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

FULL PUBLIC REPORT

Synocure 892 BA 70

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**Director
NICNAS**

TABLE OF CONTENTS

FULL PUBLIC REPORT	4
1. APPLICANT AND NOTIFICATION DETAILS	4
2. IDENTITY OF CHEMICAL	4
3. COMPOSITION	4
4. INTRODUCTION AND USE INFORMATION	5
5. PROCESS AND RELEASE INFORMATION	5
6. PHYSICAL AND CHEMICAL PROPERTIES	6
7. TOXICOLOGICAL INVESTIGATIONS	9
8. ENVIRONMENT	10
9. RISK ASSESSMENT	10
10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS	12
11. MATERIAL SAFETY DATA SHEET	12
12. RECOMMENDATIONS	12
13. BIBLIOGRAPHY	13

FULL PUBLIC REPORT

Synocure 892 BA 70

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

T R (Chemicals Australia) Pty Ltd (ABN: 57 001 268 006)

195 Briens Rd

NORTHMEAD NSW 2152

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 No., molecular weight, molecular and structural formulae, polymer constituents, purity and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Vapour pressure, adsorption/desorption, dissociation constant, partition coefficient, flammability and explosivity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES

Korea.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Synocure 892 BA 70

SPECTRAL DATA

METHOD	Infrared (IR) and Nuclear Magnetic Resonance (NMR) spectroscopy
Remarks	IR, ^1H and ^{13}C -NMR reference spectra were provided.
TEST FACILITY	Centre de Recherches de L'oise, Verneuil en Halatte.

METHODS OF DETECTION AND DETERMINATION

METHOD	IR, ^1H and ^{13}C -NMR spectroscopy
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3. COMPOSITION

DEGREE OF PURITY

High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

All hazardous monomers were present at levels under the concentration cut-offs.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

None.

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be introduced into Australia in 205 L steel drums as a 70% component of a solution in n-butyl acetate.

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

The import volume has been claimed as exempt information but less than 100 tonnes of the notified polymer is to be imported per annum for the first five years.

USE

Component of two pack non isocyanate industrial coatings and industrial paints.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
NSW

IDENTITY OF RECIPIENTS
Notifier.

TRANSPORTATION AND PACKAGING
Steel 205 L containerised drums.

5.2. Operation description

Coatings containing the notified polymer will be prepared by high speed dispersion and mixing then automatically packed into containers at 50% suitable for industrial applications. The coatings will be applied to on-site metal structures by brush, roller or spray.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Transport and storage	3	Less than one shift	12 days/year
Blending	2	8 hours per day	24 days/year
QC	2	8 hours per day	24 days/year
Spray painters	2	8 hours per day	24 days/year

Exposure Details

Transport and storage workers may come into contact with the imported solvent solution (70% polymer) or blended paints only in the event of accidental rupture of containers.

Blending

Blenders typically transfer polymer solution to the blending vessel under local exhaust ventilation using a drum pump. Exposure to drips and spills is possible on an intermittent basis. Personal protective equipment (PPE: respirators and solvent resistant gloves and goggles as well as industrial clothing) will be used to control exposure. QC workers can potentially be exposed to smaller amounts of paint taken for testing and typically wear laboratory protective attire to control exposure.

Application

Spray painters will mix the paint as part of a two-pack system and will be spraying in a dry dock for

marine applications with minor application by brush or roller in areas where spraying is difficult. Appropriate respiratory and dermal PPE will be used to control exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The release of the notified polymer at the paint manufacturing sites will be minimal. The notified polymer is mixed with other solvents and ingredient in a mixer. During this process any spilled material is collected and recycled.

Once mixing is complete the product is automatically pumped to filling machines for packaging into containers. Empty containers, mixing vessels and transfer lines are cleaned with a suitable solvent which is recycled where possible. Waste generated during the reformulation process is expected to be less than 500 kg per year (0.5%), resulting from residues in import containers (0.25%) and spills and leaks (0.25%). Empty drums will be sent to a drum recycler for reclamation. Spills and leaks will be contained and collected and either recycled or disposed of to landfill.

The formulated product containing the notified polymer will be distributed to industrial customers only.

RELEASE OF CHEMICAL FROM USE

The notified polymer is formulated into one part of a two part coating system to be mixed prior to application to metal surfaces. The majority of the coatings will be applied by using spray application techniques with small areas applied using brushes or rollers. Losses through spray application include overspray (generally 15-20%) and equipment cleaning (1-2%). Application using brushes and rollers results in releases from dripping (<1%) and equipment cleaning (generally 5%).

Residues in coating containers are expected to account for less than 1% of the import volume of the notified polymer. At the maximum proposed import volume this would equate to 5000 kg of the notified polymer which will be disposed of through drum recyclers or disposed of to landfill while adhering to the containers.

As a worst case, assuming 100% of the paint is applied through spray application, the maximum total amount of the notified polymer landfilled or incinerated as a result of use of the coatings containing it is:

$$1\%_{\text{container}} + 20\%_{\text{over spray}} + 2\%_{\text{cleaning}} = 23\% \text{ of the notified polymer imported into Australia.}$$

Thus, at the maximum proposed import volume of 100 tonnes per annum, 23 tonnes is the maximum that will be lost to the environment through use.

5.5. Disposal

The majority of the notified polymer will be disposed of at the end of its useful life adhering to the metal surfaces and either be disposed of to landfill or be recycled.

5.6. Public exposure

The notified polymer will not be sold to the public. The public may be exposed to the polymer or paint in the event of a transport accident. Otherwise the public may be exposed to the cured coating at which time the polymer will be part of dry paint film and will not be bioavailable.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Light brown solid.

Melting Point/Freezing Point 81°C (pour point)

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Pour point was determined with a cloud and pour point apparatus.

TEST FACILITY	Huntingdon Life Sciences (2005a)
Boiling Point	Not Determined
Density	1070 kg/m ³
METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined using a pycnometer.
TEST FACILITY	Huntingdon Life Sciences (2005a)
Vapour Pressure	Not Determined
Remarks	Based on the relatively high molecular weight of the polymer the vapour pressure is expected to be low.
Water Solubility	0.847 g/L at pH 2, 0.005 g/L at pH 7 and 0.006 g/L at pH 9
METHOD	In-house gravimetric method
Remarks	Test substance applied as a solvent based resin to a polyethylene film and dried in a vacuum drying oven to constant weight at 120°C. The dried film is then immersed in water (23±2°C) for 48 h and then dried and reweighed. The difference in weight pre and post immersion is used to determine the water solubility. Given non-specific nature of the gravimetric determination the relatively higher water solubility at low pH (2) may reflect the hydrolytic instability of the polymer or protonation of the tertiary amine functionalities within the polymer or a combination of both.
TEST FACILITY	Cray Valley Resin Coatings (2003a-c)
Hydrolysis as a Function of pH	Hydrolytically stable under neutral or basic conditions and unstable under acidic conditions.
METHOD	Japanese Polymer Flow Scheme, Polymer Commission, 1985 (page 840, Section IV, 1.2 Tests for physicochemical stability and solubility under acid and alkaline conditions).
Remarks	<p>The test substance was placed in a mortar, made brittle by the application of liquid nitrogen and then ground to a white crystalline powder. For each pH (1.2, 4.0, 7.0 and 9.0) two portions of (approximately 200 mg) of ground test substance were weighed accurately into separate vessels and 100 mL of the appropriate buffer added. The vials were shaken at 40°C in a waterbath (24 h for the samples at pH 1.2, 14 days for samples at pH 4 and 9). After shaking the solids were collected via filtration and analysed using GPC and infrared absorption (IR) spectroscopy.</p> <p>The appearance of the samples at pH 1.2 and pH 4 in solution were significantly different from those at pH 7 and pH 9. The former samples were distinctly turbid, indicating possible reaction, whereas the latter samples remained as an unreacted mass in a clear liquid. These observations are in agreement with the GPC analysis which clearly showed a different profile for the samples treated at pH 1.2 and pH 4, indicating reaction. The IR analysis tentatively suggested that the reaction results from hydrolysis of ester functionalities within the polymer.</p> <p>The results indicate that the polymer is hydrolytically stable under neutral or basic conditions but hydrolytically unstable under acidic conditions.</p>
TEST FACILITY	Huntingdon Life Sciences (2004a)
Partition Coefficient (n-octanol/water)	Not determined
Remarks	The low water solubility under the environmental pH range (4-9) suggests and miscibility with a range of organic solvents (toluene, xylene, acetone, methyl ethyl

ketone, ethyl acetate, butyl acetate and methoxypropyl acetate) suggest that the notified polymer is likely to have a relatively high partition coefficient and tend to preferentially partition to the organic phase.

Adsorption/Desorption

Not determined

Remarks The low water solubility under environmental conditions and expected high partition coefficient indicate the hydrophobic nature of the polymer and it is expected to bind to or associate with the organic matter of soils.

Dissociation Constant

pKa ~10.3

Remarks The notified polymer contains functionalities which are expected to display typical basicity. Based on comparison with similar functionalities the pKa is expected to be around 10.3. Thus it is expected to be fully ionised over the environmental pH range (4-9).

Particle Size

Not applicable.

Flash Point

30°C

METHOD Setaflash closed cup
Remarks Solvent solution as imported. Data supplied on MSDS.

Flammability Limits

Upper: 1.2%
Lower: 7.5%

METHOD Not stated.
Remarks Solvent solution as imported. Data supplied on MSDS. The notified polymer lacks flame retardant functionality and can be combustible. However, there are not groups with particularly energetic bonds and there is a relatively low oxygen content (23%).

Autoignition Temperature

370°C

METHOD Not stated.
Remarks Solvent solution as imported. Data supplied on MSDS.

Explosive Properties

Not determined.

Remarks Does not contain any groups which indicate explosive properties.

Reactivity

Remarks Not oxidising based on structure. Limited hydrolysis expected with pendant groups.

7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Genotoxicity – bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method. EPA Health Effects Guidelines OPPTS. 870.1100 Acute Oral Toxicity. EPA 712-C-02-190, 2002. Japanese Ministry of Agriculture, Forestry and Fisheries, Test Data for Registration of Agricultural Chemicals, Acute oral toxicity (2-1-1), 12 Nohsan No. 8147, Agricultural Production Bureau, November 24, 2000.
Species/Strain	Rat/Sprague-Dawley.
Vehicle	DMSO
Remarks - Method	None.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3/sex	1000	None

LD50	>1000 mg/kg bw
Signs of Toxicity	None.
Effects in Organs	None.
Remarks - Results	None.

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY Huntingdon Life Sciences (2005b).

7.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. US EPA (1998) Health Effects Test Guidelines. OPPTS 870.5100 Bacterial reverse mutation test. EPA 712-C-98-247. Japanese Ministry of Agriculture, Forestry and Fisheries, Test Data for Registration of Agricultural Chemicals, 12 Nohsan No. 8147, Agricultural Production Bureau, November 24, 2000. Plate incorporation procedure/Pre incubation procedure
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA
Metabolic Activation System	Aroclor induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 5 - 5000 µg/plate b) Without metabolic activation: 5 - 5000 µg/plate
Vehicle	DMSO
Remarks - Method	None.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>		
	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>			
Test 1	> 5000	None noted.	Negative
Test 2	> 5000	“	“
<i>Present</i>			
Test 1	> 5000	“	“
Test 2	> 5000	“	“

Remarks - Results

Negative controls were within historical limits and positive controls demonstrated the sensitivity of the tests.

CONCLUSION

The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Huntingdon Life Sciences (2004b)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

There will be no manufacturing of the notified polymer in Australia, and therefore no release during this stage.

Up to 500 kg of notified polymer is expected to enter the environment each year due to paint manufacture, while up to 23 tonnes of notified polymer will be released locally due to wastes generated during paint use. It is expected that waste generation and disposal will occur in a diffuse manner owing to the nationwide use of the paint products, with the majority being released through overspray (accounting for up to 20 tonnes annually), which after recovery will be directly disposed of to landfill. Up to 2 tonnes from cleaning of equipment will go to solvent recovery companies and then to landfill in the sludge that is generated. Residues in coatings containers (<1 tonne) will be disposed of to landfill as a cured coating on the containers or incinerated during container recovery. In soil environments, the notified polymer is not expected to be mobile or leach from the soil into ground or surface water, but rather is expected to bind to the organic phases in soils. Under these conditions it would be slowly degraded to gases such as carbon dioxide and oxides of nitrogen through the agency of abiotic and biotic processes.

Under normal usage, the notified polymer is not expected to enter the aquatic environment. The majority of the notified polymer will end up being applied as a two pack coating system which will be mixed prior to application. The coating components will react to form an inert cross-linked coating on the metal surface to which it has been applied. The polymer incorporated in this coating will ultimately be disposed of along with the metal surface which will generally go to metal recycler. Thus, the coating matrix will be destroyed via incineration generating water

and oxides of carbon and nitrogen.

Due to the nature of the release pattern a Predicted Environmental Concentration (PEC) cannot be estimated.

In the event that the polymer enters the aquatic environment, it is expected to partition mainly into sediment and sludge owing to its low water solubility in the environmental pH range.

9.1.2. Environment – effects assessment

The notified polymer has a number average molecular weight greater than 1000 and therefore is not likely to cross biological membranes. The polymer is also potentially polycationic throughout the whole environmental pH range of 4-9. Polycationic polymers have been shown to be very highly toxic to aquatic organisms (Boethling and Nabholz, 1997).

9.1.3. Environment – risk characterisation

A risk quotient cannot be calculated as an accurate PEC cannot be estimated. However, the notified polymer is not expected to pose any significant risk to the environment. The proposed application and the anticipated nationwide use of the product indicate that the levels of release of the notified polymer to the environment will be low. Though the notified polymer is potentially toxic, under normal usage there will be no release into the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and storage of the imported polymer solvent solution should only result in exposure in the event of accidental rupture of the imported drums.

The imported polymer solution will be blended into paints at 50% notified polymer for industrial applications. Exposure of workers will result from intermittent drips and spills on an intermittent basis and will occur mainly from transfer operations. Exposure, which is mainly expected to be dermal, will be controlled by the use of PPE. The mixing and drumming off operations will be enclosed. QC workers may be exposed to smaller quantities of the notified polymer than blenders and exposure is also controlled by the use of PPE.

Drumming off of paints is normally automatic and should not result in exposure. Some limited exposure may occur due to cleaning of equipment and maintenance operations.

The currently identified use is marine involving (mainly) spraying of paint in a dry dock. Inhalation exposure from aerosols and dermal exposure from spraying as well as the use of brush or roller on certain parts of the job is potentially high and is controlled by the use of appropriate PPE.

9.2.2. Public health – exposure assessment

The imported polymer solution and paints derived from it will not be sold to the public. The public may be exposed to the notified polymer in the event of a transport accident but the clean up procedures outlined in the MSDS are expected to be used and should result in minimal exposure to the public.

The public may come in contact with the paint in a cured form at which time the polymer will be highly crosslinked and will not be bioavailable.

9.2.3. Human health – effects assessment

The notified polymer was shown to be of low toxicity via the oral route and was not mutagenic in bacteria. It has a high molecular weight and is unlikely to be absorbed through the skin.

Based on the available data, the notified chemical is **not classified** for acute toxicity or mutagenicity as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The notified polymer can be predicted to be of low hazard on the basis of known properties. In addition, when used in the manufacture of paints, there is a low probability of exposure of transport, storage, process or maintenance workers. Therefore the risk to these workers is low.

Workers involved in spraying the paint in dry dock are potentially highly exposed but this is controlled by the use of respiratory and dermal PPE. Thus, the risk to these workers is also low.

9.2.5. Public health – risk characterisation

The public are unlikely to be exposed to the notified polymer except when it is extensively crosslinked and not bioavailable. Therefore the public health risk associated with importation of the notified polymer 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 not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Negligible Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the imported [product containing the notified chemical](#) 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 imported product containing the notified chemical 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

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the use of spray paints containing the notified polymer should be in accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC, 1999).
- 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.

Environment

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
 - Do not allow material or contaminated packaging to enter drains, sewers or water courses

Disposal

- The notified polymer should be disposed of by incineration or to landfill in accordance with State/Territory waste disposal regulations.

Emergency procedures

- Accidental spills/release of the notified polymer should be handled by absorbing onto an inert material, scooping up and placing in marked 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 Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

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- Cray Valley Coating Resins (2003b) Water solubility pH = 7, 19 November 2003. Reference CAF-GDE-03-026. Cray Valley Coating Resins Centre, Centre de Recherche De L'oise (unpublished report submitted by notifier)..
- Cray Valley Coating Resins (2003c) Water solubility pH = 9, 19 November 2003. Reference CAF-GDE-03-030. Cray Valley Coating Resins Centre, Centre de Recherche De L'oise (unpublished report submitted by notifier)..
- Huntington Life Sciences (2004a) Synocure 892 BA 70- Stability under acidic and basic conditions Study No CVP182/042790, Huntington Life Sciences Ltd, Cambridgeshire, England (unpublished report submitted by notifier)..
- Huntington Life Sciences (2004b) Synocure 892 BA 70: Bacterial Reverse Mutation Test. Study No CVP181/042681, Huntington Life Sciences Ltd, Cambridgeshire, England (unpublished report submitted by notifier).

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