

File No: LTD/1551

December 2011

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

PUBLIC REPORT

Polymer in Synolite 7044-M-1

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, 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

SUMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS	4
1. APPLICANT AND NOTIFICATION DETAILS	4
2. IDENTITY OF CHEMICAL.....	4
3. COMPOSITION	5
4. PHYSICAL AND CHEMICAL PROPERTIES	5
5. INTRODUCTION AND USE INFORMATION	6
6. HUMAN HEALTH IMPLICATIONS	6
7. ENVIRONMENTAL IMPLICATIONS.....	8
BIBLIOGRAPHY	10

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/1551	Karpelo Holdings Pty Ltd	Polymer in Synolite 7044-M-1	ND*	≤ 3 tonnes per annum	A component of automobile putties

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicity data was provided the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment

On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during reformulation and handling:
 - Gloves, overalls and goggles. 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.
- 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 chemical, 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;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of automobile putties, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 3 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)

Karpelo Holdings Pty Ltd (ABN 79 003 741 035)
Suite 2B, 14 Glenn Street
EASTWOOD NSW 2122

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, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: melting point, boiling point, density, vapour pressure, water solubility, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, particle size, flash point, flammability limits, autoignition temperature and explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada and Korea

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Synolite 7044-M-1 (contains < 65% notified polymer)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference NMR, IR, and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS Below classification cut-off levels.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Not expected to occur under normal conditions of use.

DEGRADATION PRODUCTS
Not expected to occur under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Dark brown solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 60°C	Estimated based on the state of the polymer during use.
Boiling Point	Not determined	The notified polymer is a solid at room temperature.
Density	1,100 kg/m ³	Measured (test report not available)
Vapour Pressure	< 1.3 × 10 ⁻⁹ kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2007)
Water Solubility	Not determined	The notified polymer is expected to be insoluble in water due to structural characteristics and experience in use.
Hydrolysis as a Function of pH	Not determined	Hydrolysis is not expected to occur due to the polymer being shown to be stable at pH 1.2 – pH 9 according to stability test over 4 weeks using GPC analysis (LabFrontier, 2009)
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to be insoluble in water.
Adsorption/Desorption	Not determined	Based on the structural characteristics (potentially cationic) and its expected lack of solubility in water, the notified polymer is expected to adsorb to soil and sediment and have low mobility in soil.
Dissociation Constant	Not determined	The notified polymer has functional groups which are potentially cationic at environmental pH.
Particle Size	Not determined	Introduced in solution.
Flash Point *	32°C	MSDS
Flammability limits *	Upper: 6.1% Lower: 1%	MSDS
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not expected to be explosive	The structural formula contains no

explosophores.

* For the product containing the notified polymer at a concentration of < 65%.

DISCUSSION OF PROPERTIES

Reactivity

Stable under normal conditions of use.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified polymer can not be classified according to the Australian Dangerous Goods Code (NTC, 2007), although the imported product (Synolite 7044-M-1) containing < 65% notified polymer would be classified as a flammable liquid. 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.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. The notified polymer will be imported at a concentration of < 65% by sea.

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	< 3	< 3	< 3	< 3

PORT OF ENTRY

Melbourne, Sydney and Brisbane

TRANSPORTATION AND PACKAGING

The product containing the notified polymer at < 65% will be imported in 0.6-3.5 L containers. The reformulated automobile putty products containing < 1% notified polymer will be transported to end use sites by road.

USE

The notified polymer will be used as a component of automobile putties at a concentration of < 1%.

OPERATION DESCRIPTION

The notified polymer will not be manufactured within Australia.

Reformulation

The product Synolite 7004-M-1 (containing < 65% notified polymer) will be manually weighed and then pumped into a closed mixing vessel for blending with other components at room temperature. The mixing facilities are expected to be automated, well ventilated (local exhaust ventilation) and closed systems. After being reformulated, the finished automobile putties containing the notified polymer at concentrations < 1% will be packaged via an automated process under exhaust ventilation.

End use

The products containing the notified polymer will not be sold to the public.

The application of automobile putties containing the notified polymer (< 1%) to the vehicle is expected to be performed manually with the use of a tool such as a spatula. The putty will be applied to the vehicle and allowed to dry before being sanded to ensure the surface is appropriate for the application of surface coatings.

6. HUMAN HEALTH IMPLICATIONS**6.1. Exposure Assessment****6.1.1. Occupational Exposure**

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	10	1	200
Operators	30	4	200
Cleaning and Maintenance	10	1	200

EXPOSURE DETAILS

It is anticipated that transport and warehouse/store personnel would only be exposed to the notified polymer in the event of an accident.

Reformulation

During reformulation, dermal and ocular exposure of workers to the product containing the notified polymer (at < 65%) may occur when weighing and transferring to the mixing tank. It is expected that there will be a low potential for exposure during the fully automated and closed blending process. Workers involved in the reformulation process are expected to wear impermeable gloves, eye protection and protective clothing to further minimise exposure. Exposure to the notified polymer at concentrations < 1% during transfer of the formulated product to packaging is expected to be low due to the largely automated processes used.

Inhalation exposure, during reformulation, is expected to be negligible given the very low estimated vapour pressure of the notified polymer. In addition, blending and packaging facilities are expected to use local exhaust ventilation.

End-use

Exposure to the notified polymer (< 1%) when used in automobile putties may result via the dermal or ocular routes when the putty is applied.

Inhalation exposure of workers to the notified polymer (< 1%) may occur during sanding of the dried putty. Exposure is expected to be reduced by the use of dust masks during sanding.

6.1.2. Public Exposure

The notified polymer is intended for industrial use only; therefore the public may be exposed to the imported product (< 65% notified polymer) only in the event of an accident during transportation. The public may come into contact with automobiles to which putty containing the notified polymer has been applied. However, exposure is not expected as the notified polymer (< 1%) will be bound within the putty which will have been painted over.

6.2. Human Health Effects Assessment

No toxicity data were submitted

Toxicokinetics, metabolism and distribution.

The notified polymer is not expected to be dermally absorbed, based on the high molecular weight (> 1,000 Da.).

Irritation

The notified polymer contains a functional group which is a structural alert for irritation. However, given the high molecular weight and the moderately low level of low molecular weight (< 1,000 Da.) species the potential for irritation is expected to be significantly reduced.

Health hazard classification

As no toxicity data was provided the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer has the potential to be an irritant. However, the risk of irritation effects from exposure to the notified polymer is expected to be reduced by the high molecular weight ($> 1,000$ Da) and the moderately low level of low molecular weight ($< 1,000$ Da.) species.

During reformulation workers will handle the notified polymer at concentrations of $< 65\%$, however exposure is expected to be low given the proposed use of PPE and largely enclosed, automated processes. During end use workers will be exposed to automobile putties containing the notified polymer at concentrations $< 1\%$. Exposure to the notified polymer during end use is also expected to be low due to the reduced concentration and the use of engineering controls and appropriate PPE.

Given the expected low potential hazard, the proposed use of PPE and the engineering controls in place, the risk to workers of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The finished automobile putties containing the notified polymer will not be sold to the public. The public may experience dermal exposure to automobiles to which putty containing the notified polymer has been applied. However, exposure is not expected as the notified polymer ($< 1\%$) will be bound within the putty which will have been painted over. Therefore the risk to the public from the notified polymer 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 not be manufactured in Australia. No significant release is expected during reformulation into putties in automated closed system. During reformulation, it is expected that 2% of the annual import volume will be lost to spills and the cleaning of reformulation equipment. Any spills are likely to be contained within bunding. The notified polymer collected in aqueous waste is expected to be flocculated and disposed of to landfill by a licensed waste disposal contractor. Empty import containers containing 1% of the notified polymer will be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

A maximum of $< 1\%$ of the import volume will be present as waste from the application of the putties. Waste may be generated from cleaning of equipment, spillage and from the disposal of packaging. The waste putty is expected to be disposed of to landfill. There is very little potential for aquatic exposure during use as the notified polymer will be irreversibly combined within the cured putty matrix and given its use pattern.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer in putties is expected to share the fate of the automobiles to which it has been applied. The cross-linked cured putty in the form of excess solid material and discarded articles will therefore either be thermally decomposed during metal reclamation processes or disposed of to landfill where it will undergo slow degradation processes via biotic and abiotic pathways, eventually forming water and oxides of carbon and nitrogen.

7.1.2. Environmental Fate

No environmental fate data for the notified polymer were submitted. The majority of the notified polymer is expected to be cured into an inert matrix as part of its normal use pattern as putties for application to automotive vehicles by professionals. The majority of the notified polymer is likely to be disposed of by thermal decomposition or disposed of to landfill. Thermal decomposition would destroy the notified polymer, while disposal to landfill would result in its immobilisation because of the expected strong sorption to soil organic carbon. Given the notified polymer's use pattern, it is not expected to be disposed of to surface water. Either in landfill or through thermal decomposition, the notified polymer will finally be decomposed into water and oxides of carbon and nitrogen. The notified polymer has a low solubility in water and a high molecular weight, and is irreversibly combined in a putty matrix and therefore, is not expected to be bioavailable or bioaccumulative to aquatic organisms.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the notified polymer as, based on its assessed 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 for the notified polymer. The notified polymer contains functionality which, when ionised, has the potential to cause adverse effects to aquatic biota. However, the release to the aquatic compartment is expected to be very low.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its assessed use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental Risk Assessment

The risk quotient ($Q = PEC/PNEC$) for the notified polymer has not been calculated as ecotoxicologically significant concentrations are not expected to be reached based on its assessed use pattern as a component of putties. The notified polymer is not likely to be released into the aquatic environment in a bioavailable form as the notified polymer is irreversibly combined in a putty matrix and is expected to adsorb to soil and sediment. Therefore, the risk of the notified polymer to the environment is not expected to be unreasonable based on its assessed use pattern.

BIBLIOGRAPHY

- LabFrontier (2009) Stability Polymer Test (Study No. PS-577, 05 November 2009). Gyonggi-do, Korea, LabFrontier Co Ltd (Unpublished report submitted by the notifier).
- NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>.
- US EPA (United States Environmental Protection Agency) (2007), Interpretive Assistance for the Assessment of Polymers, Updated 22 January 2007:
<http://www.epa.gov/oppt/sf/pubs/InterpretiveAssistancePolymers0107.pdf> (Accessed 05 September 2011)