

File No: PLC/341

21 July 2003

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

FULL PUBLIC REPORT

Polymer in Allianz OPT

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**Director
Chemicals Notification and Assessment**

TABLE OF CONTENTS

FULL PUBLIC REPORT.....	3
1. APPLICANT AND NOTIFICATION DETAILS.....	3
2. IDENTITY OF CHEMICAL	3
3. COMPOSITION.....	3
4. INTRODUCTION AND USE INFORMATION.....	3
6. PHYSICAL AND CHEMICAL PROPERTIES.....	4
7. HUMAN HEALTH IMPLICATIONS.....	4
7.1 Toxicology.....	4
Toxicological Investigations.....	4
Human Health Hazard Assessment.....	4
7.2 Occupational Health and Safety.....	5
Occupational Exposure	5
Exposure Assessment	5
7.3 Public Health	5
Exposure Assessment	5
8. ENVIRONMENTAL IMPLICATIONS	5
8.1. Environmental fate.....	5
8.2 Ecotoxicology	6
8.3 Environmental Contamination.....	8
Environmental Exposure.....	8
Exposure Assessment.....	8
9. RISK ASSESSMENT	9
9.1. Environment	9
9.2. Occupational health and safety	9
9.3 Public health	9
10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS.....	9
10.2. Environmental risk assessment	9
10.3. Human health risk assessment	9
11. MATERIAL SAFETY DATA SHEET	9
11.1. Material Safety Data Sheet	10
12. RECOMMENDATIONS.....	10
12.1. Secondary notification	10
13. BIBLIOGRAPHY	10

FULL PUBLIC REPORT**Polymer in Allianz OPT****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Rohm and Haas Australia Pty Ltd (ABN 29 004 513 188) of 969 Burke Road CAMBERWELL VIC 3124

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formula, molecular weight, polymer constituents, residual monomers, and import volumes.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES

None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Allianz OPT

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

Functional Group	Category	Equivalent Weight (FGEW)
Carboxylic acid	Low Concern	

Charge Density	The notified polymer has low charge density.
Elemental Criteria	The notified polymer contains only approved elements.
Degradability	The notified polymer is not biodegradable.
Water Absorbing	The notified polymer is not a water-absorbing polymer.
Residual Monomers	All residual monomers are below the relevant cut-off.
Hazard Category	The notified polymer is not classified as a hazardous substance.

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

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

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

USE

The notified polymer will be used as a binder in a variety of cosmetics and sunscreen lotions.

The notified polymer will be imported in 200 L plastic drums, and the reformulated product will be packaged into consumer-sized containers.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	An aqueous emulsion with acrylic odour (Allianz OPT)
Melting Point/Glass Transition Temp	The polymer is in an aqueous emulsion
Density	1020 kg/m ³
Water Solubility	1 mg/L at 20°C The solubility of the notified polymer was determined using a turbidity method. Various concentrations of the polymer were prepared in Milli-Q water ranging between 20 and 1100 mg/L. The turbidity was determined of each solution and graphed against polymer concentration. The water solubility of the notified polymer was obtained by extrapolation from the plot to zero turbidity (ACTC 2002).
Particle Size	The polymer is in an aqueous emulsion
Degradation Products	Not stated.
Loss of monomers, other reactants, additives impurities	Not stated.

OTHER PROPERTIES

Hydrolysis as a Function of pH	The notified polymer contains ester linkages that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur.
Partition Coefficient (n-octanol/water)	The notified polymer's low expected water solubility and likely hydrophobic nature are indicative of partitioning into the octanol phase.
Adsorption/Desorption	The notified polymer is expected to have a high affinity for soil and sediment and be immobile in the environment due to its low expected water solubility.
Dissociation Constant	The notified polymer contained some carboxylic acid groups which are expected to have typical acidity.

7. HUMAN HEALTH IMPLICATIONS

7.1 Toxicology

Toxicological Investigations

No toxicological data were submitted.

Human Health Hazard Assessment

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

7.2 Occupational Health and Safety

Occupational Exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hour)</i>	<i>Exposure Frequency (day/year)</i>
Transport & storage	15-25		
Formulation	10-15	4-6	40
QC control	4-8	6	50
Packaging	10-20	6-8	80

Exposure Assessment

The notified polymer will be imported as a component of Allianz OPT comprising 45.5% of the product. It will be reformulated into a variety of cosmetics and sunscreen lotions in Australia. The final concentration of the notified polymer in formulated products is <5%.

Dermal and ocular exposure can occur during certain formulation processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls for example, enclosure blending facilities and local exhaust ventilation. Personal protective equipment will be worn by workers.

Exposure to professionals such as beauticians may occur by dermal route. They will handle the products containing <5% notified polymer. However, they may be exposed to the notified polymer on the daily basis.

7.3 Public Health

Public Exposure

Public exposure to the notified polymer as imported in Allianz OPT could occur only in the event of a transport accident. Public exposure from the formulation process is unlikely but exposure to the consumer products containing the notified polymer at a maximum concentration of 5% will be widespread.

Exposure Assessment

Cosmetic products containing the notified polymer are for sale to the general public. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified polymer. However, exposure will be low because the notified polymer is present at low concentrations.

8. ENVIRONMENTAL IMPLICATIONS

8.1. Environmental fate

The following fate study was submitted on a structural analogue polymer consisting of 3 of 6 monomers comprising about 70% of the notified polymer. Since the remainder are less polar, the data are considered relevant.

8.1.1. Inherent biodegradability

TEST SUBSTANCE	Structural analogue.		
METHOD	OECD TG 302B Inherent Biodegradability: Modified Zahn-Wellens Test.		
Inoculum	Sewage microorganisms		
Exposure Period	28 days		
RESULTS	The test substance was incubated for 28 days at a nominal concentration of 400 mg/L.		

<i>Test substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% degradation</i>	<i>Day</i>	<i>% degradation</i>
15	91	15	60

	28	106	28	81
Remarks - Results	The biodegradation of the reference substance, sodium benzoate was approximately 81% after 28 days, indicating the test conditions were valid. After 28 days at 22°C, the test substance underwent approximately 100% biodegradation (based on CO ₂ evolution) which indicates the test substance is inherently biodegradable in aerobic environments. The test substance was also found to be non-inhibitory to microorganisms.			
CONCLUSION	The test substance is inherently biodegradable.			
TEST FACILITY	Inveresk (1994a).			

8.2 Ecotoxicology

Ecotoxicological Investigations

The following toxicological studies were submitted on a structural analogue polymer consisting of 3 of 6 monomers comprising about 70% of the notified polymer. Since the remainder are less polar, the data are considered relevant.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Structural analogue.
METHOD	Fish, Acute Toxicity Test – 96 h static test.
Species	Rainbow trout (<i>Oncorhynchus mykiss</i>)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical	pH, O ₂ , temperature monitored and were within acceptable limits.

RESULTS

Nominal Concentration mg/L	Number of Fish	Mortality			
		24 h	48 h	72 h	96 h
control	10	0	0	0	0
100	10	0	0	0	0

EC50 > 100 mg/L at 96 hours.

NOEC 100 mg/L at 96 hours.

Remarks – Results The tests were performed under static conditions with observations performed at 24, 48, 72 and 96 hours using 10 specimen fish per test concentration at a temperature range of 15°C. After 96 h no mortalities were observed at the test substance concentration 100 mg/L, nor were any sub-lethal effects observed. The 96-hour EC50 for the notified chemical to Rainbow trout was estimated to be greater than 100 mg/L. The authors indicated that after 24 h a “scummy” foam formed on the surface of the test vessels and that the test solutions were opaque in appearance throughout the study period.

CONCLUSION	The results indicate the test substance is non-toxic to fish up to the limit of its solubility.
TEST FACILITY	Inveresk (1994b).

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Structural analogue.
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METHOD	OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test – 48 h test
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	184 mg CaCO ₃ /L
Analytical	pH, O ₂ , temperature monitored and were within acceptable limits.

RESULTS

Concentration mg/L Nominal	Number of <i>D. magna</i>	Number Immobilised	
		24 h	48 h
control	5	0	0
100	25	0	0

LC50 > 100 mg/L at 48 h

NOEC (or LOEC) 100 mg/L at 48 h

Remarks - Results The immobilisation tests with *Daphnia* were performed at a temperature of 20°C with observations performed at 24 and 48 hours. After 48 h, no immobilised daphnids were observed at the nominal test substance concentration of 100 mg/L and no sub-lethal effects were noted during the study. The authors reported that the test solution was cloudy in appearance throughout the study. The 48-hour LC50 for the test substance to *Daphnia magna* is greater than 100 mg/L.

CONCLUSION The results indicate the test substance is non-toxic to daphnia up to the limit of its solubility.

TEST FACILITY Inveresk (1994c).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Structural analogue.

METHOD OECD TG 201 Alga, Growth Inhibition Test.
Species (Green Algae) *Selenastrum capricornutum*
Exposure Period 72 hours
Concentration Range 0, 62.5, 125, 250, 500 and 1000 mg/L.
Nominal

RESULTS

Growth E _r C50 mg/L at 72 h	NOEC mg/L at 72 h	Biomass E _b C50 mg/L at 72 h	NOEC mg/L at 72 h
>1000	500	777.4	250

Remarks - Results Algae were exposed to the test substance for 72 h at between 21 and 23°C under constant illumination and shaking. Both biomass and growth rate of *Selenastrum capricornutum* were adversely affected by the test substance at concentrations of 500 and 1000 mg/L.

CONCLUSION The results indicate the test substance is practically non-toxic to algae.

TEST FACILITY Inveresk (1994d).

8.2.4. Microtox Assay

TEST SUBSTANCE Structural analogue.

METHOD Microtox Model 500 Toxicity Test System Manual Protocol.

Species	<i>Photobacterium phosphoreum</i>
Exposure Period	15 minutes
Remarks - Method	The study report stated that the assay was carried out in accordance with the Microtox Model 500 Toxicity Test System Manual Protocol. Three dilutions of the test substance were tested at four concentrations (0, 0.5625, 1.125, 2.25 and 4.5%) and a control and the EC50 calculated for each dilution.
Results	The 15 min colour corrected EC50 and 95% confidence limits for a 1:10 dilution of the test substance was 1.60% (95% confidence intervals of 1.24 and 2.08%). This is equivalent to 16039 mg/L.
CONCLUSION	The results indicate the test substance is practically non-toxic to <i>Photobacterium phosphoreum</i> .
TEST FACILITY	Bio-Aquatic (1994).

8.2.5. Activated Sludge Respiration Inhibition Test

TEST SUBSTANCE	Structural analogue.
METHOD	OECD TG 209 Activated Sludge Respiration Inhibition Test
Inoculum	Activated sludge
Exposure Period	3 h
RESULTS	The test substance was incubated for 3 h at a nominal concentration of 100 mg/L.
Remarks - Results	The EC50 of the reference substance, 3,5-dichlorophenol was determined to be 8 mg/L after 3 h, indicating the test conditions were valid. After 3 h at room temperature, the EC50 of the test substance was determined to be greater than 100 mg/L.
CONCLUSION	The results indicate the test substance is non-inhibitory to microorganisms.
TEST FACILITY	Inveresk (1994e).

8.3 Environmental Contamination

Environmental Exposure

Manufacture:

During cosmetics formulation, the notifier estimates that up to 100 kg per annum of notified polymer waste will be generated. This will be derived from the spills (50 kg per annum) and equipment cleaning (50 kg per annum). Formulation equipment will be cleaned with water and the resulting wastes will be treated prior to disposal. The notifier indicates that solid wastes (45 kg/annum) will be disposed to landfill and the treated liquid wastes containing the remaining 5 kg/annum will be released to sewer. It is expected that empty import drums and any residual notified polymer they contain will be disposed of to landfill. This will result in up to a further 50 kg per annum of the notified polymer may be disposed of to landfill.

Use:

The notified polymer will be used in the cosmetics and sunscreen lotions and, as such, this will result in the eventual release of almost all the entire import to the environment.

Exposure Assessment

The notified polymer is not soluble in water and as such is unlikely to be mobile in either aquatic or terrestrial compartments. When released to landfill, as a consequence of its low water solubility, the notified polymer is expected to associate with soil and sediment and degraded through the abiotic and biotic processes to water and oxides of carbon.

Based on annual releases of 9850 kg per annum to sewer and no removal during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 269.9 kg/day. Assuming a national population of 19,500,000 and that each person contributes an average 200 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 0.0069 mg/L. However, removal processes such as adsorption to sludge would reduce this value further.

The surrogate ecotoxicity data and biodegradation study submitted suggest that the notified polymer is likely to be non-toxic to fish, daphnia, algae and microorganisms and inherently biodegradable. Given the notified polymer's low water solubility, its removal from the wastewater stream is expected to be high.

Due to its large molecular weight ($>>1000$ MW), the notified polymer is not expected to bioaccumulate.

9. RISK ASSESSMENT

9.1. Environment

The notified polymer will be used in the cosmetics and sunscreen lotions and, as such, this will result in the eventual release of the entire import to the environment from use. However, as a consequence of its low water solubility, the notified polymer is expected to associate with soil and sediment and degraded through the abiotic and biotic processes to water and oxides of carbon.

Surrogate toxicity data provided suggest that the toxicity (EC50) values for the notified polymer are likely to be greater than 100 mg/L. Given that the predicted concentration in sewage effluent on a nationwide basis (0.0069 mg/L) is expected to be several orders of magnitude below these values, there is no immediate concern to the aquatic compartment.

The notified polymer is not likely to present a hazard to the environment when it is stored, transported and used in the proposed manner.

9.2. Occupational health and safety

The OHS risk presented by the notified polymer is expected to be low due to the expected low toxicity of the polymer and the low potential for exposure by workers. The notified polymer may be present in formulations containing hazardous ingredients.

9.3. Public health

The notified polymer will not be available to the public before reformulation. Members of the public will make dermal contact with cosmetic products containing the notified polymer. However, the risk to public health will be low because the notified polymer is present at low concentrations and, given its high molecular weight, unlikely to cross biological membranes.

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

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Low Concern to public health based on its reported use pattern.

11. MATERIAL SAFETY DATA SHEET

11.1. 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.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.
 - Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified 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

- Wastes containing the notified polymer should be disposed of to landfill.

Emergency procedures

- Spills/release of the notified polymer should be contained as described in the MSDS (ie. collect spilled material with an inert absorbent) and the resulting waste disposed of to an authorised landfill.

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 subsection 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

- (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.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

ACTC (2002) Technical Document No: TD2002-160, Allianz OPT Characterisation: Molecular Weight, Oligomer Fractions, Water Solubility, Infrared Spectrum, Analytical and Computational Technology Centre, (unpublished report submitted by Rohm and Haas Australia).

Bio-Aquatic (1994) Report No RH-101: EC50 Determination for Rhoplex AC-388K by Microtox® Analysis, Bio-Aquatic Testing Inc, Carrollton, Texas, USA, (unpublished report submitted by Rohm and Haas Australia).

Inveresk (1994a) Report No 10177: Rhoplex AC-388K Determination of Inherent Biodegradability by the Modified Zahn-Wellens Test on Rhoplex AC-388K, Inveresk Research International, Tranent, Scotland, (unpublished report submitted by Rohm and Haas Australia).

Inveresk (1994b) Report No 10004: Rhoplex AC-388K Determination of Acute Toxicity to Rainbow Trout (96 h Static Limit Test), Inveresk Research International, Tranent, Scotland, (unpublished report submitted by Rohm and Haas Australia).

Inveresk (1994c) Report No 10071: Rhoplex AC-388K Alga, Growth Inhibition Test (72 h, EC50), Inveresk Research International, Tranent, Scotland, (unpublished report submitted by Rohm and Haas Australia).

Inveresk (1994d) Report No 9997: Rhoplex AC-388K Determination of Acute Toxicity to Daphnia (48 h Static Limit Test) Inveresk Research International, Tranent, Scotland, (unpublished report submitted by Rohm and Haas Australia).

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