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

FULL PUBLIC REPORT

Tylose HX 8000 YP2 and Tylose HX 4000 YP2

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water Resources, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
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
NICNAS**

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FULL PUBLIC REPORT

Tylose HX 8000 YP2 and Tylose HX 4000 YP2

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Admil Adhesives Pty Ltd (ABN 85 092 730 562) of 4 Carmen Street, Dandenong, VIC 3175

NOTIFICATION CATEGORY

Limited: Synthetic polymer with NAMW \geq 1000 Da

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, Other Names, CAS Number, Molecular and Structural Formula, Molecular Weight, Spectral Data, Purity, Hazardous Impurities, Non Hazardous Impurities, Additives/Adjuvants, Import Volume, Identity Of Sites, Polymer Constituents, Residual Monomers/Other Reactants, Oligomeric content.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Melting Point/Boiling Point, Specific Gravity/Density, Vapour Pressure, Water Solubility, Hydrolysis As A Function Of pH, Partition Coefficient, Adsorption/Desorption, Dissociation Constant, Particle Size, Flash Point, Flammability Limits, Autoignition Temperature, Explosive Properties, and Reactivity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada (2006), China (2006), USA (2004), Europe (2004)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

Hydroxyethylcellulose – chemically modified

Chemically modified hydroxyethylcellulose

MARKETING NAME(S)

Tylose HX 8000 YP2

Tylose HX 4000 YP2

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn) >100000 Da

% of Low MW Species < 1000 Da <1%

ANALYTICAL DATA

Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

>95%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

No losses are expected from the notified polymer by volatilisation, exudation or leaching.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa

Whitish to slightly yellow solid powder with no odour

Property	Value	Data Source/Justification
Melting Point	Not determined	Decomposed before melting.
Bulk Density	~500 kg/m ³ at 20°C	MSDS
Vapour Pressure	Involatile	Estimated, based on high Mn
Water Solubility	>40 g/L at 20°C	Estimated
Hydrolysis as a Function of pH	Not expected to hydrolyse under environmental pH conditions	Estimated, based on the chemistry of cellulose
Partition Coefficient (n-octanol/water)	Not expected to partition into oil	Estimated, based on ionisation, ready water solubility, and high Mn
Surface Tension	Expected to be surface active	Estimated
Adsorption/Desorption	Expected to partition to soil and sludge	Estimated, based on the high Mn
Dissociation Constant	Ionised over the full environmental pH range	Predicted from the functional group chemistry of the notified polymer
Particle Size	Inhalable fraction (<100 µm): 69.5% Respirable fraction (<10 µm): 0.69% MAD* = 75.5 µm	Measured
Flash Point	No flash point expected	Estimated from similar polymers
Flammability	Expected to be combustible	Estimated from similar polymers
Autoignition Temperature	From 360°C	Estimated from similar polymers
Explosive Properties	Not explosive under heating or pressure	Estimated from similar polymers

* MAD = Mean Aerodynamic Diameter

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, please refer to Appendix A.

The notified polymer is expected to be highly water-soluble and surface active. It is water absorbing; it is able to absorb many times its weight in water to form a gel (tested up to five times its weight).

The majority of particles of the notified polymer will be in the inhalable (<100 µm) range and will deposit in the upper respiratory tract upon inhalation. However, as only a very small proportion of particles were found to be in the respirable range (<10 µm) it is not expected to be able to reach the lower respiratory tract in significant quantities.

Reactivity

The notified polymer is considered to be stable, with no degradation, decomposition or depolymerisation expected under normal conditions of use. It is expected to be non-oxidizing, but may contribute to a fire based on its likely combustible properties. Like every other cellulose containing substance (e.g. pulp, cotton, wood) the notified polymer reacts with oxidizing agents at high temperatures. Thermal decomposition may release toxic fumes containing products of combustion such as carbon monoxide, carbon dioxide and sulphur oxides.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer (~90% in the imported products) will be imported by sea.

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

Year	1	2	3	4	5
Tonnes	10-50	10-50	10-50	10-50	10-50

PORT OF ENTRY

The notified polymer will be imported into the ports of Brisbane, Melbourne and/or Sydney.

IDENTITY OF MANUFACTURER

S E Tylose GmbH & Co. KG, Rheingaustraße 190 – 196, 65203 Wiesbaden, Germany.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 25 kg multi-ply paper bags (with polyethylene inner liner), on shrink-wrapped pallets of 1 tonne. Following importation, it will be transported by road to contracted warehouses in Melbourne, Sydney and Brisbane for a short period of interim storage before distribution by road to customers.

USE

The notified polymer will be used as a thickener for water based architectural paints. It will be incorporated into these paints to impart the following properties: thickening effect, anti-spattering (when applied by roller or brush) and wet scrub resistance.

OPERATION DESCRIPTION

Importation and transport

At contracted warehouses in Melbourne, Sydney and Brisbane, the notified polymer (~90% concentration) will be unloaded from shipping containers, with the aid of a forklift, and stored in the general chemical storage area until required by customers.

Formulation of architectural paints

At customer sites, the notified polymer will likely be poured from the import bag into a weighing bucket, under local exhaust ventilation (LEV). It will then be added into a mixing vessel (also under LEV), along with other ingredients, which will be closed during high-speed blending to form architectural paints (containing <1% notified polymer). These paint formulations will then be packaged into 0.5 L, 1 L, 4 L and 20 L steel cans for sale nationwide to tradesmen and DIY consumers.

End-use

The paint formulations (containing the notified polymer at <1%) will be applied using brushes, rollers or conventional spray by tradesmen and members of the public.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours per day)</i>	<i>Exposure Frequency (days per year)</i>
Transport and storage	20-50	4-6	20-50
Paint manufacture and filling	10-300	2-8	200-240
End use - Retail workers	100-1000	4-8	200-240
End use - Trade use	>1000	4-8	200-240

EXPOSURE DETAILS

Transport and storage

Exposure to the notified polymer during importation, transport and storage is not expected except in the event of an accident where the bags containing the notified polymer (~90%) may be breached.

Formulation of architectural paints

The workers who will experience the greatest exposure are those involved with weighing and transfer of the notified polymer (at ~90%) to the mixing vessel. Shaking and pouring of the powdered notified polymer are likely to generate airborne dusts from import bags during weighing and addition to the mixer. Therefore, the exposure of paint manufacturing workers will primarily be via the dermal, ocular and inhalation routes. These operations are expected to be carried out under LEV, which will reduce the exposure of workers from airborne dusts.

As the mixing and blending of the paint components will take place in closed mixing vessels, the potential for worker exposure during these processes is expected to be low. The finished paint products (<1% notified

polymer) are likely to be of high viscosity, and so aerosol generation is likely to be low if the vessels were opened for sampling or additions. Transfer of the finished paint products to the packaging line may take place via a dedicated pipeline (automated filling) or potentially via transport of mixing vessels (manual filling). Exposure to the paint containing the notified polymer is not anticipated during automated filling of paint cans, except in the case of leaking pipes or fittings or unscheduled repairs, where maintenance workers may experience dermal and/or ocular exposure to residual paint. Workers involved in the manual filling of paint cans will likely experience dermal and/or ocular exposure.

All paint manufacturing workers are expected to wear personal protective equipment (PPE) such as overalls, safety glasses, gloves and safety boots, and reformulation plants are often equipped with LEV at most of not all workstations. The MSDS for the notified polymer indicates a minimum of rubber gloves.

End-use

Occupational exposure during the sale and professional use of architectural paints is likely to be widespread and often under poorly controlled conditions. Dermal exposure during handling and application of finished paints (<1% notified polymer) is most likely, but accidental ocular or oral exposure may also occur.

Inhalation exposure may also occur where application is performed using spray equipment and the paint products form airborne particles. Tradesmen are expected to wear overalls and shoes during application with brush or roller, and respiratory protection during spray application.

Once dried upon surfaces, the notified polymer will be trapped within the paint matrix and is not expected to be available to cause further exposure.

6.1.2. Public exposure

The exposure that would arise from public DIY use of paint products containing the notified polymer (at <1%) would be expected to largely resemble that of professional painters, although this is likely to occur far less often. Dermal exposure may be higher during use, but use is expected to be for shorter periods of limited duration. As spray application of architectural paints is uncommon in DIY use, inhalation exposure is not expected to be a significant route of public exposure.

Members of the public are very likely to make dermal (and possibly oral) exposure with painted surfaces containing the notified polymer. However, once paints have dried upon surfaces, the notified polymer will be trapped within the paint matrix and is not expected to be available to cause exposure. Given its molecular weight, no significant leaching from dry painted surfaces is expected.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD ₅₀ >2000 mg/kg bw; low toxicity
Rabbit, skin irritation	Non-irritating
Rabbit, eye irritation	Slightly irritating

Toxicokinetics

Given the high water solubility and high molecular weight of the notified polymer, and its low concentration of oligomeric species, it is unlikely to be significantly absorbed following exposure by any route.

Acute toxicity, irritation and sensitisation

The notified polymer was shown to be of low acute oral toxicity, but it is likely that it was not actually absorbed from the gastrointestinal tract during the study.

In rabbits, the notified polymer was shown to be non-irritating to skin, but slightly irritating to eyes. However, the observed effects were not sufficiently severe for it to be classified as an irritant.

Repeated dose toxicity

No data on the repeated dose toxicity of the notified polymer was available. However, given that it is unlikely to be absorbed following exposure, it is not expected to show toxicity following repeated oral or dermal administration.

High molecular weight, water-insoluble but water-swellaable polymer particles of respirable size may be a potential health concern (US EPA, 2007). Lung tumours have been observed following exposure of rats to 0.2-0.8 mg/m³ of a water-absorbing polyacrylate polymer in a 2-year chronic inhalation rat study. A speculated

mode of action of water absorbing polymers is that they may cause lung damage when the lungs are unable to clear the inhaled particles.

However, while the notified polymer may be water absorbing (see Appendix A), it is highly water-soluble. It is noted that only a small fraction of the notified polymer is of particle sizes small enough to reach the deep lung. Any inhaled particles of the notified polymer are expected to sufficiently dissolve in lung fluids that they will be able to be removed through normal mucociliary clearance mechanisms. Therefore, it is unlikely to be a concern for potential lung toxicity.

Genotoxicity

No genotoxicity data was available for the notified polymer. However, it does not contain any structural alerts for mutagenicity, and contains little oligomeric content that might lead to the induction of genetic toxicity.

Health hazard Classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Transport and storage

As the exposure of transport and storage workers is unlikely to occur, any risk expected from the notified chemical is likewise expected to be low.

Formulation of architectural paints

Workers involved with weighing and transfer of the notified polymer (at ~90%) to the mixing vessel are likely to experience the highest exposure. As the notified polymer is of low irritancy and low acute oral toxicity, and because it is unlikely to be absorbed across the skin, only inhalation exposure is likely to be significant for consideration of risk. However, as the notified polymer is water-soluble and as the majority particle sizes are larger than respirable (<10 µm), low levels of inhaled notified polymer are not expected to pose a significant risk to workers. The Time-Weighted Average (TWA) exposure standard for airborne “dusts not otherwise classified” of 10 mg/m³ should be adhered to during handling of the notified polymer.

Due to the low inhalation exposure and the lack of dermal absorption and irritancy, other workers involved in formulation (that do not handle the powdered notified polymer) are not expected to experience any significant risk. Given the slight eye irritation observed in animal studies, the notified polymer may present some risk of minor eye irritation.

End-use

Workers exposed to paints containing the notified polymer (<1% concentration) are unlikely to experience any significant risk from exposure to the notified polymer. The health risks associated with paint inhalation during spray painting are well known, and the use of the notified polymer is unlikely to contribute any further risk.

6.3.2. Public health

The use of paints containing the notified polymer is unlikely to present any significant risk to the public, given the low hazard of the paints and given that use will be occasional and of limited duration. The risk resulting from the exposure of members of the public to dry, painted surfaces containing the notified polymer is expected to be negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured in Australia. Releases to the environment during shipping, transport and warehousing will only occur through accidental spills or leaks from the filled 25 kg multi-ply paper bags. It is expected that accidental spills of the powdered material from the import bags would be swept up and disposed of to landfill.

The reformulation process has the potential to release quantities of the notified polymer as a result of minor spills, the cleaning of formulation equipment, and disposal of residues contained within empty containers. It is

expected that accidental spills of the solid material would be swept up and disposed of to landfill. Liquid wastes will be processed to reclaim solvents and the solid residue containing the notified polymer will be disposed of to landfill. In the event of major spills, the solution containing the notified polymer would be contained within the plant by bunding and collected by absorbent material. The residue would be treated to form an inert solid that would be disposed of to landfill. The cumulative losses of notified polymer to landfill as a result of the reformulation process are not expected to exceed 1% of the total annual import volume.

RELEASE OF CHEMICAL FROM USE

The use of the notified polymer in architectural paints will confine the majority of the imported quantity of polymer in dried paint on building structures. The application of paint to surfaces with brushes or rollers will involve limited release of liquid paint in the form of droplets and splashes. For indoor applications, these quantities of wasted paint will be captured on drop sheets or paper that will be disposed of to landfill or incinerated. For outdoor applications, droplets of liquid paint will fall to the ground and become immobilised on the soil surface as dried paint-soil agglomerates. Application of paints by spraying will involve losses of the notified polymer in the form of overspray. The majority of the paint overspray will be bound to sheets or paper forming an inert matrix, which will be disposed of to landfill or incinerated. Alternatively, overspray will be allowed to settle on the ground where the paint will form dry inert surface coatings or agglomerations with soil particles.

The major potential route for releases to aquatic ecosystems involves the cleaning of application equipment, especially the brushes or rollers used by DIY painters. It is expected that up to 5% of the imported quantity of notified polymer will be disposed of to sewer systems during the clean up of paint application equipment. The residual quantity of paint in used paint cans and pails is expected to be up to 5% of the initial volume, which will be consigned to landfill with the discarded containers. The residual paint in used paint containers is expected to dry *in situ*, forming an inert solid mass that will immobilise the remaining quantity of notified polymer.

RELEASE OF CHEMICAL FROM DISPOSAL

The disposal of the major fraction of the imported quantity of notified polymer will be linked to the ultimate disposal of the dried paint on building structures. As large portions of architectural paints are removed before repainting, it is expected that the majority of the notified polymer will ultimately be disposed of to landfill in the form of discarded paint chips. Alternatively, paint chips will be allowed to fall onto the ground where they will become degraded over time to small paint particles. A small proportion of painted building structures may also be incinerated in mainly domestic situations resulting in combustion of the notified polymer.

7.1.2 Environmental fate

The majority of the imported quantity of notified polymer will enter the environment combined with other components in solid paint chips. The notified polymer is expected to be strongly bound to the other components of the inert matrix of these paint chips and will be only slowly released as the matrix degrades. In soil or in landfill, the notified polymer is expected to bind to soil particles or organic matter and is unlikely to be mobile in aquatic or terrestrial eco-systems. The quantities of notified polymer that are bound to soil particles are expected to undergo degradation by a combination of biotic and abiotic processes.

The majority of the quantity of notified polymer that enters the sewer system in rinsates from painting equipment is expected to bind to soil and sludge particles in sewage treatment plants and will be removed in the sludge waste. The quantity of notified polymer discharged in sludge would be degraded by a combination of biotic and abiotic processes. The notified polymer is not expected to cross biological membranes and therefore does not present a bioaccumulation hazard in aquatic or terrestrial eco-systems.

The incineration of the notified polymer in domestic situations will yield water, oxides of carbon, and inorganic solids.

For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The products containing the notified polymer are likely to be used throughout Australia. The major exposure of aquatic eco-systems to the notified polymer is expected to occur as a result of the disposal of rinsates from the cleaning of painting equipment into sewers. Based on a worst case scenario in which there is no removal of the notified polymer in sewage treatment plants, the resultant predicted environmental concentration (PEC) for a nationwide release scenario is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	2500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	6.85	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.62	µg/L
PEC - Ocean:	0.16	µg/L

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	LC50 >100 mg/L	Not harmful to fish
<i>Daphnia</i> Toxicity	EC50 >100 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	E _r C50 >100 mg/L	Not harmful to algae

The results of toxicity testing on representative organisms from all three trophic levels of aquatic eco-systems indicate that the notified polymer is not harmful to aquatic organisms.

7.2.1 Predicted No-Effect Concentration

The toxicity tests on aquatic organisms with the notified polymer were carried out as limit tests and these did not reveal any signs of adverse biological effects at a concentration of 100 mg/L. Hence, no definitive ecotoxicological end-points have been determined for the notified polymer. In this case, the PNEC for the notified polymer is derived from the upper limit for the acute toxicity end-point for aquatic organisms which has been shown to be >100 mg/L for all three trophic levels. As the upper limit for acute toxicity to aquatic organisms has been determined for all three trophic levels, an assessment factor of 100 is applied in the derivation of the PNEC. Therefore, the PNEC for the notified polymer is >1 mg/L (i.e. >(100÷100) mg/L).

7.3. Environmental risk assessment

Based on the above PECs and the estimated PNEC value, the following Risk Quotients (Qs) have been calculated:

Risk Assessment	PEC (µg/L)	PNEC (µg/L)	Q
Q - River:	1.62	>1×10 ³	<1.62×10 ⁻³
Q - Ocean:	0.16	>1×10 ³	<0.16×10 ⁻³

The Risk Quotients are much less than 1 for both the river and ocean disposal scenarios. Therefore, the notified polymer is not expected to pose an unacceptable risk to the environment based on the reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

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

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to workers.

When used in the proposed manner, the risk to the public is not considered to be unacceptable.

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.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced, during weighing and addition to mixing vessels:
 - *Local exhaust ventilation*
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced, during weighing and addition to mixing vessels:
 - *Eye protection and dust mask*

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

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in products intended for spray application:
 - *Spray painting should be carried out according to 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 polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of by to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight (Mn) of less than 1000 Da.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a thickener for architectural paints, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 50 tonnes, or is likely to increase, significantly;
 - if the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point	Not determined
Remarks	No melting point was able to be determined. The notified polymer decomposed before melting.
Bulk Density	~500 kg/m ³ at 20°C
Method	Proprietary method
Remarks	No details of the test were available. Data sourced from the MSDS for the notified polymer.
Vapour Pressure	Involatile
Remarks	The notified polymer is a high molecular weight polymer (Mn >100000 Da), and is therefore not expected to have a significant vapour pressure.
Water Solubility	>40 g/L at 20°C
Remarks	The miscibility of the notified polymer with water was assessed visually by mixing the polymer with water in various mass ratios from 1:24 to 1:1. The notified polymer forms a clear foaming solution in water at the lowest ratio of polymer to water and gels at higher ratios (1:5 to 1:2). This gel-forming behaviour is typically displayed by water-absorbing polymers.
Test Facility	Clariant GmbH (2003)
Hydrolysis as a Function of pH	Hydrolytically stable in the environmental pH range (4–9)
Remarks	In acidic conditions, cellulose and its derivatives are degraded by acid hydrolysis to monosaccharides through cleavage of the glycosidic bonds between two anhydroglucose units. Cellulose and its derivatives are known to be hydrolytically stable at a pH > 4. As such, at environmentally relevant pHs, the notified substance is expected to be hydrolytically stable.
Test Facility	Klemm <i>et al.</i> (1998)
Partition Coefficient (n-octanol/water)	Not expected to partition into oil
Remarks	The notified polymer is not expected to partition into oil from water or cross biological membranes under environmentally relevant conditions based on its ionic form, ready water solubility, and high molecular weight.
Test Facility	
Surface Tension	Expected to be surface active
Remarks	The notified polymer is expected to be surface active based on experiences in the use of this polymer and on the published properties of similar chemically modified celluloses. Solutions of the notified polymer in water show a slight foaming behaviour (Clariant GmbH, 2003).
Adsorption/Desorption	Not determined
Remarks	The high molecular weight of the notified polymer indicates that it will adsorb to soil and organic matter.
Dissociation Constant	Ionised over the full environmental pH range (4–9)
Remarks	The functional group chemistry of the notified polymer indicates that it will be partly or fully dissociated over the entire environmentally relevant pH range.

Particle Size

Inhalable fraction (<100 µm): 69.5%
Respirable fraction (<10 µm): 0.69%
MAD* = 75.5 µm

Method Determined by light scattering method.

<i>Range (µm)</i>	<i>Mass (%)</i>
<10.024	0.68 – 0.69
<20.000	1.34 – 1.36
<39.905	11.77 – 11.83
<70.963	45.48 – 45.50
<200.00	95.64 – 95.62

Remarks * MAD = Mean Aerodynamic Diameter
Test Facility Unknown (data only provided)

Flash Point

No flash point expected

Remarks No flash point is expected based on the high molecular weight of the notified polymer (and hence its low vapour pressure).

Flammability

Expected to be combustible

Remarks Based on the properties of similar cellulose derivatives.

Autoignition Temperature

From 360°C

Remarks Value given is that for a similar cellulose derivative.
Test Facility Unknown

Explosive Properties

Not explosive under heating or pressure

Remarks Based on the properties of similar cellulose derivatives.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Tylose HX 8000 YP2 (notified polymer)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/HanRcc:WIST
Vehicle	Polyethylene glycol (PEG) 300
Remarks - Method	No significant protocol deviations

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose (mg/kg bw)</i>	<i>Mortality</i>
1	6F	2000	0

LD ₅₀	>2000 mg/kg bw
Signs of Toxicity	No clinical signs or changes in body weight were observed during the course of the study.
Effects in Organs	Congestion of the lungs was observed macroscopically in two animals. This was not considered to be treatment-related as it is commonly observed in animals of the strain used.
Remarks - Results	None.

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

TEST FACILITY RCC Ltd (2005a)

B.2. Irritation – skin

TEST SUBSTANCE	Tylose HX 8000 YP2 (notified polymer)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	1M/2F
Vehicle	Moistened with distilled water (1:1 w/w H ₂ O)
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	The animals were not sacrificed at the end of the study period (they were used for the eye irritation study on the notified polymer).

RESULTS

Remarks - Results	No skin irritation, oedema, flaking, colouration or corrosion was observed at any of the observation times.
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CONCLUSION The notified polymer is non-irritating to the skin.

TEST FACILITY RCC Ltd (2005b)

B.3. Irritation – eye

TEST SUBSTANCE	Tylose HX 8000 YP2 (notified polymer)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	1M/2F
Observation Period	10 days
Remarks - Method	No significant protocol deviations.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	1.0	1.0	1.0	2	<7 days	0
<i>Conjunctiva: chemosis</i>	0	0.3	0.3	2	<48 hours	0
<i>Conjunctiva: discharge</i>	0	0	0	0	-	0
<i>Corneal opacity</i>	0	0	0	1	<24 hours	0
<i>Iridial inflammation</i>	0	0	0	0	-	0

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

Remarks - Results	<p>Obvious swelling of the conjunctivae was observed at the 1-hour observation, with partial eversion of the eyelids. This persisted in two animals until 24 hours.</p> <p>Moderate reddening of the sclerae were observed in all animals at the 1-hour observation. Slight to moderate reddening was noted at 24 and 48 hours, and this persisted in two animals up to the 72-hour observation and to day 7 in one animal.</p>
CONCLUSION	The notified polymer is slightly irritating to the eye.
TEST FACILITY	RCC Ltd (2005c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Bioaccumulation

REMARKS The notified polymer is a high molecular weight polymer that is ionised under environmental pH conditions. It is therefore not expected to partition into biological membranes. In the environment, the notified polymer is expected to adsorb to surfaces including soil and sediment where it will be degraded by a combination of biotic and abiotic processes. The notified polymer has a low potential to bioaccumulate.

C.1.2. Inherent biodegradability

TEST SUBSTANCE Notified polymer

METHOD Zahn-Wellens/EMPA Test

Inoculum Washed sewage sludge of an industrial waste water treatment plant

Exposure Period 28 days

Auxiliary Solvent None

Analytical Monitoring Dissolved Organic Carbon

Remarks - Method The notified polymer was dissolved in purified water to give a strongly foaming solution. The eliminability and inherent biodegradability of the notified polymer was evaluated at a nominal test concentration equivalent to 196 mg/L DOC. An abiotic control test was performed using the notified polymer at the same nominal test concentration, but with 30 mg/L of added HgCl₂ and no activated sludge inoculum.

A positive control test was performed with sodium benzoate at a nominal test concentration equivalent to 203 mg/L DOC.

RESULTS

<i>Notified polymer</i>				<i>Sodium benzoate</i>			
	<i>Day</i>	<i>% elimination*</i>			<i>Day</i>	<i>% degradation</i>	
7 11	2	71%	63%	7	2	100%	82%
	15		71%		11		100%
	22		67%		15		101%
	28		63%				
			69%				

* The percentage reduction in DOC of the notified polymer test sample relative to the initial level after adjustment for the DOC in the inoculum control.

Remarks - Results The biodegradation of the reference substance reached the pass value within 2 days of test initiation. The test is therefore valid.

The overall elimination of the notified polymer initially present in the test sample is 69% after 28 days. However, the abiotic control test indicates that 42% of the notified polymer is lost in the absence of the sludge bacteria and this may reflect losses due to foaming of the polymer in the test vessels. A further 15% of the notified polymer is lost through adsorption in the first 3 hours of the test. As elimination through abiotic processes was dominant in this test, the inherent biodegradability of the notified polymer could not be established.

This test indicates that the notified polymer is partially eliminable mainly through abiotic processes.

CONCLUSION The notified polymer is partially eliminable.

TEST FACILITY Infraserb Höchst (2003)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified polymer

METHOD OECD TG 203 Fish, Acute Toxicity Test – Static Limit Test

Species Zebra fish (*Danio rerio*)

Exposure Period 96 h

Auxiliary Solvent None

Water Hardness 52 mg CaCO₃/L

Analytical Monitoring Dissolved Organic Carbon

Remarks – Method The notified polymer test medium was a foaming solution prepared by ultracentrifugation and aeration of a mixture of the polymer with filtered and dechlorinated mains water.

The test and control media were gently aerated over the test period.

The Dissolved Organic Carbon content of the notified polymer and control test media was measured at test initiation and after the 96-hour exposure period.

RESULTS

Nominal Concentration mg/L	Number of Fish	Mortality				
		1 h	24 h	48 h	72 h	96 h
100	7	0	0	0	0	0
Control	7	0	0	0	0	0

LC50 >100 mg/L at 96 hours.

NOEC 100 mg/L at 96 hours.

Remarks – Results The physicochemical parameters of the test and control media remained within the limits specified by the Guideline, and there were no mortalities in the control group. This limit test is therefore valid.

The DOC of the test solution was 76% of the level expected based on the nominal concentration of the notified polymer and the approximate elemental composition of the polymer. After 96 hours, the DOC was 87% of the expected level. The DOC of the controls was < 6% of the levels in the test media. The nominal concentration in these tests has therefore been reported as the exposure concentration.

The notified polymer did not have any observable acute toxic effects on fish after 96 hours exposure to a single test concentration of 100 mg/L. Therefore, the notified polymer cannot be classified as harmful to fish.

CONCLUSION The notified polymer is not harmful to fish.

TEST FACILITY Dr. U. Noack-Laboratorien (2005a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test – Static Limit Test.

Species *Daphnia magna* STRAUS

Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	259 mg CaCO ₃ /L
Analytical Monitoring	Dissolved Organic Carbon
Remarks - Method	The notified polymer was dissolved in standard dilution water by means of ultra-sonication.
	The Dissolved Organic Carbon content of the notified polymer and control test media was measured at test initiation and at the end of the 48-hour exposure period.
	A positive toxicity control test was carried out with five concentrations of potassium dichromate in the range 0.58–5.8 mg/L.

RESULTS

Nominal Concentration mg/L	Number of <i>D. magna</i>	Number Immobilised	
		24 h	48
100	20	0	0
Control	20	0	0

EC50	>100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	<p>The physicochemical parameters of the test and control media remained within the limits specified by the Guideline, and no <i>Daphnia</i> in the control group were immobilised. The EC50 end-point for the acute toxicity of potassium dichromate to <i>Daphnia</i> under these test conditions is 1.47 mg/L (95% CI: 1.36–1.58 mg/L), which is within the prescribed range for this laboratory. This limit test is therefore valid.</p> <p>In a preliminary range finding test, no immobilised <i>Daphnia</i> were observed after 24- and 48-hours of exposure to 100 mg/L of the notified polymer.</p> <p>In the limit test, the average DOC in two replicate test samples at the beginning and end of the trial period was 82% of the level expected based on the nominal concentration of the notified polymer. The DOC of the controls was approximately 2% of the level in the test media.</p> <p>The notified polymer did not have any biologically significant effects on daphnia at a test concentration of 100 mg/L. The notified polymer cannot be classified as harmful to aquatic invertebrates.</p>

CONCLUSION The notified polymer is not harmful to aquatic invertebrates.

TEST FACILITY Dr. U. Noack-Laboratorien (2005b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition – Static Limit Test.
Species	<i>Desmodesmus subspicatus</i> CHODAT 86.81
Exposure Period	72 hours
Concentration	100 mg/L
Auxiliary Solvent	None
Water Hardness	Nominally: 0.24 mmol (Ca + Mg)/L
Analytical Monitoring	Dissolved Organic Carbon
Remarks - Method	The notified polymer was dissolved in the OECD standard test medium by agitation. The limit test was carried out with three replicate test solutions and six replicate blank solutions as controls. The Dissolved Organic Carbon content of the notified polymer test and control media

was measured in duplicate at test initiation and after the 72-hour exposure period.

The growth of algae was followed by determining cell densities at 24-hour intervals. The cell densities were determined from measurements of chlorophyll-A fluorescence and no correction for sample self-fluorescence was required. The morphology of cells at the beginning and end of the test period was checked microscopically.

A positive toxicity control test was carried out with six concentrations of potassium dichromate in the range 0.10–3.2 mg/L.

RESULTS

<i>Biomass</i>		<i>Growth</i>	
<i>E_bL50</i> mg/L at 72 h	<i>NOE_bC</i> mg/L	<i>E_rL50</i> mg/L at 72 h	<i>NOE_rC</i> mg/L
> 100	100	> 100	100

Remarks - Results

The growth of cells in the six replicate control samples was exponential over the 72-hour test period and the cell density in the controls increased by an average of 191-fold. The physico-chemical parameters of the test and control media remained within the limits specified by the Guideline. In addition, the positive control test showed that the potassium dichromate reference substance is very toxic to *D. subspicatus* under these conditions: $E_bC50 = 0.29$ mg/L (95% CI: 0.26–0.33 mg/L); $E_rC50 = 0.59$ mg/L (95% CI: 0.55–0.63 mg/L). Hence, this limit test is valid.

A preliminary range finding test at nominal test concentrations of 1, 10, and 100 mg/L showed that the notified polymer caused modest stimulation of algal growth. The rate-related negative inhibition was in the range (-3.21)–(-8.37)%.

In the limit test, the DOC of the test solution was 85% of the level expected based on the nominal concentration of the notified polymer. After 72 hours, the DOC was 115% of the expected level. These calculations are not corrected for the DOC of the controls which increased from an average of 1.5% to 17% of the DOC levels in the test media over the course of the test.

The growth rate of the algae in the limit test of the notified polymer was exponential and the cell density increased by an average of 235-fold over the course of the exposure period. The 72-hour inhibition of biomass was a statistically significant -22.04%, as compared with the controls. The 72-hour average rate-related inhibition for the notified polymer was -3.55%.

Based on the results of this test, the notified polymer has a modest stimulatory effect on the growth rate of *D. subspicatus* at polymer concentrations up to 100 mg/L. Hence, the notified polymer cannot be classified as harmful to algae.

CONCLUSION

The notified polymer is not harmful to algae.

TEST FACILITY

Dr. U. Noack-Laboratorien (2005c)

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