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

FULL PUBLIC REPORT

Polymer in Glascol C44

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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
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.....	4
6. PHYSICAL AND CHEMICAL PROPERTIES.....	4
7.1 Toxicology.....	5
7.1.1 Skin Irritation	5
7.1.2 Eye Irritation	5
7.1.3 Human Health Hazard Assessment	6
7.2 Occupational Health	6
7.3 Public Health	6
8. ENVIRONMENTAL IMPLICATIONS	7
8.1. Environmental fate.....	7
8.1.1. Ready biodegradability	7
8.2 Ecotoxicology	7
8.2.1. Acute toxicity to fish.....	7
8.2.3. Algal growth inhibition test	8
8.3.4. Environmental Hazard Assessment.....	9
8.3 Environmental Contamination.....	9
9. RISK ASSESSMENT	10
9.1. Environment.....	10
9.2 Occupational health and safety	10
9.3 Public health.....	10
10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS.....	10
10.2. Environmental risk assessment	10
10.3. Human health risk assessment	10
10.3.1. Occupational health and safety.....	10
10.3.2. Public health.....	10
11. MATERIAL SAFETY DATA SHEET	10
11.1. Material Safety Data Sheet	10
12. RECOMMENDATIONS.....	10
12.1. Secondary notification	11
13. BIBLIOGRAPHY	11

FULL PUBLIC REPORT**Polymer in Glascol C44****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Ciba Specialty Chemicals (ABN 97 005 061 469)
235 Settlement Rd Thomastown VIC 3074

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical name

Other names

CAS number

Molecular formula

Structural formula

Molecular weight information

Polymer constituents and residual monomers

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

USA

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

TKA 45026

MARKETING NAME(S)

Glascol C44

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

Functional Group	Category	Equivalent Weight (FGEW)
epoxide	High Concern	2500

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 as it has NAMW > 10000 and functional group content is therefore not a criterion. In addition, crosslinking is likely to reduce the amount of free epoxide; also the aqueous environment of the polymer emulsion will result in low levels of available epoxide.

4. INTRODUCTION AND USE INFORMATION

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>	100	100	100	100	100

USE

The notified polymer will be used as a resin component of inks for printing onto plastic substrates. Its main application will be in printing onto bread bags. It can also be used in printing inks for wallpaper.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	White to slightly yellow emulsion
Melting Point/Glass Transition Temp	Not determined
Density	1080 kg/m ³ (emulsion)
Water Solubility	Not determined
	The notifier has identified the notified substance as being an emulsion polymer. The polymerisation process used to produce emulsion polymers occurs in the aqueous phase. However, once a critical molecular weight is reached the polymer become insoluble in water. Therefore, the notified polymer is not soluble but dispersible in water.
Particle Size	Not determined
Degradation Products	No degradation is expected under normal environmental conditions.
Loss of monomers, other reactants, additives impurities	None expected
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 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 does not contain any functional groups expected to dissociate in the environmental pH range of 4-9.

The notified polymer will be produced and imported as an aqueous emulsion. Therefore the particle size and melting point could not be determined. The water solubility of the notified polymer is expected to be very low, however it forms a stable emulsion with water as imported.

7. HUMAN HEALTH IMPLICATIONS

7.1 Toxicology

Toxicological Investigations

The following toxicological studies were submitted:

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral	low toxicity; LD50 > 2000 mg/kg bw
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test.	no evidence of sensitisation.
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity - in vitro chromosome aberration in CHO cells	non genotoxic

All results were indicative of low hazard apart from the skin and eye irritation testing. Summaries of the irritation test reports are appended below.

7.1.1 Skin Irritation

TEST SUBSTANCE	TKA 45026
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of animals	3
Vehicle	None.
Observation period	72 hours.
Type of dressing	Semi-occlusive.

RESULTS

<i>Lesion</i>	<i>Mean Score* 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>Erythema/Eschar</i>	0	0.7	0	1	48 hours	0
<i>Oedema</i>	0	0.3	0	1	24 hours	0

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

CONCLUSION The notified chemical is slightly irritating to skin.

TEST FACILITY Covance Laboratories (1999a)

7.1.2 Eye Irritation

TEST SUBSTANCE	TKA 45026
METHOD	OECD TG 404 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of animals	3
Vehicle	None.
Observation period	72 hours.

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>	0.3	0	0	1	24 hours	0
<i>Conjunctiva: chemosis</i>	0	0	0	0	0	0
<i>Conjunctiva: discharge</i>	0	0	0	0	0	0
<i>Corneal opacity</i>	0	0	0	0	0	0
<i>Iridial inflammation</i>	0	0	0	0	0	0

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

CONCLUSION The notified chemical is slightly irritating to eye.

TEST FACILITY Covance Laboratories (1999b)

7.1.3 Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. The results of the toxicity testing are supportive of this conclusion; it is likely that the slight positive results seen in the irritation tests (also during irritation screening in the sensitisation test) pertain to surfactant components of the emulsion.

7.2 Occupational Health

Occupational Exposure

The notified polymer will be imported in 200 L polyethylene lined drums. The polymer emulsion will be transported from the dockside to formulation sites, where it will be pumped to a mixing vessel together with other additions. The inks are formulated in batch sizes of up to 10 tonne. The resulting inks are drummed off into 20 L or 200 L drums for transport to application sites. Prior to packaging, sampling and quality testing of the ink is carried out in the laboratory.

During reformulation and end use (application to plastic substrates) the following workers will come into contact with the notified polymer.

<i>Category of Workers</i>	<i>Exposed To</i>	<i>Hours /Day</i>	<i>No. Days/Year</i>	<i>Number</i>
Transport and Warehouse Workers	imported emulsion; ink formulation	2 - 3	10 - 15	4 - 6
Manufacturing Operators	imported emulsion; ink formulation	up to 8	50 - 70	5 - 10
Application operators	ink formulation	up to 8	up to 230	50 - 100
Quality control	ink formulation	1	50 - 70	1 - 2

Manufacturing and application operators and quality control workers may come into dermal contact with the emulsions containing the notified polymer. Engineering controls during ink manufacture include enclosure and local exhaust ventilation. During application of ink to plastic substrates, the printing machine is fitted with local exhaust ventilation. Personal protective equipment used includes appropriate clothing, safety glasses and impervious gloves.

Exposure Assessment

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 and personal protective equipment worn by workers.

After application and once dried, the inks containing the notified polymer are cured into an inert matrix and the notified polymer is hence unavailable to exposure.

7.3 Public Health

Public Exposure

The public will come into contact with the notified polymer only as a dried ink of plastic substrates.

Exposure Assessment

The notified polymer will not be available to the public. Members of the public may come into contact with products containing the notified polymer. The notified polymer will be part of a solid matrix and will not be bioavailable.

8. ENVIRONMENTAL IMPLICATIONS

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	ASTM 1720-95 Sealed Vessel and the ISO/DIS-14593 Headspace CO ₂ biodegradation test.
Inoculum	Effluent from the Wareham Wastewater Treatment Plant
Exposure Period	28 days
RESULTS	The notified chemical was incubated for 28 days at a nominal test substance concentration of 32.9 mg/L or 10 mg C/L.

<i>Test substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% degradation</i>	<i>Day</i>	<i>% degradation</i>
14	0.43	14	93.5
28	7.04	28	94.4

Remarks - Results	The biodegradation of the reference substance, sodium benzoate was approximately 95% after 28 days, indicating the test conditions were valid. After 28 days at 22°C, the test substance underwent approximately 7% biodegradation (based on CO ₂ evolution) which indicates the notified polymer is not readily biodegradable in aerobic environments.
CONCLUSION	The notified chemical is not readily biodegradable.
TEST FACILITY	Springborn (1999a).

8.2. Ecotoxicology

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
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	40-42 mg CaCO ₃ /L
Analytical	pH, O ₂ , temperature monitored and was within acceptable limits.

RESULTS

<i>Nominal Concentration</i> <i>mg/L</i>	<i>Number of Fish</i>	<i>Mortality</i>			
		<i>24 h</i>	<i>48 h</i>	<i>72 h</i>	<i>96 h</i>
control	10	0	0	1	1

0.1	10	0	0	0	0
0.5	10	0	0	0	0
1.0	10	0	0	0	0
10	10	0	0	1	2
100	10	0	1	1	1

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 13-15°C. Test solutions at 10 mg/L were slightly milky white and those at 100 mg/L were milky white in colour. After 96 h the mortality observed at the test substance concentrations of 10 and 100 mg/L were 20 and 10%, respectively. The 96-hour EC50 for the notified chemical to Rainbow trout was empirically estimated to be greater than 100 mg/L.

CONCLUSION The ecotoxicity data indicates the notified polymer is non-toxic to fish up to the limit of its solubility.

TEST FACILITY Springborn (1999b).

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer.

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – 48 h test
 Species *Daphnia magna*
 Exposure Period 48 hours
 Auxiliary Solvent None
 Concentration Range 0.1 – 100 mg/L
 Water Hardness 160 mg CaCO₃/L
 Analytical pH, O₂ and temperature were monitored and were within acceptable limits.

RESULTS
 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 range of 19-20°C with observations performed at 24 and 48 hours. After 48 h, no immobilised daphnids were observed at any test substance concentration. Some sub-lethal effects were observed during study such as swimming near the surface of the test vessel and daphnia becoming caught on particulate matter. Also after 48 h, the authors reported that the test solution was slightly milky white in colour at a substance concentration of 100 mg/L. The 48-hour LC50 for the notified chemical to *Daphnia magna* is greater than 100 mg/L. The 48-hour NOEC for the notified chemical to *Daphnia magna* is 100 mg/L.

CONCLUSION The ecotoxicity data indicates the notified polymer is non-toxic to daphnia up to the limit of its solubility.

TEST FACILITY Springborn (1999c).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 201 Alga, Growth Inhibition Test.
 Species (Green Algae) *Pseudokirchneriella subcapitata*

Exposure Period	72 hours
Concentration Range	
Nominal	0, 0.1, 0.52, 1.0, 10 and 100 mg/L.

RESULTS

Growth	Biomass
E_rC50 mg/L at 72 h	E_bC50 mg/L at 72 h
10-100	>100

Remarks - Results	Algae were exposed to the test substance for 72 h at 24°C under constant illumination and shaking. Both biomass and growth rate of <i>Pseudokirchneriella subcapitata</i> were adversely affected by the test substance at a concentration of 100 mg/L. Percentage inhibition of biomass and growth rate were 61 and 21%, respectively at a test substance concentration of 100 mg/L. Negligible inhibition was observed at all other test substance concentrations. The authors reported in the acute daphnid study discussed above that the test solution was slightly milky white in colour at a substance concentration of 100 mg/L.
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CONCLUSION	The ecotoxicity data indicates the notified chemical is harmful to algae.
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TEST FACILITY	Springborn (1999d).
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8.3.4. Environmental Hazard Assessment

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

8.3 Environmental Contamination**Environmental Exposure***Manufacture:*

During formulation of the ink, the notifier estimates that up to 1500 kg per annum of notified polymer waste will be generated. This will be derived from the spills (50 kg per annum) and equipment cleaning (1000 kg per annum). It is expected that empty import drums will be rinsed and either recycled or disposed of to landfill. The resulting rinseate will be added to the ink formulation process. However, if this rinsing process does not occur, up to a further 450 kg per annum of the notified polymer may be disposed of to landfill.

Use:

During use of the ink, the notifier estimates that up to 500 kg per annum of notified polymer waste will be generated from equipment cleaning. These wastes will either be recycled in production or collected for treatment by flocculation and the resulting solid waste disposed of to landfill. Virtually all of the notified chemical will eventually be released to the environment. The majority of the notified polymer will be bound to plastic food bags that will either be buried in landfills or incinerated.

Exposure Assessment

The notified polymer is expected to have low water solubility and, as a result, will be immobile in both terrestrial and aquatic compartments. As a consequence, the notified polymer released to sewer or landfill is expected to rapidly associate with the soil matrix and sediments and slowly degrade through abiotic and biotic processes to water vapour and oxides of carbon. Liquid wastes resulting from the cleaning of formulation and application equipment will either be reused in subsequent formulations or undergo treatment by flocculation prior to release to sewer. Solid wastes derived from wastewater treatment will be disposed to landfill where the notified polymer will degrade via the processes described above.

The ecotoxicity data and biodegradation study submitted indicate that the notified polymer is non-toxic to fish and daphnia, is harmful to algae and is not biodegradable. Given the notified polymer's expected low water solubility, its removal from the wastewater stream is expected to be high.

The notified polymer is not expected to cross biological membranes due to its very high molecular weight and low water solubility and is therefore not expected to bioaccumulate (Connell 1989).

9. RISK ASSESSMENT

9.1. Environment

Most of the notified polymer will interact with other ink components to form a stable polymer matrix and, once dry, is expected to be immobile and pose little risk to the environment. 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 low toxicity of the notified polymer and the high level of engineering controls during ink manufacture and application.

9.3 Public health

The notified polymer will not be available to the public. Members of the public may make dermal contact with products containing the notified polymer. However, the risk to public health will be negligible because the notified polymer is bound within a matrix and unlikely to be bioavailable.

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 No 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 a component of inks for printing on consumer packaging.

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 in landfill or by incineration.

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

- Connell DW (1989). Bioaccumulation of xenobiotic compounds. Boca Raton, USA, CRC Press, pp 47-57.
- Covance Laboratories (1999a) Primary Dermal Irritation/Corrosion Study of TKA 45026 in Rabbits. Study No. 90600272. Covance Laboratories Inc, WI, USA (unpublished report submitted by Ciba Specialty Chemicals).
- Covance Laboratories (1999b) Primary Eye Irritation/Corrosion Study of TKA 45026 in Rabbits. Study No. 90600273. Covance Laboratories Inc, WI, USA (unpublished report submitted by Ciba Specialty Chemicals).
- NOHSC (1999b) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
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- Springborn (1999b): TKA 45026-Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*), Study No. 13658.6169, Springborn Laboratories, Massachusetts, USA (unpublished report submitted by Ciba Specialty Chemicals).
- Springborn (1999c): TKA 45026-Acute Toxicity to Daphnids (*Daphnia magna*), Study No. 13658.6168 Springborn Laboratories, Massachusetts, USA (unpublished report submitted by Ciba Specialty Chemicals).

Springborn (1999d): TKA 45026-Acute Toxicity to Green Algae (*Pseudokirchneriella subcapitata*), Study No. 13658.6170, Springborn Laboratories, Massachusetts, USA (unpublished report submitted by Ciba Specialty Chemicals).