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

SELF ASSESSMENT FULL PUBLIC REPORT

Dehypon 3697 GRA M

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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**

TABLE OF CONTENTS

SELF ASSESSMENT REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. COMPOSITION	3
4. INTRODUCTION AND USE INFORMATION.....	4
5. PROCESS AND RELEASE INFORMATION	4
5.2. Operation Description.....	4
6. EXPOSURE INFORMATION	4
6.1. Summary of Occupational Exposure	4
6.2. Summary of Public Exposure	5
6.3. Summary of Environmental Exposure.....	5
6.3.1. Environmental Release	5
6.3.2. Environmental Fate.....	5
7. ESTABLISHMENT OF LOW PHYSICAL AND CHEMICAL HAZARD	6
8. ESTABLISHMENT OF LOW HUMAN HAZARD	6
8.1. Toxicology.....	6
8.2. Human Health Hazard Assessment.....	6
9. ENVIRONMENTAL HAZARDS	6
9.1. Ecotoxicology.....	6
9.1.1 Discussion of Observed Effects.....	6
9.2. Environmental Hazard Assessment	7
10. RISK ASSESSMENT	7
10.1. Environment	7
10.2. Occupational health and safety	8
10.3. Public health	8
11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS.....	8
11.1. Environmental risk assessment.....	8
11.2. Human health risk assessment	8
11.2.1. Occupational health and safety	8
11.2.2. Public health.....	8
12. MATERIAL SAFETY DATA SHEET	8
12.1. Material Safety Data Sheet	8
13. RECOMMENDATIONS	8

SELF ASSESSMENT REPORT**Dehypon 3697 GRAM****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Cognis Australia Pty Ltd
83 Maffra Street, Broadmeadows, Victoria, 3047
ABN: 87 006 374 456

NOTIFICATION CATEGORY

LRCC: Synthetic Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Data items and details claimed exempt from publication:

Chemical Name

Other Names

Molecular Formula

Structural Formula

CAS Number

Polymer Constituents

Use

Volume

Molecular weight

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

China. Inventory of Existing Chemical Substances (IECSC), 2003

USA PMN, 2004

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

Modified Fatty Alcohol Polyglycoether

MARKETING NAME(S)

Dehypon 3697 GRA M

3. COMPOSITION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</i>
Meets Molecular Weight Requirements	Yes
Meets Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
No Substantial Degradability	Yes
Not Water Absorbing	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazardous Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

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

The polymer will be imported into Australia, no manufacturing is proposed.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	3-5	6-12	8-14	8-14	8-14

USE

As a minor ingredient in special Rinse Aid Granule for Automatic Dish Tablets / Powders

5. PROCESS AND RELEASE INFORMATION

5.2. Operation Description

The solid-state notified polymer will be imported in 25 kg bags of Dehypon 3697 GRA M. Dehypon 3697 GRA M, which contains 92.5% of the notified polymer, will be used as an ingredient in automatic dish tablets / powders at approximately 2 - 8%. The bags will be transported to a small number of formulation sites in Australia, estimated to be up to 8 sites at the end of five years. At the formulation sites the contents of the bags will be weighed, opened and added to a powder blending vessel under the influence of local exhaust ventilation, and mixed. After mixing with remaining ingredients the finished product is manually or automatically weighed into smaller containers under exhaust ventilation or charged to the hopper under local exhaust ventilation, to be formed into tablets in an automatic tableting machine. The process is normally at ambient temperature or at slightly elevated temperature (max 35°C), if required. Sampling and testing of the notified polymer on receipt to the facility warehouse and of the dishwasher powder / tablet formulations, will be carried out as part of quality control.

6. EXPOSURE INFORMATION

6.1. Summary of Occupational Exposure

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached. Dermal and ocular exposure can occur during formulation, quality control and filling processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls (including local exhaust ventilation) and personal protective equipment worn by workers.

Transfer of the notified chemical from 25 kg bags to a powder blending vessel containing other inert ingredients may expose workers to accidental spills. However, inhalation exposure is unlikely given the low volatility of the notified polymer and the fact that no process that would be likely to result in the formation of aerosol, will be used. Dispersion of dust in workplace air is not expected to be created during transfer. Dermal and ocular exposure of workers is neither frequent nor at a high level. As workers wear goggles, respirator, nitrile gloves and overalls, there is little likelihood of any adverse health effect, either from skin absorption or from inhalation.

The notified chemical is a coarse particle with less than 3% of particles below 100 micron in size. Workers may be exposed to dust particles during formulation. therefore, an insignificant proportion in the respirable range.

The commercial form (automatic dish tablets / powders) of the notified polymer is a free-flowing solid

and forms a low concentration (2-8%) in the final product.

As local exhaust ventilation is employed during mixing, tableting & packing and as the system is largely enclosed and workers are expected to wear personal protective equipment, worker exposure and consequent risk of adverse health effects is negligible. A similar conclusion can be drawn for transfer of the notified chemical to the tableting machines or smaller containers where exposure is controlled by the use of local exhaust ventilation and the wearing of respirators. Once the dishwasher powder / tablet is packaged worker exposure to the notified polymer will be negligible.

6.2. Summary of Public Exposure

The notified polymer will not sold to the public except in the form of finished products. Automatic dishwasher powder / tablets containing up to approximately 8% of the notified polymer will be sold to the general public. The finished product will be handled by the public only to add to the dishwasher dispensing compartment. Members of the public will have only brief, if any, dermal contact with the product. It is unlikely, although not impossible, that ocular contact with products containing the notified polymer could occur.

The daily dermal contact with the notified polymer would be limited because of the normal manner of adding the dishwashing detergent to machines. That is, the product is normally poured into the dispenser or dropped in as a tablet, avoiding dermal contact. Skin contact with detergent products containing from 2 % to 8 % (0.08 g to 0.8 g per load), would, therefore, be intermittent or infrequent. In addition, during intermittent contact, exposure will be low because the notified polymer has a high molecular weight (NAMW > 1000) and would not be expected to pass through the skin.

6.3. Summary of Environmental Exposure

6.3.1. Environmental Release

There is a potential for environmental release of the notified polymer during the formulation of the products. Any spilt material that cannot be put to use and the traces remaining in "empty" import containers will go to landfill. The effluent, containing any notified polymer, generated during equipment cleaning will go to on site treatment plants and will then be released to trade waste after treatment and removal of solids. The solids will be sent to landfill.

During the formulation of auto dishwashing products the estimated annual losses of notified polymer to waste are:

Spill and Equipment cleaning:	10 kg per annum
Import container residuals:	20 kg per annum
Total Annual Loss:	30 kg per formulating site per annum.
Remaining in consumer purchased package:	5 kg per annum.

The majority of the notified polymer will be incorporated into the auto dishwashing product to be released within the confines of an automatic dishwasher and then to sewer. Less than 0.1% of the end product will remain in the box which will be disposed of into local council landfill.

6.3.2. Environmental Fate

Fate

As the notified polymer is partially water soluble, the major portion is not expected to be adsorbed onto solids and would be either biologically degraded or pass into the facility's liquid waste stream. The facility may have a licence to discharge to community sewer, in which case, the polymer may be substantially degraded by microbiological activity throughout the STP (sewerage treatment plant).

The autodishwashing waste-water will pass to sewer, thus releasing the majority of the notified polymer to community waste-water STP. The end-user container, containing any residual material will be disposed into general rubbish, which goes to landfill. The notified polymer is not expected to hydrolyse in the environmental pH range of 4-9 as it contains no hydrolysable groups. In sediment/landfill, it is expected that the polymer will degrade substantially.

The notified polymer is partly soluble in cold water and as such is expected to be somewhat mobile in

either the aquatic or terrestrial compartments. Residual chemical disposed of into landfill within empty containers or in spill clean-up material, is expected to be degraded before it has opportunity to be mobile.

The polymer's high molecular weight will preclude absorption across biological membranes. Hence the notified polymer is not expected to bioaccumulate.

7. ESTABLISHMENT OF LOW PHYSICAL AND CHEMICAL HAZARD

Appearance at 20°C and 101.3 kPa	solid material
Melting Point/Glass Transition Temp	45 - 49°C
Density	1,030 - 1,050 kg/m ³ at 70°C
Water Solubility	Partially soluble at 20°C
Dissociation Constant	The notified polymer does not contain any functional groups which would be expected to dissociate under environmental conditions (pH 4-9).
Particle Size	70% of material is 0.80 to 2.50mm particle size. Less than 3% of particles below 100 micron.
Reactivity	Stable under normal conditions of use.
Degradation Products	Oxides of carbon.

8. ESTABLISHMENT OF LOW HUMAN HAZARD

8.1. Toxicology

The following toxicological endpoint was submitted.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>
Skin sensitisation - Repeated Insult Patch Test	no evidence of sensitisation.	No	No

Under the conditions of this study, the notified polymer did not indicate a potential for dermal irritation or allergic contact sensitization.

A review of toxicology based on analogous polymers, a number of which have been produced by the applicant, indicated low concern. The review concludes that the polymer is not classified as hazardous, is not irritating eyes or skin, has no potential for sensitisation and is not mutagenic to bacteria (Ames Test).

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

The following ecotoxicological studies were submitted:

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>
Ready biodegradability	68% in 28 days	Biodegradable
Algal Toxicity (<i>Scenedesmus subspicatus</i>)	E _b C50 230 mg/L, E _t C50 660 mg/L	Yes

9.1.1 Discussion of Observed Effects

The test substance was used in the concentration range from 62.5 to 1000 mg product/L (nominal). The incubation of 72 hours in total was carried out statically (without changing the test water). The EC50

was determined using the probit method.

As the analytical recovery of the test substance was below 80% of the nominal concentration, the arithmetic mean of all recovery rates (50.4%, measured as Biomass active substance (BIAS)) was used to calculate the effect concentrations:

E _b C ₀ (0-72 h):	63 mg product/L
E _b C ₅₀ (0-72 h):	230 mg product/L
E _r C ₅₀ (0-72 h):	660 mg product/L

The test substance has low toxicity to algae. The results were indicative of low hazard.

9.2. Environmental Hazard Assessment

The notified polymer is not toxic to algae (E_bC₅₀ = 230 mg/L and E_rC₅₀ = 660 mg/L) so that toxicity to aquatic and soil dwelling organisms is expected to be low.

10. RISK ASSESSMENT

10.1. Environment

Based on annual imports of 10,000 kg per annum of the notified polymer, and assuming the majority of this is eventually released to sewer and not removed during sewage treatment processes, the following Predicted Environmental Concentration can be estimated

Amount of notified polymer entering sewer annually 10 000 kg

Population of Australia 20 million

Amount of water used per person per day 200 L

Number of days in a year 365

$$\begin{aligned} \text{PEC}_{\text{sewer}} &= \frac{10\,000\,000\,000 \text{ mg}}{20\,000\,000 \times 200 \times 365 \text{ L}} \\ &= 0.0068 \text{ mg/L} \\ &= 6.8 \text{ } \mu\text{g/L} \end{aligned}$$

Almost all of the new polymer is expected to be released to the environment as a consequence of its use in domestic or commercial dishwashing machines. Almost all of the import quantity will be released to sewer, although traces left in "empty" packaging would pass to domestic garbage. The polymer is readily and rapidly biodegradable (OECD 301) so that is expected to be substantially removed in the STP. Any polymer not degraded would be expected to partition mainly to the aqueous phase and pass from the STP to receiving waters.

The use pattern will result in a fully dispersed release and practically all of the notified polymer is expected to be released to the aquatic environment as a consequence of its use in domestic or commercial dishwashing machines. The polymer is readily and rapidly biodegradable so that it is expected to be substantially removed in the STP.

For example, assuming all of the predicted 10 tonnes per annum expected to be imported after 5 years is released to sewer, that each individual in Australia produced 200 L of sewage per day, that there are 20,000,000 individuals, that none is removed in the STP, then the Predicted Environmental Concentration (PEC) would be 6.8 $\mu\text{g/L}$. This estimate is conservative given the nature of the polymer, in that it has hydrophobes that are n-alkyl in nature and hence susceptible to biological degradation.

When released to receiving waters (ocean or major river) the concentration is generally understood to be reduced by a further factor of at least 10. However, as the dishwasher rinse aid products containing the notified polymer will be used nationwide, no further dilution on released to receiving waters will be assumed as a worst-case estimate.

Biodegradation is expected to occur in landfill where trace residues in packaging may find their fate. The polymer is non-toxic to algae. The hydrophilicity of the polymer would lead to the conclusion

that it will not bio-accumulate.

The E_bC50 (OECD 201) is 230 mg/L resulting in a PNEC using a factor of 1000 of 230 µg/L. Therefore, risk quotients (PEC/PNEC) of $6.8/230 = 0.030$ (for fresh water organisms) and $0.68/230 = 0.003$ (for marine water organisms) indicates a minimal environmental risk.

Given the diffuse and widespread use of the product and its ready biodegradability, the notified polymer is unlikely to pose an environmental risk in the aquatic compartment. It is expected that any waste generated during formulation and use will be disposed of by discharge to sewer or to landfill. In landfill the notified polymer contained in the sludge or in consumer containers will degrade readily in soil via abiotic and biotic process.

It is unlikely that the notified polymer will present a risk to the environment when handled and used as indicated. Hence, environmental risk from the proposed use is expected to be low.

10.2. Occupational health and safety

Given the expected low acute oral toxicity, non-classification as irritant to skin or eyes based on closely analogous polymers, the use pattern and manufacturing process, engineering controls and PPE used, the OHS risk presented by the notified polymer is expected to be low.

The notified polymer may be present in formulations containing hazardous ingredients. If these formulations 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.

The level of atmospheric nuisance dust should be maintained as low as possible. The NOHSC exposure standard for atmospheric dust is 10 mg/m³.

10.3. Public health

Members of the public will make dermal contact with products containing the notified polymer. However, the risk to public health will be negligible because the notified polymer is present at low concentrations and unlikely to be bioavailable.

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

11.1. Environmental risk assessment

The polymer is considered to be of low concern for risk to the environment, based on its reported use pattern.

11.2. Human health risk assessment

11.2.1. Occupational health and safety

There is low concern to occupational health and safety under the conditions of the occupational settings described.

11.2.2. Public health

There is negligible concern to public health when used in the manner proposed.

12. MATERIAL SAFETY DATA SHEET

12.1. Material Safety Data Sheet

The notifier has provided MSDS in accordance with the schedule item B 12 of the *ICNA Act*. The accuracy of the information on the MSDS remains the responsibility of the applicant.

13. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupation exposure to the powder form of the notified polymer.
- local exhaust ventilation where import containers are emptied into the blending process.
- Safe work practices and personal protective equipment are required for the safe use of the notified polymer itself in the end-product blending and packing operations, however, these should be selected on the basis of all ingredients in the formulation. Employers should implement the following PPE to minimise occupation exposure to the powder form of the notified polymer:
 - Nitrile rubber gloves

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

- Service personnel should wear nitrile rubber gloves and ensure adequate ventilation is present when servicing equipment containing the notified polymer and during routine maintenance and repairs.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified polymer should be disposed of by re-use/internal recycle where possible, in the blending facility. Wastes should be disposed of to landfill or incineration after negotiation with the respective authority.

Emergency procedures

- Spills/release of the notified polymer should be contained as described in the MSDS.