 700

METHOD OECD TG 412 Repeated Dose Inhalation Toxicity: 28-day Study.
Subacute (28-day) inhalation toxicity study#

Species/Strain	Rats/Wistar
Route of Administration	Inhalation – nose only exposure.
Exposure Information	Total exposure days: 20 days; Dose regimen: 5 days a week for 4 weeks; Duration of exposure (inhalation): 6 hours/day;
Vehicle	
Physical Form	Aerosol liquid
Particle Size Distribution	MMAD (geometric standard deviation) at 30, 10 and 3 mg/m^3 test atmosphere: 0.80 (1.7)-0.96 (1.9) µm (at 30 mg/m$^{3)}$ 0.94 (1.7)-0.97 (1.8) µm (at 10 mg/m^3) 0.92-0.96 (1.7) µm (at 3 mg/m^3)
Remarks - Method	• Four groups: A- Control (air), B-3 mg/m^3, C-10 mg/m^3, D-30 mg/m^3. The doses were selected based on a 5-dose range study (TNO Research and Nutrition Study, 1998b) (see results below). • Nose-only inhalation chamber: The animal was secured in animal holders and positioned radially through the outer cylinder. Only the nose of the rats protruded into the interior of the column. • Rats were exposed to a continuous supply of fresh test atmosphere diluted with measured amounts of humidified clean air. • The test atmosphere was generated by nebulizing the test material into small droplets.

- Mean daily airflows were 54.0, 62.8, 74.0 and 89.6 L/min for groups A, B, C and D, respectively.
- The test material was diluted with demineralized water and was continuously stirred to prevent stabilising and flocculating.
- Control animals were exposed to air in a nose only chamber similar to treated groups
- Animals were observed 15 minutes after the end of the exposure period and 7 and 14 days after exposure

Certain deviations were noted including relative humidity and temperature measurement, and protocol used for neuropathology. The deviations were not considered to compromise the study.

Neurobehavioural observations were performed using a standardised functional observational battery (FOB) and automated motor activity assessment, and neuropathological examination of nervous tissue. The assessment was made within one week prior to testing, 15 minutes after the end of the exposure period and 7 days and 14 days following exposure.

Neuropathological examinations were conducted on five males and five females.
Neurobehavioural observations were carried out on all animals

RESULTS
Summary of the five-day range finding inhalation study (using Epilink 700):

- 5 males and 5 females were exposed to 0.019, 0.052, 0.1005 mg/L
- Exposure duration was for 6 hr/day for 5 days
- MMAD 0.95-1.27 μm/nose only exposure; flow rate at 44-76 L/min

The animals showed breathing difficulties. Exposed male rats showed reduced body weight; the body weight of female rats was slightly decreased. Absolute and relative lung and brain weights were increased in all exposed groups. Absolute and relative spleen weight was decreased in all treated male groups.

Pathological investigations showed changes to the lungs and lymph nodes.
A No Observed Adverse Effect Level (NOAEL) cannot be established from the 5-day range finding study. The Lowest Observed Adverse Effect Level (LOAEL) is established at 0.019 mg/L.

Group	*Number and Sex of Animals*	*Target concentration mg/L*	*Measured Concentration mg/L*	*Mortality*
A (control)	10 males and females	0	-	None
B (low dose)	10 males and females	0.003	0.0030	None
C (mid dose)	10 males and females	0.010	0.01	None
D (high dose)	10 males and females	0.030	0.030	None

Mortality and Time to Death
During exposure, no changes in breathing pattern were noted. No mortalities were reported during the exposure period.

Clinical Observations
Red discoloured nose was seen in all test animals. A concentration-related decrease in body weight gain was observed in all male exposure groups reaching a statistical significant degree in males of group D during the entire exposure period, group C on days 14 and 28, and group B on day 14 only. In females no changes in body weight gain were noted.

Food consumption was lower in all exposed groups showing a concentration-related response.

Functional Observations and Motor Activity
There were incidences of abnormal signs observed during the exposure period. In females, the following observations were found to be not statistically significant when compared with the control group: larger mean foot splay, increased forelimb grip strength, repetitive jaw movements and decreased motor activity in group D. In group D males, there were significant effects on arousal. Motor activity observations in group D males were noted but were not found to be significant.

Laboratory Findings – Clinical Chemistry, Haematology
Slight, but significant changes were observed on haematology parameters in the treated groups. Clinical chemistry changes were observed; the effects were slight and sometimes occurring in one group but not the other. In males, there were effects on albumin content, alkaline phosphatase, protein and calcium content and inorganic-phosphate content. In females, effects were seen on liver enzymes, creatinine, cholesterol content and phospholipid content. The changes were mainly seen in groups C and D.

Effects in Organs
Concentration-related increase in absolute and relative weight of the lungs was observed in male and female rats of groups C and D. Absolute spleen weight and absolute heart weight were decreased in males of group D.

Macroscopic Pathology
Collapsed lung was noted in 1 male and 1 female of group D.

Histopathological Examinations
Histopathological changes in the complete respiratory tract and lungs of treated animals:

Nasal cavity
Nasal lesions were found in all types of epithelium of animals of group D.
In groups C and B, basal cell hyperplasia occurred only incidentally and often only focally.
The transitional epithelium of groups C and D and few of group B showed atypical hyperplasia.
All animals of groups C and D showed respiratory epithelial hyperplasia and/or atypical hyperplasia at all levels.
The olfactory epithelium of all animals showed similar cytoplasmic inclusions as observed in the respiratory epithelium.

Larynx
Atypical epithelial hyperplasia of the respiratory or transitional-type epithelium was shown in the larynx of groups C and D.

Trachea
Atypical hyperplasia was shown in 1 male of group C and 1 male of group D.

Pulmonary
Fibrosis occurred in all treated animals of groups C and D and in 7/10 animals of group B.
Bronchial goblet cell hyperplasia was observed in 9/10 animals of group D and 2/10 animals of group C
Red-pigmented macrophages in all animals of group D and 7/10 animals of group C were reported.

Neuropathological changes
Neuronal micro-vacuolisation was observed in animals of group D and one female control. The lumbar spinal ganglion of group C and trigeminal ganglion of all groups were examined. It was shown that in the lumbar spinal ganglion, a single, few or several neurons with micro-vacuolisation was observed in all groups. In the trigeminal ganglion, neuronal vacuolisation was observed in groups C, B and A.

Degenerating axons were observed in groups D and A.

Neuronal central chromatolysis was observed in 2 females of group D.

DISCUSSION AND CONCLUSION

Epilink 700 caused adverse effects on body weight gain and overall food consumption of all treated groups.

The mid and high dose groups showed the following effects:

- Organ weights: increase in absolute and relative lung weights in the mid and high dose group and decrease in absolute and relative spleen weight in males exposed to high doses.
- Histopathological lesions in the respiratory tract as indicated by effects seen on epithelial hyperplasia, indicating that the test chemical causes respiratory irritation. Pulmonary fibrosis may be caused by the presence of particle-loaden macrophages as there were no indications of toxic alveolar cell damage or increased inflammatory events.

Effects on nasal olfactory epithelium was observed in all treated animals and suggests that the test chemical irritates the olfactory epithelium.

There were no clear neurobehavioural effects seen from repeated exposure to Epilink 700 in female treated animals. However in males there were effects seen in group high dose group on arousal level and motor activity.

Neuropathological observations (neuronal micro-vacuolisation) were considered to be reversible in nature and may occur as an adaptive response due to toxic damage to neuronal cells.

A NOAEL was not established based on effects seen on body weight gain, food consumption and concentration-related histopathological changes of the nasal cavity and lungs in all treated animals. Therefore, the LOAEL is 0.003 mg/L.

TEST FACILITY TNO Nutrition and Food Research Institute (1998c)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data for the notified polymer were submitted. The notifier provided information for a structural analogue, ethylenediamine ($NH_2C_2H_4NH_2$), representing the component amines in the polymer, which comprise repeating units of NC_2H_4. These data showed ethylenediamine was readily biodegraded in activated and acclimated sewage sludge, but poorly degraded in unacclimated conditions. However, as noted previously, any extrapolation of the properties and behaviour of a monomer to a complex polymer should be treated with extreme caution.

Ethylenediamine can form five-member rings by coordination of the two unshared electrons on the nitrogen atoms with metallic ions, leading to metal complexes which are more stable than those formed with other amines. While data from studies in natural systems is lacking, it is thought that metal ions in soils or natural water may form stable complexes with ethylenediamine, which suggests that the notified polymer may partially adsorb to soils or sediments in the aquatic environment. Humic acids containing aldehyde groups could also potentially react with the amine groups to form adducts, but again, data in natural systems is lacking. The quaternary ammonium functionality in the polymer should further assist adsorption to soils.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted. However, data are available in the literature for the analogue monomer, ethylenediamine. Verschueren (1996) lists the following endpoints: 96 h EC_{50} for algae (*Chlorella pyrenoidosa*) = 100 mg/L, 48 h LC_{50} for *Daphnia magna* = 26.5 mg/L, and LC_{50} for *Daphnia magna* = 0.88 mg/L (test duration not stated), 96 h LC_{50} for fish (*Poecilia reticulata*) = 275 mg/L, and 48 h LC_{50} for rainbow trout yearlings of 230 mg/L, 15 min. EC_{50} for *Photobacterium phosphoreum* = 20 mg/L. Again these data for the monomer should be treated with extreme caution when extrapolating to the notified polymer.

Based on existing information, the aquatic toxicity of polycationic polymers is most strongly influenced by cationic charge density and the type of polymer backbone. Boethling and Nabholz (1997) give toxicity endpoint for polymers based on their charge density, MW, and type of cation. Assuming a charge density of 0.7, these data suggest acute aquatic toxicity endpoints as follows: Fish = 9.2 mg/L, Daphnia = 300 mg/L and green algae = 2.2 mg/L.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The environmental exposure resulting from use of the notified polymer is expected to be low. Most of the imported volume of the polymer will be formulated into paints and coatings, which once cured will be bound up in an inert paint matrix. Approximately 1500 kg of the notified polymer could be generated as waste, predominantly during spray painting, and from residues in empty containers. Disposal of these wastes is expected to occur in a diffuse manner, with most oversprayed paint being captured on paper and incinerated or sent to landfill, although approximately 240 kg of the notified chemical contained in the uncaptured paint could enter the soil directly via spray drift. Solid wastes removed from empty containers are also expected be landfilled, while approximately 62.5 kg per year of notified polymer (taking into account 25% water solubility) could enter waterways via on site wastewater treatment facilities after washing drums.

A worst-case daily Predicted Environmental Concentration (PEC) in the sewer is 3.8×10^{-4} mg/L, assuming the entire 62.5 kg of notified polymer residing in untreated wash water from drum cleaning is released at one location into the municipal sewer of a large metropolitan area. Also, assumed is a population of 3 million people, using 150 L of water per day.

In the sewer, the notified polymer is expected to be relatively water soluble due to the presence of cationic nitrogen groups, and other water-soluble functionalities. However, protonated groups may adsorb to sediment in the sewer. Biodegradation in the sewer is also a possible degradation pathway for the polymer. Direct photolysis in water is not anticipated.

Some of the notified polymer entering the environment through spray drift is expected to be deposited on the soil surface and to quickly dry. Once dried, the polymer will form a high molecular weight solid that will be immobile. The notified polymer is not expected to biodegrade or undergo hydrolysis when disposed of in solidified form, but should eventually break down through biotic and abiotic processes.

When wastes are incinerated, the polymer will be destroyed by combustion, forming combustion products, which include oxides of carbon and nitrogen and ammonia gas.

9.1.2. Environment – effects assessment

Ecotoxicity data in the published literature for ethylenediamine indicate the notified polymer is likely to be only very slightly toxic to fish and algae, and slightly toxic to *Daphnia* and microorganisms, while data provided in Table 10.7 of Boethling and Nabholz (1997) indicate the notified polymer will be slightly toxic to fish and algae, very slightly toxic to *Daphnia* (Mensink *et al*. 1995). This is based on a cationic charge density of 0.7%, i.e. one quaternary amines per polymer repeating unit. Using the worst-case acute toxicity endpoint of 2.2 mg/L for the most sensitive species, green algae, a Predicted No Effects Concentration (PNEC) of 0.022 mg/L is presumed, assuming a safety factor of 100 (OECD, 1995).

9.1.3. Environment – risk characterisation

The notified polymer is not expected to pose a significant risk to the environment because most of the imported volume will be incorporated into an inert paint matrix. The levels of release to the environment via waste streams are expected to be low, and occur in a diffuse manner, mainly in a solidified form, with minor amounts entering waste streams via on-site treatment facilities.

A daily PEC in the sewer arising from release of drum washings is calculated to be 3.8×10^{-4} mg/L. This assumes a worst-case water solubility of 25%, and no volatilisation, adsorption, or degradation. The PEC/PNEC ratio, using the lowest acute endpoint for the polymer, is 0.017, which is significantly less than 1, indicating a low aquatic risk. The PEC would be further diluted upon entering the receiving waters, and by processes such as adsorption and biodegradation.

Solid wastes entering landfill are expected to be immobile and not to pose a leaching hazard for groundwater or aquatic environments, although the solid wastes are not expected to break down quickly in landfill, but may persist for some time in the environment. The combustion products arising from incineration are unlikely to pose a hazard when incineration is carried out in an approved manner in suitable incineration facilities.

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, paint 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.

Paint formulators are potentially exposed to the notified polymer when transferring Anquamine 701 into formulating tanks, during stirring and packing the formulated paint-hardener (20-50% Anquamine 701) into 18.4 L containers. The processes are expected to be almost completely enclosed and local exhaust ventilation is expected. Inhalation exposure is not expected to be significant because of the engineering controls. However, if ventilation is not adequate there is potential for inhalation exposure to the hardener.

Professional applicators will handle the formulated products (hardener containing 20-50% notified polymer) and coating mixture containing up to 40% notified polymer. Dermal and/or ocular exposure to the hardener may occur when workers empty the 18.4 L cans of hardener in a mixing station and add the second component to make the coating mixture containing 20-40% notified polymer, when applying by brush, roller or spray to steel structures, and when cleaning up spills and equipment.

During application (up to 40% notified polymer), the worst case scenario for worker exposure is likely to be during spraying with a spray gun. Dermal, ocular and inhalation exposure to aerosols may occur.

Transport and storage workers may become exposed to the notified polymer when handling the imported product Anquamine 701 and formulated paint-hardener products. Unless there is an accidental spill or packaging breach, exposure during transport and storage is not likely.

Modelled Worker Exposure:

Dermal and inhalation worker exposure were estimated during formulation and application using the software ‘Estimation and Assessment of Substance Exposure’ (EASE). The scenarios and assumptions are tabulated below:

Scenario	Assumptions	Dermal Exposure	Inhalation* Exposure
Scenario 1: Formulation: 60% notified polymer	Enclosed process (sampling may occur) Non dispersive use (formulators) Not direct handling (Aerosols not expected to generate)	Very low	10-20 (LEV)
Scenario 2: End use: preparing the coating mix 60% notified polymer or 20-40% notified polymer	Non dispersive use (controlled procedure) Direct handling Incidental (ie. splashes and spills) (Aerosols may generate)	0-0.1 mg/cm^2/day	500-1000 ppm (no LEV) 100-200 ppm (with LEV)
Scenario 3: Application spraying	Wide dispersive use (application not controlled) Direct handling Intermittent contact level (Aerosols may generate)	Dermal 1-5 mg/cm^2/day	>1000 ppm (without dilution ventilation) 500-1000 ppm (with dilution ventilation)
Scenario 4: Application brush or roller	Wide dispersive use (application not controlled) Direct handling Intermittent contact level (Aerosols not expected to generate)	Dermal 1-5 mg/cm^2/day	500-700 ppm (without ventilation dilution) 200-300 ppm (with ventilation dilution)

LEV-local exhaust ventilation

* the notified polymer is not expected to be volatile; the values were based on vapour pressure for the aqueous dispersion

9.2.2. Public health – exposure assessment

Professional applicators will use the products containing notified chemical. The public is not likely to come in contact with the notified polymer unless there is a spill during transport or upon contact with treated surfaces. Exposure is not expected to be significant as the notified polymer cures in 3 hours and the public are not expected to access treated areas before the material is completely cured.

9.2.3. Human health - effects assessment

Acute oral, dermal and ocular toxicity and eye irritation studies were submitted on the notified polymer. Acute and repeated dose inhalation studies and skin irritation studies were submitted on Epilink 700, chemically similar to the notified polymer.

The notified polymer is harmful by the oral route (oral LD_{50} 1890 mg/kg bw in rats), of low acute dermal toxicity (LD_{50} >2000 mg/kg bw), toxic by inhalation (4 hr LC_{50} 0.25 mg/L for aerosols). The notified polymer is mildly irritating to rabbit skin, but corrosive to rabbit eyes.

Acute inhalation neurotoxicity study in rats showed that Epilink 700 caused neurobehavioural changes shortly after exposure. The signs of neurotoxicity were not persistent and were not accompanied by neuropathological changes.

A NOAEL was not established in a 28-day repeated dose inhalation study in rats which showed concentration-related changes in the following:

- Decreases in body weight gain in all male exposed groups;
- Decreases in overall food consumption in all male and female exposed groups;
- Increases in absolute and relative lung weight in animals at 0.001 and 0.003 mg/L.
- Histopathological changes of the respiratory tract in all exposed groups suggesting that repeated exposure may cause respiratory irritation.

The LOAEL was established in the 28-day inhalation study as 0.003 mg/L and 0.019 mg/L in a 5-day inhalation range finding study.

Skin sensitisation studies were not provided, however it contains a residual (at 1%) listed in the NOHSC List of Designated Hazardous Substances as a skin sensitiser with cut-off level at greater than or equal to 1%. Also, formaldehyde is present as a residual at a maximum of 0.1% (lowest cut-off level is 0.2% for skin sensitisation). The NOHSC exposure standard for formaldehyde is 1.2 mg/m^3 (8 hr TWA) and 2.5 mg/m^3 (STEL) (NOHSC, 1995).

9.2.4. Occupational health and safety – risk characterisation

The critical health effects of the notified polymer are injury to eyes, skin sensitisation due to residual monomers present, and acute and chronic respiratory tract effects. These hazards are recognised when considering the imported product, formulated paint-hardener and application of the coating mixture.

Acute-toxic potential

An estimate of the human acute toxic inhalation dose is extrapolated from animal data. The empirical inhalation LD50 is 24.86 mg/kg bw [LC_{50} (0.25 mg/L) x Min Vol (29 L/min) x minutes exposed (4 hr x 60) / Body wt (70 kg)]. This is equivalent to a 70 kg worker absorbing 1.74 g of notified polymer [2.9 g of imported product (60%), 3.48 g (formulated paint 50%) or 4.35 g (coating mix 40%)] within 4 hours (duration of the animal test) through the inhalation route. This calculation does not include a safety factor.

Formulation:

Formulators may come in contact with the notified polymer when transferring the imported product (60% notified polymer) into the mixing vessel and when packing the formulated hardener-paint (20-50% notified polymer). The mixing process is expected to be enclosed, and packing is likely to be automated. The risk of ocular effects is significant even if workers come into contact with small amounts of the products from accidental splashes. Workers should wear goggles during formulation.

Local exhaust ventilation is expected to reduce the potential of exposure to the notified polymer by inhalation. However, considering that the notified polymer is toxic by inhalation, workers should wear respiratory protection if ventilation is not adequate.

End use

The worst-case scenario is during application and preparation of the coating mixture (20-40% notified polymer). Workers can become potentially exposed to the notified polymer from splashes and spills while preparing the coating mix, when applying by roller, brush or spraying and when cleaning up spills and equipment as this is not a controlled situation.

The coating mixture contains up to 40 % notified polymer. The risk of ocular and inhalation adverse effects is significant if exposure occurs. The notified polymer itself is not expected to be volatile, however the aqueous dispersion is of moderate volatility due to the low molecular weight species present in the mixture. The coating mixture should be prepared under local ventilation or respiratory protection should be worn if ventilation is not adequate. Small amounts of ocular splashes during preparation may cause injury to the eyes and workers should wear goggles.

During spraying with a spray gun, inhalation exposure to aerosols and contact with the mixture on the skin and eyes is expected to be greater than during roller or brush application, because of the increased potential for direct contamination from spray drift and formation of aerosols. The risks during spraying are not acceptable due to the increased potential of contamination with the coating mix during spray and the acute hazards, i.e. eyes and respiratory system effects. On the other hand, the acute risk to workers using the brush or roller is acceptable if workers wear goggles and a respirator or work in ventilated areas.

Repeated-dose toxic potential

Based on the exposure estimates derived using EASE and the repeat dose LOAEL of 0.003 mg/L, the following corresponding human doses and Margins of Exposure (MOE) are estimated:

Scenario	Dermal Absorbed Dose* (mg/kg/day)	Inhalation Exposure (mg/L)**	MOE (Dermal)***	MOE (Inhalation)***
Scenario 1: Formulation: Imported product (60% notified polymer)	Very low	5.5-11 mg/L (LEV)	Very high	0.00055-0.00027 (LEV)
Scenario 2: End use: preparing the coating mix 60% notified polymer or 20-40% notified polymer	0-0.12 mg/kg bw/day	275-550 mg/L (no LEV) 55-110 mg/L (with LEV)	0-3.8	0.000011-0.0000055 (no LEV) 0.000055-0.000027 (with LEV)
Scenario 3: Application (spraying)	1.2-5.9 mg/kg bw/day	>550 mg/L (no dilution ventilation) 275-550 mg/L (with dilution ventilation)	0.38-0.08	0.0000055 (no dilution ventilation) 0.000011-0.0000055 (with dilution ventilation)
Scenario 4: Application (brush or roller)	1.2-5.9 mg/kg bw/day	275-385 mg/L (without dilution ventilation) 110-165 mg/L (with dilution ventilation)	0.38-0.08	0.000011-0.0000078 (without dilution ventilation) 0.000027-0.000018 (with dilution ventilation)

* Based on 70 kg body weight, surface area for hands 820 cm^2, default dermal absorption 10%

** Based on 1ppm aerosol equivalent to 1 mL/10^6 mL air or 1.1 g/10^6 mL air (density of aqueous dispersion is 1.1g/mL) and 50% of the droplet is notified polymer

*** Based on LOAEL of 0.46 mg/kg/day [3 mg/m^3 (LOAEL) x 0.16 m^3/day (rat respiratory vol) x 6 hr (exposure duration/day) ÷0.26 (rat wt in the study) x 24 hrs (no. of hrs in one day) = 0.46 mg/kg/day]

**** Based on LOAEL of 0.003 mg/L

MOE for all the scenarios are low except for dermal MOE during formulation.

The following uncertainties and conservative assumptions are noted:

- Workers were not using personal protective equipment
- 100% of inhaled amounts are absorbed internally
- Inhalation exposure was based on vapour pressure of the aqueous dispersion (not the notified polymer)
- Half of an aerosol droplet contains the notified polymer
- The extent of the curing process once the coating is mixed is not certain and it is not known how much of the low MW species remains in the final mixture
- The scenarios did not take into account that only professional workers will handle the notified polymer
- LOAEL was used to calculate the MOE (NOAEL not established), so risk estimates could be higher
- Exposure estimates were based on model calculations as no measured data are available
- EASE assumes 8 hr exposure/day

Formulators

Repeated inhalation exposure to aerosols generated by the notified polymer caused neurobehavioural effects and histopathological lesions in the respiratory tract. However, the inhalation risk during formulation is not expected to be significant as the formulation facility is expected to be enclosed with local exhaust ventilation unless there are steps where workers may

directly handle the formulated paint such as during sampling. The Table above shows that inhalation MOE is low, ie. the risk of adverse health effects is high. The notified polymer itself is not volatile and this value is contributed to other ingredients in the formulation. Workers should have access to local exhaust ventilation at any stage of the formulation process or wear a respirator if ventilation is not adequate. Dermal exposure is not expected where the process is enclosed and automated. However, workers may come into contact with the notified polymer when transferring and packing the formulated paint. The notified polymer has a high molecular weight and it is unlikely to be substantially absorbed through the skin. However, because of the sensitisation effects due to the presence of residual monomers, workers should wear protective clothing and gloves.

End use

The notified polymer is not expected to be volatile; however, spraying generates aerosols, which may cause effects on the respiratory system. The risk of spray application is higher than roller or brush application because workers may become contaminated with the coating mixture from spray drift or splashes.

The Table above shows that inhalation MOE during spraying is lower than the other scenarios. The estimated MOE is higher when workers are using engineering controls. When preparing the coating mix, the estimated dermal MOE (3.8) is considered acceptable given that some of the uncertainties in the risk assessment are tending to over-estimate the risk. Workers are likely to prepare the mixture less frequently than applying it. Skin sensitisation, ocular and inhalation risk of adverse effects is greater during spraying. Workers preparing the coating mix and applying by brush or roller should have adequate ventilation (or use respirator) and wear gloves, goggles, boots, and protective clothing to avoid the risk of adverse effects from accidental spills and splashes.

The risk of application by a spray gun is not acceptable because of the increased potential of exposure to aerosols and ocular contamination. The MOE during spraying were very low and it would be difficult for a sprayer to avoid exposure to the notified polymer.

Professional workers who had special training in preparing and applying the coating mix containing the notified polymer are only permitted to use the product.

Formaldehyde residual is present at 0.1%, which is just below the cut-off level for skin sensitisation (0.2%) and has an allocated NOHSC exposure standard. Workers should have access to health surveillance facilities if the employer has identified that there is a risk of adverse effects due to exposure to formaldehyde and the employer should ensure that the NOHSC exposure standard for formaldehyde is not exceeded.

Conclusion

The risks and personal protective equipment are tabulated below:

Risk Assessment	Personal Protective Equipment
Acute Risk:	
Acute ocular	Goggles
Acute inhalation	Respirator
Eye irritation	Goggles
Repeated-dose risk:	
Inhalation	Respirator
Skin sensitisation	Protective clothing and gloves
	Boots

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 of the product containing 60 % notified polymer during transport. 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 available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R22 Harmful if swallowed
R23 Toxic by inhalation
R41 Risk of Serious damage to eyes
R48 Danger of serious damage to health by prolonged exposure

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

The concerns related to occupational health and safety under the conditions of the occupational settings described are ranked as:

- Medium during formulation processes
- High during application, particularly during spraying

10.3.2. Public health

There is No Significant Concern to public health when the notified polymer is used in accordance with the use pattern described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following hazard classification for the notified polymer:

  Risk phrases:
  R23 Toxic by inhalation
  R22 Harmful if swallowed
  R41 Risk of Serious damage to eyes

R48 Danger of serious damage to health by prolonged exposure

Safety phrases
S24 Avoid contact with skin
S36 Wear suitable clothing
S37 Wear suitable gloves
S39 Wear eye protection
S51 Use in well ventilated areas
S38 In case of insufficient ventilation, wear suitable respiratory equipment

- The risk and safety phrases listed above should appear on the label and material safety data sheet for the notified polymer and products containing it.

- Use the following risk phrases for products/mixtures containing the notified polymer:

Product	Risk phrases
≥ 25%	R48/23, R41, R22
10-<25%	R48/23, R41
5- <10%	R36, R48/20
1-<5%	R48/20

End Use:

- Application of the coating mix should only be by roller or brush. Spray application is not supported.

- The paint products containing the notified polymer should not be accessible to the public and should only be used by professional trained paint applicators.

Exposure Standard

- Employers should ensure that the NOHSC exposure standard for formaldehyde does not exceed 1.2 mg/m^3 (8 hr TWA) and 2.5 mg/m^3 (STEL).

Health Surveillance

- As formaldehyde present as a residual 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 skin sensitisation.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation of the paint and when preparing the epoxy resin mixture:
  - During formulation: automated and enclosed process; exhaust ventilation
  - When preparing the epoxy mix: local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced, during re-formulation and end use:
  - Avoid spills and splashes

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced, during re-formulation and end use:
  - Protective gloves (neoprene rubber, butyl rubber or nitrile rubber gloves)

- Respirator with vapour cartridge
- Goggles
- Protective clothing with long sleeves
- Rubber boots

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

- Atmospheric monitoring should be conducted for formaldehyde to measure workplace concentrations during formulation and use of the notified polymer.

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

- Products and mixtures containing Anquamine 701 /Epilink 701 are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances;* therefore, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified chemical should be disposed of by incineration in an approved facility. Unwanted paints containing the notified polymer should be allowed to dry before disposal. Residual paints or washings from paint equipment should not be poured into drains.

Emergency procedures

- Spills/release of the notified chemical should be contained and placed in suitable labelled containers for 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 subsubsection 64(1) of the Act; if
- the concentration of the notified polymer in the reformulated paint product is more than 40%;
- the notified polymer is manufactured locally;
- workers other than professional paint applicators such as home handymen plan to use the product;
- a 90-day repeat dose study is completed.

(2) 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.

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