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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Poly[oxy(methyl-1,2-ethanediyl)], α -hydro- ω -hydroxy-, polymer with 1,1'-methylenebis[isocyanatobenzene], 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, 5-amino-1,3,3-trimethylcyclohexanemethanamine, 1,4-butanediol and 2-aminoethanol (Polymer in Technologic Varnish 84FI400)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (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 National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, National Occupational Health and Safety Commission, Plaza level, Alan Woods Building, 25 Constitution Avenue, Canberra ACT 2600 between 9am to 5pm Monday to Friday.

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

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Director
Chemicals Notification and Assessment

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1. APPLICANT

SICPA Australia Pty Ltd of 3 Millers Rd, Brooklyn VIC 3025 (ACN 007 114 338) has submitted a notification statement in support of their application for an assessment certificate for the synthetic polymer of low concern (PLC) Polymer in Technologic Varnish 84FI400.

2. IDENTITY OF POLYMER

Chemical name: poly[oxy(methyl-1,2-ethanediyl)], α -hydro- ω -hydroxy-, polymer with 1,1'-methylenebis[isocyanatobenzene], 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, 5-amino-1,3,3-trimethylcyclohexanemethanamine, 1,4-butanediol and 2-aminoethanol

CAS number: none allocated

Other names: polypropylene glycol, polymer with MDI, isophorone diisocyanate, isophoronediamine, 1,4-butanediol and monoethanolamine
94Z1266160

Marketing names: Technologic Varnish 84FI400

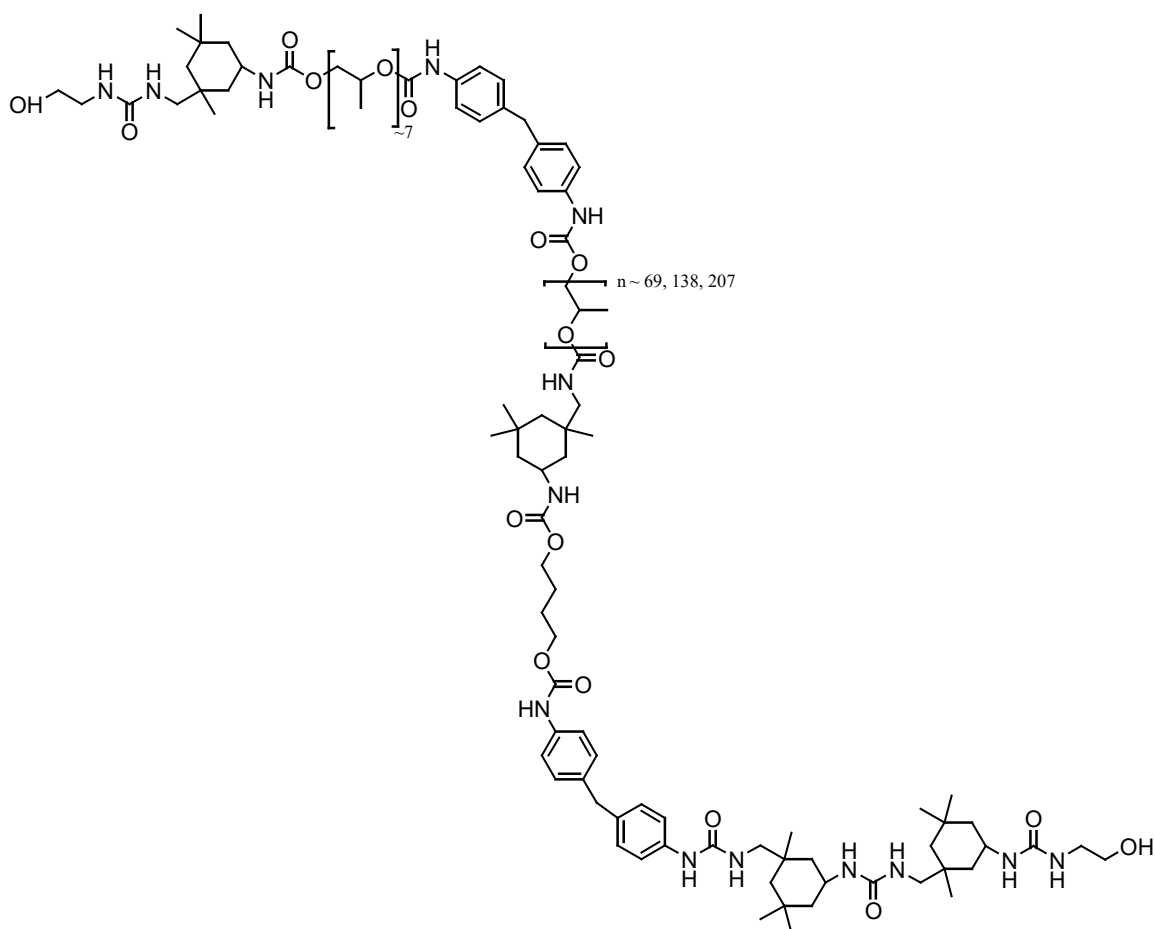
Molecular formula: $((C_3H_6O)_n \cdot H_2O) \cdot C_{15}H_{10}N_2O_2 \cdot C_{10}H_{18}N_2O_2 \cdot C_{10}H_{22}N_2 \cdot C_4H_{10}O_4 \cdot C_2H_7NO$

Reactive functional groups: The notified polymer contains only hydroxyl (low concern) functional groups.

Molecular weight (MW):

Number-average MW	Weight-average MW	% MW < 1000	% MW < 500	Method
18385	114375	2	1	GPC

Structural formula:



Structural identification method: Infrared spectroscopy

Peaks at 3330, 2970, 2920, 2895, 2882, 1730, 1645, 1545, 1460, 1367, 1350, 1305, 1235, 1104, 1020, 935, 870, 835, 670 cm^{-1}

3. POLYMER COMPOSITION AND PURITY

Polymer constituents

Constituent	Synonym	CAS no.	% weight	% residual
poly[oxy(methyl-1,2-ethanediyl)], α -hydro- ω -hydroxy-	polypropylene glycol	25322-69-4	87.5	1.6
1,1'-methylenebis [isocyanatobenzene]	MDI	26447-40-5	5.2	
5-isocyanato-1-(isocyanatomethyl)-1,3,3-	isophorone diisocyanate	4098-71-9	4.3	

trimethylcyclohexane

5-amino-1,3,3-trimethylcyclohexanemethanamine	isophoronediamine	2855-13-2	2.0	
1,4-butanediol		110-63-4	0.9	0.9
2-aminoethanol	monoethanolamine	141-43-5	0.3	0.3

Purity (%): > 99 %

Hazardous impurities (other than residual monomers and reactants):

Chemical name	CAS no.	% weight (on polymer dry weight)
dibutyl tin dilaurate	77-58-7	0.10

Non-hazardous impurities at 1% by weight or more: none

Additives/adjuvants:

Chemical name	Synonym	CAS no.	% weight
benzenepropanoic acid, 3,5-bis(1,1-dimethylethyl)-4-hydroxy-, octadecyl ester	Irganox 1076	2082-79-3	0.06
ethyl acetate		141-78-6	49.99
ethanol		64-17-5	10

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

Property	Result	Comments
Appearance	transparent solution	colourless 40 % solution in ethyl acetate and ethanol
Glass transition temperature	-50 - -60°C	
Density	920 kg/m ³	
Water solubility	not determined	see comments below
Particle size		not applicable as the notified polymer is prepared and used in solution

Flammability	not flammable (notified polymer)	the solution containing the notified polymer is highly flammable
Explosive properties	not explosive	based on structure
Stability/reactivity	stable under normal environmental conditions	
Hydrolysis as function of pH	not determined	see comments below
Partition coefficient	not determined	see comments below
Dissociation constant	not determined	see comments below

5.1 Comments on physical and chemical properties

The notifier provided some results from a test involving mixing of a varnish (40 % notified polymer in ethanol and ethyl acetate) with water in a 1:3 ratio. The aqueous phase was found to contain 0.2 % non-volatile constituents (2 g/L); this phase also contained solvents which partitioned to the aqueous phase, increasing the solubility of the notified polymer.

The notified polymer is likely to be stable under normal conditions of use. Although it contains carbamate linkages, hydrolysis of the polymer is unlikely to occur in the pH range of 4-9 encountered in the environment.

While the partition coefficient was not determined, the chemical composition and structure of the polymer suggests that it would be at best only slightly soluble in water and therefore likely to preferentially partition into the organic phase and associate with soils or sediments.

The polymer contains no acidic or basic function groups.

6. USE, VOLUME AND FORMULATION

Use:

The polymer will be used as a component of printing inks for application in laminated food packaging. The ink layer will be laminated between two films of materials such as oriented polypropylene (OPP), low density polyethylene (LDPE) or polyethylene terephthalate (PET).

Manufacture/Import volume:

The notifier estimates the import volume as 26 tonnes in the first year, increasing to 85 tonnes per annum during the fifth year of importation.

Formulation details:

The notified polymer will be imported in the product Technologic Varnish 84FI400, containing 40 % notified polymer in ethanol and ethyl acetate, in 200 L drums. It will be reformulated at the notifier's site by addition of small amounts of other components to

produce coloured ink dispersions, containing approximately 40 % notified polymer, and packaged generally in 200 L steel drums, but sometimes in 20 L steel pails. These will be distributed to industrial printing sites where the inks will be applied to food wrapping materials, dried and laminated.

7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier
Formulation		
<i>Blending of Ink Dispersions (20-30 workers, weekly)</i>		
Dermal, 40 % solution	The notified polymer solution will be decanted using a drum lifter into enclosed blending vessels under local exhaust ventilation. After addition of other ingredients, the inks will be sampled for testing, filtered and packaged into end product drums. Small amounts of notified polymer may be available for dermal exposure from spills during addition or packaging, and during sampling and laboratory testing.	Local exhaust ventilation; protective eyewear, gloves, overalls and industrial footwear
End use		
<i>Application of Inks (Several hundred workers, daily)</i>		
Dermal, 40 % solution	Inks will be weighed and mixed in an automated enclosed system, and dispensed through permanent piping to printing machines. After printing, the inks will be laminated and not available for exposure. Worker exposure is only likely while installing and removing drum spears when drums are replaced.	Local exhaust ventilation; protective eyewear, gloves, overalls and industrial footwear
Transport and storage		
<i>Transport and Storage (no details provided)</i>		
None	Workers are likely to handle the notified polymer only in sealed containers, and no exposure is expected except in the case of an accident. Transport is expected to occur on a weekly basis.	None

8. PUBLIC EXPOSURE

Inks that contain the polymer will be used for printing on food wrappings and packaging. For this purpose the inks concerned will be laminated and trapped between two plastic films. These films have been formulated to prevent the migration of ink or other material through them. There is not then any potential for the polymer to transfer to the skin of a person holding the wrapper or to the food contained in the wrapping.

Because the inks containing the polymer are applied between two plastic films and because the inks are unable to transfer to the packaged food therein or to the skin of a person holding a wrapper, the extent of public exposure to the notified polymer is assessed as negligible.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

The notifier anticipates that release of the product may occur through residue on drums and equipment. The empty drums are sent to a drum recycler. The estimated release through these routes is 4 % indicating a release of 3.4 tonnes per annum at the maximum import volume.

In the event of spills at the reformulation site the product would be contained by bunding. The subsequent waste is likely to be disposed of to landfill. The notifier uses a licensed carrier.

No estimates for release of the polymer at the customer sites were provided in the notification dossier. Release may occur through residue on drums containing the final ink product and the cleaning of printing equipment, although this is expected to be minimal. The European Commission Technical Guidance Document (TGD) (European Commission, 1996) indicates that for end use of chemicals used in printing and allied processes, a fraction of around 0.85 % may be expected to be released to waste water. In the absence of information from the notifier, this figure will be assumed for purposes of assessment.

This suggests that based on the maximum suggested importation volume, around 722 kg per annum may be released with waste water. Assuming operations are conducted for 300 days of the year, and all release goes to one sewage treatment plant (STP) with an output of 250 ML per day, the concentration in the STP may be around 0.01 mg/L prior to release to receiving waters. The low water solubility suggests a relatively high level of removal from the STP, with the polymer becoming associated with sewage sludge, and the concentration of the notified polymer in receiving waters is likely to be much less than 1 µg/L (ppb).

9.2. Fate

Polymer residue from the reformulation process will ultimately be sent to landfill either as waste collected by the notifier or from recycling of the empty drums. Up to 3.4 tonnes per annum of the notified polymer will end up in landfill at maximum import volumes. It is expected that this polymer waste would degrade very slowly through abiotic and biotic processes.

Most of the polymer will be incorporated into laminated ink for food packaging. Therefore the fate of most of the notified polymer will ultimately be disposal to landfill as domestic waste. Eventually the packaging material will degrade whereupon the polymer is likely to become part of the soil matrix in landfill due to its predicted low water solubility. In this environment it will slowly degrade through abiotic and biotic processes.

Under normal conditions of use the notified polymer would not be expected to enter the aquatic environment. If a spill occurs at the reformulation site, as well as bunding, the notifier has measures in place to prevent the product entering stormwater drains.

The notified polymer is not expected to bioaccumulate given its high molecular weight (Connell, 1990).

10. EVALUATION OF HEALTH EFFECTS DATA

No toxicological data were submitted.

The concentrations of residual monomers and hazardous impurities are present at below the relevant cutoff values for the notified polymer to be classified as a hazardous substance. At higher concentrations than those present in the notified polymer, the hazardous impurity, dibutyltin dilaurate, is toxic if swallowed and a skin and eye irritant (Lewis, 1996).

The product, Technologic Varnish 84FI400, is a hazardous substance due to the presence of the solvents ethanol and ethyl acetate, which have respective NOHSC exposure standards of 1000 and 400 ppm (NOHSC, 1995).

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were provided.

12. ENVIRONMENTAL RISK ASSESSMENT

The environmental hazard posed by the normal use of the notified polymer is expected to be very low for the following reasons. Firstly, the potential for release during reformulation is very small. The nature of its use i.e. in ink to be laminated between plastic films also limits the release of the polymer to the environment. Secondly, the potential for release to the environment during application at customer sites is limited with the PEC in receiving waters predicted to be in the sub-ppb range. Thirdly, the environmental fate of the polymer is disposal to landfill as industrial waste and as domestic waste between the plastic substrate films to which most of it will be bound after printing. In landfill the polymer will be relatively stable and its high molecular weight and low water solubility would prevent it from entering the aquatic environment and prevent bioaccumulation.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

No toxicological information has been provided for the notified polymer. Therefore, the substance cannot be assessed against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). The polymer itself meets the criteria for a Synthetic Polymer of Low Concern, and is not reactive and non-volatile, and because of the high molecular weight is not expected to cross biological membranes. The notifier states that there have been no reported incidences of adverse effects on the occupational health of workers using similar polymers in Australia and overseas. The polymer solution Technologic Varnish 84FI400 is a hazardous substance due to the presence of the solvents ethanol and ethyl acetate. It is classed as a Class 3 dangerous good (flammable liquid) because of the solvent content.

The MSDS for the polymer solution Technologic Varnish 84FI400 lists a number of potential health effects, namely eye, skin, respiratory system and mucous membrane irritation, and headache, shortness of breath, dizziness, drowsiness, nausea, vomiting and central nervous system depression. Dermatitis may also occur on repeated exposure. The symptoms relate mainly to the solvents, ethanol and ethyl acetate, rather than the notified polymer.

13.2. Occupational health and safety

There is little potential for occupational exposure to the notified polymer in the transport and storage of the imported polymer solution. The greatest exposure is in the formulation and use of printing inks. As these processes occur mainly in enclosed, automated systems, exposure is likely to be limited to small scale dermal exposure to drips and spills when containers are decanted or filled and when drum spears are inserted or removed. The use of protective gloves will minimise the exposure to the notified polymer.

The primary hazard associated with the use of the notified polymer arises from the volatile and highly flammable solvents used. Precautions including a high level of ventilation and removal of ignition sources, along with use of gloves, safety eyewear, industrial clothing and footwear, are required to control exposure to the solvents, and these should result in minimal exposure to the notified polymer.

The notified polymer is of low concern during occupational use, and no additional controls are required.

13.3. Public health

The inks containing the polymer are applied between two plastic films and, because the inks are unable to transfer to the packaged food therein or to the skin of a person holding a wrapper, the extent of public exposure to the notified polymer is assessed as negligible.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the products containing the notified polymer, Technologic Varnish 84FI400 and Access Lam Blending Varnish, provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). They are published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

14.2. Label

The label for the product containing the notified polymer, Access Lam Blending Varnish, provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

15. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer in the products Technologic Varnish 84FI400 and Access Lam Blending Varnish:
 - adequate exhaust ventilation should be used to control solvent vapours
 - employers should ensure that the NOHSC exposure standards for solvent vapours are not exceeded in the workplace
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer in the products Technologic Varnish 84FI400 and Access Lam Blending Varnish:
 - eye protection, impermeable gloves, overalls and industrial footwear

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.
- As the products 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.

15.1 Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if

- the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

(2) Under Section 64(2) of the Act:

- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

16. REFERENCES

Connell D. W. (1990) General characteristics of organic compounds which exhibit bioaccumulation. In Connell D. W., (Ed) Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

European Commission (1996) Technical Guidance Document in Support of the Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment of Existing Substances. Part II, ECSC-EC-EAEC, Brussels, Luxembourg.

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National Occupational Health and Safety Commission (1994b) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. Australian Government Publishing Service, Canberra.

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