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# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

# **PUBLIC REPORT**

# Polymer in Lioduras TYZ 74-02NS

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 Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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:

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Director NICNAS

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# **SUMMARY**

The following details will be published in the NICNAS Chemical Gazette:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1555	Toyo Ink	Polymer in Lioduras	ND*	<5 tonnes per	Printing industry
	Australia Pty Ltd	TYZ 74-02NS		annum	

<sup>\*</sup>ND = not determined

# **CONCLUSIONS AND REGULATORY OBLIGATIONS**

#### **Hazard classification**

Based on the structural alerts relating to functional groups of the notified polymer, it should be considered as though it is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008 (2004)] with the following risk phrases:

R36/38 Irritating to eyes and skin R43 May cause sensitisation by skin contact

and

The classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	Hazard statement
Skin irritation	2	Warning: Causes skin irritation
Eye irritation	2B	Warning: Causes eye irritation
Skin sensitisation	1	May cause an allergic skin reaction

#### Human health risk assessment

This risk to occupational health and safety is considered acceptable provided that the notified polymer is only used under controlled conditions by trained workers wearing PPE.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

#### **Environmental risk assessment**

Based on its expected low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

#### Recommendations

REGULATORY CONTROLS

Health Surveillance

As the notified polymer is a potential skin sensitiser, health surveillance should be carried out for any
worker who has been identified in the workplace risk assessment as having a significant risk of
sensitisation.

CONTROL MEASURES

#### Occupational Health and Safety

• Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as imported in varnish products at <15% concentration:

- Automated processes, where possible
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as imported in varnish products at <15% concentration:
  - Avoid contact with skin and eyes
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as imported in varnish products at <15% concentration:
  - Gloves
  - Goggles
  - Coveralls

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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] 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 to landfill. Storage
- The following precautions should be taken by Toyo Ink Australia Pty Ltd regarding storage of the notified polymer as imported at <15% in varnish products:
  - Avoid strong light, heat or free radical forming conditions caused by exposure to oxidizing chemicals or reactive metals.

#### 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 of less than 1000;
  - the function or use of the polymer has changed from a component of varnish products at <15% for industrial use, or is likely to change significantly.

or

#### (2) Under Section 64(2) of the Act; if

- the amount of polymer being introduced has increased from 5 tonnes per annum, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer 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 a product containing 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.

# **ASSESSMENT DETAILS**

#### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Toyo Ink Australia Pty Ltd (ABN 29 006 294 837)
29 Garden St
KILSYTH VIC 3137

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn ≥1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, impurities, use details, import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Boiling point, Melting point, Vapour pressure, Hydrolysis as a function of pH, Partition coefficient, Dissociation constant, Adsorption/desorption, Particle size, Flash point, Flammability limits, Explosive properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

# 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polymer KRC-280 (notified polymer at <90% concentration)

Lioduras TYZ 74-02NS (imported varnish product containing the notified polymer at <15% concentration)

MOLECULAR WEIGHT

Mn >1,000 Da.

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

#### 3. COMPOSITION

DEGREE OF PURITY <90%

HAZARDOUS IMPURITIES

Chemical Name 2- Propenoic acid, 2,2-bis[[(1-oxo-2-propenyl)oxy]methyl]-1,3-propanediyl ester

CAS No. 4986-89-4 Weight % 11

*Hazardous Properties* Conc ≥20%: Xi; R36/38; R43 ≥1% Conc <20%: Xi; R43

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES None

DEGRADATION PRODUCTS

None

#### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Light yellow viscous liquid

Property	Value	Data Source/Justification	
Melting Point/Freezing Point	<0 °C	Estimated (EpiSuite, v.3.20)	
Boiling Point	Not determined	Expected to cross-link before boiling.	
Density	$1,180 \text{ kg/m}^3 \text{ at } 20 ^{\circ}\text{C}$	Analogue data	
Vapour Pressure	<1.3x10 <sup>-9</sup> kPa	Estimated based on NAMW > 1000	
		Da. (US EPA, 2010)	
Water Solubility	7.65×10 <sup>-11</sup> g/L at 20 °C	Estimated for an analogue (WSKOW	
		v1.41, US EPA, 2009)	
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality.	
		However, hydrolysis is not expected at	
		environmental pH due to limited water	
		solubility.	
Partition Coefficient	$\log Pow = 6.36$ at $20$ °C	Estimated for an analogue (KOWWIN	
(n-octanol/water)		v1.67, US EPA, 2009)	
Adsorption/Desorption	$\log K_{oc} = 3.49$ at 20 °C	Estimated for an analogue (KOCWIN	
		v2.00, US EPA, 2009)	
Dissociation Constant	Not determined	Does not contain any readily	
		dissociable functionality at	
		environmental pH	
Flash Point	>100 °C at 100 kPa	Analogue data	
Flammability	Not expected to be highly	Estimated	
	flammable		
Autoignition Temperature	Not expected to autoignite	Estimated based on stability at	
		temperatures up to 350 °C	
Explosive Properties	Not predicted to be explosive	Estimated based on chemical structure	

# DISCUSSION OF PROPERTIES

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

# Reactivity

The notified polymer may polymerise/cross-link in the presence of strong light, heat or free radical forming conditions caused by exposure to oxidizing chemicals or reactive metals.

#### Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

Note: The product containing the notified polymer at <15% concentration will be classified as a Class 3 (Flammable) dangerous good according to the Australian Dangerous Goods Code (NTC, 2007).

# 5. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Polymer (100%) Over Next 5 Years

The notified polymer will be imported as a component of a UV-curable varnish at a concentration of up to 15%.

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

Year	1	2	3	4	5
Tonnes	<5	<5	<5	<5	<5

PORT OF ENTRY Melbourne, Sydney

IDENTITY OF RECIPIENTS

Toyo Ink Australia Pty Ltd

KILSYTH VIC 3137

TRANSPORTATION AND PACKAGING

The notified polymer will be imported at <15% in UV-curable varnish products in 20 L metal cans. Cans of the varnish containing the notified polymer will be transported to customer sites by road for end use.

#### USE

The notified polymer will be used as a component of UV-curable varnish products at <15% concentration. The varnish products containing the notified polymer will be applied over the top of print to plastic and metal substrates.

#### OPERATION DESCRIPTION

Varnish products containing the notified polymer at <15% concentration will be transported from the notifier's storage to customer sites. The varnish will be poured manually into flexographic or gravure printing equipment. Once the equipment is filled with the varnish containing the notified polymer, it will be applied automatically to a plastic or metal substrate and fixed with other ink ingredients onto the substrate matrix.

#### 6. HUMAN HEALTH IMPLICATIONS

#### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	Number	Exposure Duration (hours/day)	Exposure Frequency (days/year)
Transport and Storage	10-20	4-8	50
Printer Operators	>1000	1-2	25
Service Technicians	200	8	200

#### EXPOSURE DETAILS

Transport, Warehousing and Wholesale Printer Supply Workers

Workers are not expected to be exposed to the notified polymer, as it will be transported in sealed containers. Exposure is possible in the event of an accident where the packaging is breached.

#### Print operators

Print operators may experience dermal and ocular exposure to small amounts of the notified polymer at <15% concentration during the manual addition of the varnish containing the notified polymer to printing machines, stocking substrate feeders and attending to substrate jams. Exposure of these workers is expected to be minimised by the automated and enclosed nature of the printing equipment used to transfer the varnish to the substrate. In addition, exposure will be minimised through the use of personal protective equipment (PPE) including impervious gloves, safety glasses and coveralls. Inhalation exposure may also occur to aerosols of the notified polymer during addition of the varnish and the operation of the printers. However, this is expected to be minimised using exhaust ventilation fitted to the machines and respirators (during addition of the varnish) worn by workers.

Service technicians

Service technicians may experience dermal and ocular exposure to the notified polymer during printer maintenance and cleaning but this is expected to be minimized by the use of impervious gloves, safety glasses, coveralls and safety boots. Inhalation exposure may also be possible but is expected to be minimised through the use of respirators and exhaust ventilation fitted to the machines.

After application to the substrate, the varnish containing the notified polymer will be UV-cured (fixed) onto the plastic or metal substrate. Once the varnish is dried and cured, the notified polymer is reacted into a polymer matrix and will not be bioavailable.

# 6.1.2. Public Exposure

The varnish products containing the notified polymer will not be sold to the public. Articles coated with varnish containing the notified polymer may be sold to the public. However, once the varnish is dried and cured, the notified polymer will be reacted into a polymer matrix and will not be bioavailable.

#### **6.2.** Human Health Effects Assessment

Toxicokinetics, metabolism and distribution.

The notified polymer has a high molecular weight (>1000 Da.) and limited water solubility (<1 mg/L). Based on these characteristics, it is not expected to be absorbed following oral, dermal or inhalation exposure. The notified polymer has relatively high levels of low molecular weight species (approx. 25% with molecular weight <1000 Da.). However, a large proportion of these low molecular weight species are due to the presence of an impurity.

#### Irritation and Sensitisation

The notified polymer contains a structural alert for skin sensitisation (Barratt et al. 1994) and skin and eye irritation (Hulzebos et al. 2005). An impurity known to cause skin sensitisation is also present at >1%, the cut-off concentration for classification as a skin sensitiser according to [NOHSC:1008 (2004)]). The notified polymer is considered to have the potential to cause skin sensitisation as well as skin and eye irritation.

#### Mutagenicity

The notified polymer was found not to be mutagenic in a bacterial reverse mutation test (See Appendix A for details).

# Health hazard classification

Based on the structural alerts relating to functional groups of the notified polymer, it should be considered as though it is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008 (2004)] with the following risk phrases:

R36/38 Irritating to eyes and skin

R43 May cause sensitisation by skin contact

# 6.3. Human Health Risk Characterisation

# 6.3.1. Occupational Health and Safety

The notified polymer has the potential to cause skin sensitisation as well as skin and eye irritation. However, the notified polymer in varnishes at <15% is not expected to cause irritation.

The main risk for print operators and service technicians is skin sensitisation. These workers may experience dermal and potentially ocular exposure to the notified polymer during addition of the substrate to printing equipment, stocking substrate feeders, attending to paper jams, cleaning and maintenance. However, exposure is expected to be minimised by the use of PPE such as impervious gloves, safety glasses, coveralls and safety boots.

Provided that PPE is used as described to prevent dermal and ocular exposure, the risk to workers exposed to the notified polymer at <15% is not expected to be unreasonable.

#### 6.3.2. Public Health

The public may experience contact with articles coated with varnish containing the notified polymer. However, once the varnish is dried and cured, the notified polymer will be reacted into a polymer matrix and will not be bioavailable. Therefore, when used in the proposed manner, the risk to public health is not considered to be unreasonable.

#### 7. ENVIRONMENTAL IMPLICATIONS

#### 7.1. Environmental Exposure & Fate Assessment

#### 7.1.1. Environmental Exposure

#### RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported in a finished overprint varnish and there will be no reformulation or repackaging in Australia. Therefore, there will be no release from manufacturing or reformulation activities. Release of the notified polymer to the environment may occur in the event of an accident during transport, distribution or storage. Spills are expected to be treated with adsorbent material, collected and disposed of to landfill.

#### RELEASE OF CHEMICAL FROM USE

The product containing the notified polymer is to be used in industrial applications and therefore minimal release to the aquatic environment is expected. Residues in empty import containers, accounting for 1% of the import volume, are expected to be disposed of to landfill. Spills and residues in equipment washings are estimated to account for a further 1% of the import volume and are expected to be disposed of in accordance with local regulations.

# RELEASE OF CHEMICAL FROM DISPOSAL

Notified polymer in varnish is expected to share the fate of the plastic and metal substrates to which it has been applied. Articles to which the notified polymer has been applied are expected to either be disposed of to landfill, or recycled.

#### 7.1.2. Environmental Fate

The majority of the notified polymer is expected to be UV-cured to form an inert matrix adhering to plastic and metal substrates during its normal use as a varnish. The notified polymer is irreversibly bound into the matrix and, in this form, is not expected to be bioavailable or readily biodegradable. Notified polymer in solid waste disposed of to landfill is not expected to be mobile due to its high molecular weight and the predicted adsorption coefficient of the analogue. Although the predicted partition coefficient of the analogue is greater than 5, the notified polymer is not expected to cross biological membranes due to its high molecular weight and therefore is not expected to bioaccumulate. The notified polymer will eventually degrade in landfill, or by thermal decomposition during recycling processes, to form water and oxides of carbon.

# 7.1.3. Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration (PEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

# 7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Polymers without significant ionic functionality are generally of low concern to the aquatic environment. Further, the analogue is not expected to be bioavailable at its limit of solubility in water due to its high predicted partition coefficient. Therefore, no effects on aquatic organisms were predicted for the analogue, and by inference the notified polymer, at its limit of water solubility (ECOSAR v1.00, US EPA, 2009).

#### 7.2.1. Predicted No-Effect Concentration

A Predicted No Effect Concentration (PNEC) has not been calculated as, on the basis of the predicted effects for the analogue, the notified polymer is not expected to be readily bioavailable and is predicted to have no effect on aquatic biota at its limit of water solubility.

#### 7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as release to the aquatic environment is not expected based on its reported use pattern as a varnish for metal and plastic substrates. The majority of the notified polymer will be disposed of to landfill as cured varnish where it is irreversibly bound into a solid inert matrix, and is unlikely to be bioavailable or mobile in this form. Therefore, based on its expected low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

# **APPENDIX A: TOXICOLOGICAL INVESTIGATIONS**

# A.1. Genotoxicity - bacteria

TEST SUBSTANCE Notified polymer

METHOD According to the modifications adopted by the Japanese Ministry of

Health, Labour and Welfare similar to OECD TG 471 Bacterial Reverse

Mutation Test.

Pre incubation procedure

Species/Strain S. typhimurium: TA1535, TA1537, TA98, TA100

E. coli: WP2uvrA

Metabolic Activation System S9 mix was prepared from the livers of phenobarbital/5,6-Benzoflavone

induced male Sprague-Dawley rats.

Concentration Range in a) With metabolic activation: 20, 78, 313, 1250 and 5000 µg/plate

Main Test b) Without metabolic activation: 20, 78, 313, 1250 and 5000 μg/plate

Vehicle DMS

Remarks - Method No preliminary toxicity test was conducted to determine the cytotoxicity

of the notified polymer.

#### RESULTS

Metabolic	Test Substance Concentration (µg/plate) Resulting in:				
Activation	Cytotoxicity in	Cytotoxicity in	Precipitation	Genotoxic Effect	
	Preliminary Test	Main Test	•		
Absent	•				
Test 1	5000	5000	-	negative	
Test 2	5000	5000	-	negative	
Present				_	
Test 1	-	-	5000	negative	
Test 2	_	=	5000	negative	

Remarks - Results Reduced growth of the background lawn was observed in several strains

at 5000  $\mu$ g/plate in the absence of metabolic activation. Precipitate was observed in several strains at 5000  $\mu$ g/plate in the presence of metabolic

activation.

All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the

activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION The notified polymer was not mutagenic to bacteria under the conditions

of the test.

TEST FACILITY Toyo Ink SC Holdings Co., Ltd. (2011)

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