

File No: LTD/1482

September 2010

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

FULL PUBLIC REPORT

Polymer in Daicure SD-7000

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 Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street SURRY HILLS NSW 2010.

This Full 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

| | |
|---|---|
| <u>FULL PUBLIC REPORT</u> | 3 |
| 1. APPLICANT AND NOTIFICATION DETAILS..... | 3 |
| 2. IDENTITY OF CHEMICAL | 3 |
| 3. COMPOSITION..... | 3 |
| 4. PHYSICAL AND CHEMICAL PROPERTIES..... | 3 |
| 5. INTRODUCTION AND USE INFORMATION..... | 4 |
| 6. HUMAN HEALTH IMPLICATIONS..... | 5 |
| 6.1 Exposure assessment..... | 5 |
| 6.1.1 Occupational exposure..... | 5 |
| 6.1.2 Public exposure..... | 5 |
| 6.2 Human health effects assessment..... | 5 |
| 6.3 Human health risk characterisation..... | 6 |
| 6.3.1 Occupational health and safety | 6 |
| 6.3.2 Public health..... | 6 |
| 7. ENVIRONMENTAL IMPLICATIONS | 6 |
| 7.1 Environmental Exposure & Fate Assessment..... | 6 |
| 7.1.1 Environmental Exposure..... | 6 |
| 7.1.2 Environmental fate..... | 6 |
| 7.1.3 Predicted Environmental Concentration (PEC) | 7 |
| 7.2 Environmental effects assessment | 7 |
| 7.2.1 Predicted No-Effect Concentration | 7 |
| 7.3 Environmental risk assessment | 7 |
| 8. CONCLUSIONS AND REGULATORY OBLIGATIONS..... | 7 |
| <u>BIBLIOGRAPHY</u> | 9 |

FULL PUBLIC REPORT

The notifier has submitted with the application an assessment of the chemical by a notification and assessment scheme in an OECD country (Canada). The Canadian assessment report has been taken into account in the NICNAS assessment.

Polymer in Daicure SD-7000**1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

DIC Australia Pty Ltd (ABN: 12 000 079 550)
323 Chisholm Road
Auburn, NSW 2144

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ 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, polymer constituents, residual monomers/impurities, use details and import volume.

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, Absorption/Desorption, Dissociation Constant, Flash Point, Flammability Limits, Autoignition Temperature and Explosive Properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES

Canada (2006)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Daicure SD-7000 (<15% notified polymer)

MOLECULAR WEIGHT

>1000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >84%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

With the exception of one, all hazardous impurities and residual monomers were present at levels under the concentration cut-offs for classification. The impurity is present at a concentration of >1%, which may result in sensitisation by skin contact (R43 classification provided by the notifier).

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Daicure SD-7000 is a pale-yellow solution. The notified polymer is not isolated from solution.

| Property | Value | Data Source/Justification |
|----------|-------|---------------------------|
|----------|-------|---------------------------|

| | | |
|---|----------------|---|
| Melting Point/Freezing Point | Not determined | Not isolated from solution. |
| Boiling Point | Not determined | Not isolated from solution. |
| Density | Not determined | Not isolated from solution. |
| Vapour Pressure | Not determined | Based on the high molecular weight of the polymer the vapour pressure is expected to be low. |
| Water Solubility | Not determined | Expected to have low water solubility based on its predominantly hydrophobic chemical structure and high molecular weight. |
| Hydrolysis as a Function of pH | Not determined | The notified polymer contains hydrolysable groups. However, due to its expected low water solubility, it will hydrolyse very slowly in the environmental pH range (4 – 9) at ambient temperature. |
| Partition Coefficient (n-octanol/water) | Not determined | Expected to partition to the octanol phase based on its expected low water solubility. |
| Adsorption/Desorption | Not determined | Expected to sorb to sludge, soil and sediment based on its expected low water solubility and high molecular weight. |
| Dissociation Constant | Not determined | Contains no dissociable functional groups. |
| Flash Point | Not determined | Not isolated from solution. |
| Autoignition Temperature | Not determined | Not isolated from solution. |
| Explosive Properties | Not determined | Contains no functional groups that would imply explosive properties. |

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer contains functional groups that are designed to crosslink in the presence of photo-initiators and UV light.

Dangerous Goods classification

As no physical-chemical data were provided, the notified polymer cannot be classified according to the Australian Dangerous Goods Code (NTC, 2007). However, based on the justifications provided for the above Dangerous Goods endpoints it is not expected to be classified.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer (at <15% concentration) will be introduced as a component of Daicure SD-7000

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> | <5 | <5 | <5 | <10 | <10 |

PORT OF ENTRY

Melbourne and Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS

Following its introduction into Australia, the notified polymer will be used in manufacturing processes in Melbourne and Sydney.

TRANSPORTATION AND PACKAGING

The notified polymer will be supplied as a component of Daicure SD-7000 in 20 kg square plastic carboys.

Products containing the notified polymer will be transported within Australia by road.

USE

The notified polymer will be used as a component of a bonding resin for the manufacture of DVDs.

OPERATION DESCRIPTION

The imported product containing the notified polymer (at <15%) will be manually placed adjacent to the bonding unit. The container will then be manually opened and the bonding resin containing the notified polymer will be drawn from the supplied containers into a holding tank within the bond unit in an automated fashion. During the bonding process, the bonding resin is dispensed via a nozzle onto the disc substrates, which are then bonded together. The discs will then undergo a pressing process to remove air bubbles and a spinning process that will cause the adhesive to spin outward and spread evenly between the disc substrates. The near vacuum will then draw the bonding resin towards the centre of the paired discs to ensure an even distribution of the adhesive. Following further alignment of the discs, UV curing will take place and then the discs will be packed onto spindles for distribution to retail stores. All stages within the bonding unit are automated.

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 | 10-15 | 1-2 | 20 |
| Machine operators (general) | 12-18 | 7 | 100 |
| Machine operators (changing resin containers) | 6 | 0.5 | 100 |
| Machine operators (cleaning of tanks and lines) | 6 | 0.5 | 100 |

EXPOSURE DETAILS

Transport workers and warehouse staff may come into contact with the imported solution (<15% polymer) only in the event of accidental rupture of containers.

All stages within the DVD bonding unit are enclosed and automated. Dermal or ocular exposure to the notified polymer may occur whilst opening containers, during connection/disconnection of hoses and during cleaning of machinery. Inhalation exposure is not anticipated given the expected low vapour pressure of the notified polymer. Exposure should be mitigated by the use of exhaust ventilation and personal protective equipment (PPE: goggles, impervious gloves and protective clothing).

Once cured, the notified polymer is not expected to be bioavailable and further dermal contact should not lead to exposure.

6.1.2. Public exposure

The notified polymer is intended for industrial use only, therefore the public may be exposed to the imported product (<15% notified polymer) only in the event of a transport accident. The public will come into contact with manufactured DVDs. However, the notified polymer will be cured and contained between DVD layers. Once cured, the notified polymer is irreversibly bound into the resin matrix and is not bioavailable.

6.2. Human health effects assessment

No toxicity data were submitted.

Toxicokinetics, metabolism and distribution.

Based on the high molecular weight (>1000 Da) of the notified polymer, the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is limited. However, the polymer contains a proportion of low molecular weight species (<1000 Da) that may be absorbed.

Irritation and Sensitisation.

The notified polymer contains a structural alert for a functional group that has been associated with irritation and sensitisation effects (US EPA, 2010). As no toxicity data were provided for the notified polymer, the potential for irritation and/or sensitisation effects cannot be excluded. In addition, the notified polymer contains an impurity at >1%, which may result in sensitisation by skin contact.

Health hazard classification

As no toxicity data were provided for the notified polymer, it cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

No toxicological data are provided for the notified polymer. However, the potential for irritation and/or sensitisation effects following contact with the notified polymer cannot be excluded.

Due to the control measures in place to reduce exposure, including enclosed, automated processes and the use of PPE, the overall risk of exposure to the notified polymer is expected to be low. Hence, provided these control measures are in place, the risk to the health of workers from use of the notified polymer is not considered to be unacceptable.

6.3.2. Public health

The notified polymer is intended for use in industrial applications by qualified operators. The public may be exposed to the manufactured DVDs. However, the polymer will be cured and contained within DVD layers and will not be bioavailable. Therefore, when used in the proposed manner, the risk to public health from the notified polymer is not considered to be unacceptable.

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 as a component of a ready-to-use UV-curable bonding resin used in the manufacture of DVDs. The notified polymer will not be manufactured or reformulated in Australia. Accidental spills are expected to be collected with inert material. The bonding resin, when exposed to UV-light, will slowly cross-link to form a solid inert polymer mass suitable for disposal to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer will be irreversibly cross-linked into the bonding resin matrix during the automated manufacture of DVDs. Up to 2% of the annual import volume of the notified polymer is expected to be released to landfill as waste collected from the cleaning of manufacturing equipment with rags, and from residue remaining in empty import carboys. The residue of the formulated product is expected to cross-link on exposure to UV-light to form a solid inert mass.

RELEASE OF CHEMICAL FROM DISPOSAL

DVDs containing the notified polymer bound in adhesive resin are expected to be disposed of to landfill at the end of their useful life.

7.1.2 Environmental fate

No environmental fate data were submitted. The majority of the notified polymer is expected to be disposed of to landfill as waste from the cleaning of manufacturing equipment, residues in empty import containers and DVDs at the end of their useful life. On exposure to UV-light, the formulation containing the notified polymer will slowly cross-link to form a solid inert resin matrix. Once cured, the notified polymer is irreversibly bound into the resin matrix and is not expected to be mobile or bioavailable. Abiotic hydrolysis is expected to be very slow under environmental conditions, due to the expected low water solubility of the notified polymer. It will eventually degrade, biotically or abiotically, to generate water and oxides of carbon.

The release of the notified polymer to the aquatic environment is not expected based on its reported use pattern.

In the unlikely event of release to sewer or surface waters, the notified polymer would likely be removed from the water column by sorption to sediment and sludge. As its molecular weight is >1000 Da, it is not expected to cross biological membranes and, therefore, it is not likely to bioaccumulate.

7.1.3 Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified polymer to the aquatic environment is not expected based on its reported use pattern.

7.2. Environmental effects assessment

No ecotoxicological data were submitted. Polymers without significant ionic functionality are of low concern to the aquatic environment.

7.2.1 Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as no significant aquatic exposure is expected based on its reported use pattern.

7.3. Environmental risk assessment

The risk quotient ($Q = \text{PEC}/\text{PNEC}$) 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 component in UV-curable bonding resin (industrial use only). The majority of the notified polymer will be disposed of to landfill as cured adhesive. In the cured adhesive the notified polymer is irreversibly bound into solid inert resin matrix, and is unlikely to be bioavailable or leach in this form. The low potential for environmental exposure resulting from this use pattern indicates that the notified polymer is not expected to pose a risk to the environment when used in the manner described.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicity data were provided for the notified polymer, it cannot be classified 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 unacceptable risk to the health of workers.

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

Environmental risk assessment

On the basis of the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer (as introduced):
 - Enclosed, automated processes
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer (as introduced):
 - Avoid skin and eye contact
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer (as introduced):
 - Coveralls, gloves, 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 chemical 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(2) of the Act; if
 - the function or use of the polymer has changed from a component of a bonding resin for the manufacture of DVDs, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 10 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.

No additional secondary notification conditions are stipulated.

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.

BIBLIOGRAPHY

- 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 (2010) TSCA New Chemicals Program (NCP) Chemical Categories. Washington, D. C., <http://www.epa.gov/oppt/newchems/pubs/npcchemicalcategories.pdf>