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

FULL PUBLIC REPORT

Urea, N,N-dimethyl-N'-phenyl-

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 the Environment, Water, Heritage and the Arts.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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:	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
NICNAS**

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FULL PUBLIC REPORT**Urea, N,N-dimethyl-N'-phenyl-****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

International Sales & Marketing Pty Ltd (ABN 36 467 259 314)
262 Highett Road
Highett VIC 3190

NOTIFICATION CATEGORY

Limited-small volume: Chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: purity, additives/adjuvants, use details, import volume and identity of recipients

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 reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada DSL (1994)
China IECSC (2010)
Europe EINECS (2010)
Europe REACH (2010)
Japan ENCS (2010)
Korea ECL (2010)
New Zealand NZIoC (2006)
Phillipines PICCS (2010)
USA TSCA (1985)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Omicure U405M

CAS NUMBER

101-42-8

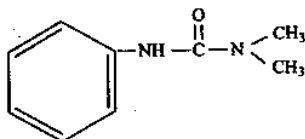
CHEMICAL NAME

Urea, N,N-dimethyl-N'-phenyl-

MOLECULAR FORMULA

C₉H₁₂N₂O

STRUCTURAL FORMULA



MOLECULAR WEIGHT

164 Da

ANALYTICAL DATA

Reference IR and HPLC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

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

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: off white powder

Property	Value	Data Source/Justification
Melting Point	133.5°C	Epi Suite v4.0 (exp database)
Boiling Point	313.70°C (pressure unknown)	Epi Suite v4.0 (adapted Stein and Brown method)
Density	> 1000 kg/m ³ (temperature unknown)	MSDS
Vapour Pressure	5.0 × 10 ⁻⁶ kPa at 25°C	Epi Suite v4.0 (exp database)
Water Solubility	3.85 g/L at 25°C	Published data
Hydrolysis as a Function of pH	t _{1/2} ~89 years at 25°C and pH 7	Published data
Partition Coefficient (n-octanol/water)	log K _{ow} = 0.98	Published data
Adsorption/Desorption	log K _{oc} = 1.43	Published data
Dissociation Constant	pK _a = 9.7 at 25°C	Published data
Particle Size	95% < 44 µm	Information provided by the notifier
Flash Point	> 100°C (pressure unknown)	MSDS
Flammability	Not determined	Not expected to form flammable mixtures in air.
Autoignition Temperature	440°C	Information provided by the notifier for an analogue*.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosives.

*Urea, N'-(3,4-dichlorophenyl)-N,N-dimethyl- (CAS No. 330-54-1).

DISCUSSION OF PROPERTIES

The notified chemical is a herbicide. The physical and chemical properties of this chemical have been widely documented in studies of the environmental fate and effects of pesticides. The environmentally relevant physico-chemical data and environmental effects used to assess this new industrial use are largely based on the literature for herbicides.

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

Reactivity

The notified chemical is expected to be stable under normal conditions.

Dangerous Goods classification

Based on the physical-chemical data in the above table the notified chemical 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 chemical.

5. INTRODUCTION AND USE INFORMATION**MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS**

The notified chemical will be imported in the neat form (> 90%).

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>	< 1	< 1	< 1	< 1	< 1

PORT OF ENTRY

Melbourne

IDENTITY OF RECIPIENTS

Formulation site in Kilsyth, Victoria

TRANSPORTATION AND PACKAGING

The notified chemical will be imported in 20 L pails and transported by road to the warehouse and the customer. The formulated adhesive product will be packaged and transported in 200 L polyethylene (PE) lined steel drums and in 20 L steel pails.

USE

An accelerator for epoxy based heat curable adhesives in paste form at < 1.0% used in the automotive industry (original equipment manufacturer only).

OPERATION DESCRIPTION

The notified chemical will be manually weighed and compounded with other ingredients in a ventilated booth. The compounded batch containing the notified chemical will then be added to a high speed mixer through an open chute with appropriate dust extraction. The mixing process will be kept below 30°C. After mixing, the paste adhesive (containing the notified chemical at < 1.0%) will be packed off into the appropriate container (either PE lined 200 L steel drums or 20 L steel pails) and stored in a cool store until ready for dispatch to customers.

At the customer site, the adhesive product in a paste form is then applied to car bodies and cured at the original equipment manufacturer.

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>
<i>Notified chemical</i>			
Distribution worker	1	1	2
Batch compounder	1	0.5	30
Batch mixer	1	0.5	30
<i>Formulated adhesive</i>			
Batch mixer	1	2	30
QC operator	1	1	30
Distribution worker	1	1	100
Customer worker	8	8	200

EXPOSURE DETAILS

Workers involved in transport and storage of imported notified chemical and formulated adhesive may be exposed to the notified chemical in the case of an accident where packaging is breached.

At formulation facilities, dermal, ocular (due to splashing) and inhalation (due to dust) exposure to the notified chemical at > 90% may occur during manual weighing when compounding, addition to the batch mixer and cleaning and maintenance of equipment. Workers involved in the formulation process are expected to wear impermeable gloves, goggles, protective clothing and respirators where appropriate to further minimise exposure. Inhalation exposure is expected to be further minimised through the use of local exhaust ventilation when handling the powdered notified chemical.

Exposure to no more than 1% notified chemical could occur during final application of the paste adhesive product. The main route of exposure is expected to be dermal. Inhalation exposure is not expected due to the paste form of the adhesive products and low vapour pressure of the notified chemical. Although the level and route of exposure will vary depending on work practices employed, exposure is considered to be low due to the low concentration of the notified chemical in the adhesive products.

After the product is applied to car bodies and cured, the notified chemical becomes irreversibly incorporated in the epoxy polymer and is unlikely to be bioavailable in this form.

6.1.2. Public exposure

Public exposure to the notified chemical in products as a result of transportation is unlikely unless there is an accident.

The notified chemical is intended for industrial use only. The public may come into contact with the dried adhesive containing the notified chemical at < 1% applied to car bodies. Once cured and dried, the notified chemical will be irreversibly bound to the polymer matrix and will not be bioavailable. Furthermore, the areas of application on the cars are such that the public are unlikely to come into contact with the cured form.

6.2. Human health effects assessment

No toxicity data were submitted for the notified chemical. The following table summarises the toxicological data for the notified chemical sourced from the MSDS provided by the notifier, TOXNET (2010) and/or RTECS (2010).

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>	<i>Source</i>
Rat, acute oral toxicity	LD50 = 6400 mg/kg bw; low toxicity	MSDS/TOXNET
Rabbit, acute dermal toxicity	LD50 = 4700 mg/kg bw; low toxicity	MSDS
Guinea pig, skin irritation	non irritating to mild irritation (intact skin) moderate irritation (abraded skin)	MSDS

Guinea pig, skin sensitisation	not sensitising	MSDS/TOXNET
Rat, repeat dose oral toxicity – 90 days.	NOEL > 500 mg/kg bw/day	TOXNET
Mutagenicity – bacterial reverse mutation	non mutagenic	MSDS
DNA inhibition, mouse, oral (no details)	Positive (500 mg/kg)	MSDS/RTECS

Toxicokinetics

Given the low molecular weight of the notified chemical and its log Kow of 0.98, it is likely to be significantly absorbed following oral, dermal or inhalation exposure.

Acute toxicity

Based on information reported in the MSDS and TOXNET, the notified chemical is expected to be of low acute oral and dermal toxicity.

Irritation and Sensitisation

The notified chemical does not contain structural alerts for irritation and sensitisation. Based on information reported in the MSDS and TOXNET, the notified chemical may be slightly irritating to skin but is not a skin sensitiser. Given some moderate irritation has been observed when applied to the abraded skin of guinea pigs there may also be potential for irritation to the eye.

Repeated Dose Toxicity

In a 90 day feeding trials, rats receiving 500 mg/kg diet showed no ill effects (TOXNET, 2010). The MSDS reports that at higher concentrations, the notified chemical may cause gastroenteritis and effects on the blood including anaemia and formation of methaemoglobin (cyanosis) based on animal data. No further details are available.

The MSDS reports that some teratogenicity and embryotoxicity effects have been reported in the literature (Talakin IuN, Nekrasova IA, Voloshina LT. 1989) and no further details are available.

Mutagenicity

Based on information reported in the MSDS, the notified chemical was found to non-mutagenic in a bacterial reverse mutation assay. However, the notified chemical has been reported to have DNA inhibition potential after oral administration at 500 mg/kg (MSDS; RTECS, 2010).

Health hazard classification

Based on the available data the notified chemical cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified chemical is expected to be of low acute oral and dermal toxicity, not a skin sensitiser but may be slightly irritating to the skin and eyes.

Workers most at risk will be those handling the notified chemical as introduced at > 90% and during formulation of the adhesive. Given these workers are expected to use PPE including respirators when handling the notified chemical in the powdered form and local exhaust ventilation will be in place for dust extraction, exposure should be limited and hence the risk to workers from use of the notified chemical is not considered unacceptable under the occupational settings described.

Given the paste-like nature of the adhesive and low concentration of the notified chemical (< 1%), exposure is expected to be negligible for application workers; hence the risk to these workers from use of the notified chemical is not considered unacceptable.

6.3.2. Public health

The public will not be exposed to the notified chemical; hence the risk to the public 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 chemical will be imported as a raw material for formulation into heat curable adhesives for use in the automotive industry. Up to 1% of the annual import volume of the notified chemical is expected to be released to landfill as waste collected from the cleaning of blending equipment and engineering controls, and from residue remaining in empty import containers. Steel import containers containing residues of the notified chemical may be sent to recycling facilities for metal reclamation. Accidental spills during transport or formulation are expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical is expected to be consumed during the application of the formulated product. The heat curable adhesive is used in original equipment manufacture, and the formulated product containing the notified chemical is applied to vehicle bodies. After application the adhesive is cured whereby the notified chemical becomes incorporated into the epoxy adhesive polymer matrix. Empty product containers containing the residue of the notified chemical are expected to be recycled or disposed of to landfill. Any spills during application or residues scraped from automobiles are also likely to be disposed of in landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

At the end of the vehicle's useful life the components containing the notified chemical within a cured matrix are expected to be disposed of to landfill or sent for metal reclamation.

7.1.2 Environmental fate

No new environmental fate data were submitted. The environmental fate properties of the notified chemical detailed in this report were obtained from literature available in the public domain.

It is expected that the majority of the notified chemical will be disposed of to landfill or metal reclamation facilities. The notified chemical is expected to be highly mobile in soil ($\log K_{oc} = 1.43$), however, in landfill the majority of the notified chemical will likely be trapped within a cured matrix. Once cured, the notified chemical becomes incorporated into the inert adhesive matrix and is not expected to leach. Abiotic hydrolysis of the notified chemical is slow and it is estimated to be not readily biodegradable (BIOWIN (v4.10), US EPA 2009), but it is not expected to bioaccumulate due to its low octanol/water partition coefficient ($\log K_{ow} = 0.98$) and its low predicted bioconcentration factor ($\log BCF < 0.5$, BCFBAF (v3.00) US EPA 2009). Notified chemical in the inert matrix of the cured product is not expected to be bioavailable. The notified chemical is likely to slowly degrade biotically in landfill, or by thermal decomposition during metal reclamation, to generate water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

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

7.2. Environmental effects assessment

The notified chemical is a herbicide and, accordingly, it has been found to exhibit toxicity towards algae. The results from ecotoxicological investigations conducted on the notified chemical (PPDB, 2010) are presented in the table below.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
-----------------	---------------	------------------------------

Fish Toxicity	LC50 (96 h) = 204 mg/L	Not harmful to fish
Aquatic Invertebrate Toxicity	EC50 (48 h) = 502 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	E _r C50 (72 h) = 1.45 mg/L	Toxic to algae

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified chemical is not harmful to fish or aquatic invertebrates, but is toxic to algae. The notified chemical was predicted to be not readily biodegradable, and based on its high acute toxicity to algae it was classified as toxic to aquatic life with long lasting effects.

7.2.1 Predicted No-Effect Concentration

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

7.3. Environmental risk assessment

The risk quotient ($Q = PEC/PNEC$) has not been calculated as release of the notified chemical to the aquatic environment is not expected based on its reported use as a component in heat curable adhesive. The majority of the notified chemical will be disposed of to landfill as cured adhesive or decomposed during metal reclamation. In the cured adhesive, the notified chemical is bound into an inert 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 chemical is not expected to pose a risk to the environment when used in the manner described.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]

and

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) 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
Aquatic environment	Acute Category 2	Toxic to aquatic life
	Chronic Category 2	Toxic to aquatic life with long lasting effects

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the reported use pattern, the notified chemical 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 chemical when in the powdered form:
 - Local exhaust ventilation
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
 - Avoid skin and eye contact
 - Avoid dust generation/inhaling dust
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and during formulation of the adhesive:
 - Coveralls
 - Impervious gloves
 - Eye protection
 - Dust masks when handling the notified chemical in powdered form

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 chemical 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 chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical 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(1) of the Act; if
 - the importation volume exceeds one tonne per annum notified chemical;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from an accelerator for epoxy based heat curable adhesives in paste form at < 1.0% used in the automotive industry (original equipment manufacturer only), or is likely to change significantly;

- the amount of chemical being introduced has increased from 1 tonne per year, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical 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 the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Water Solubility** 3.85 g/L at 25°C

Method Literature data (Sax, 1986).
Remarks The water solubility was estimated to be 9.53 g/L at 25°C based on a log K_{ow} of 0.98 (WSKOW (v1.41), US EPA (2009)).
Test Facility Sax (1986)

Hydrolysis as a Function of pH $t_{1/2} \sim 89$ years at 25°C and pH 7

Method The half-life at 25°C was extrapolated from kinetic measurements made under aqueous alkaline conditions at temperatures of 64°C and 84°C.
Test Facility Sabaliūnas et al. (1996)

Partition Coefficient (n-octanol/water) log K_{ow} = 0.98

Method Literature data (Hansch et al., 1995)
Remarks The log octanol-water partition coefficient (log K_{ow}) was calculated to be 1.38 (KOWWIN (v1.67), US EPA (2009)).
Test Facility Hansch et al. (1995)

Adsorption/Desorption log K_{oc} = 1.43
– screening test

Method Literature data (Sabljic, 1987)
Remarks The soil adsorption coefficient was calculated to be 41.55 (log K_{oc} = 1.62) by the MCI method and 24.65 (log K_{oc} = 1.39) by the K_{ow} method (KOCWIN (v2.00), US EPA (2009)). The notified chemical is expected to be highly mobile in soil.
Test Facility Sabljic (1987)

Dissociation Constant pK_a = 9.7 at 25°C

Method The pK_a value of the notified polymer (pK_a = 9.7 at 25°C) was inferred from the pK_a value of the hydrochloride salt of alpha-propyl-2-methyl-propioanilide, as the amidic bond of the propioanilide is similar to the amidic bond of the notified chemical.
Test Facility Sabaliūnas et al. (1996)

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