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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Acrylate ester in Sartomer CD278

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 and Water Resources.

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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
T.R. (Chemicals Australia) Pty Ltd (ABN: 57 001 268 006)
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:
Chemical name; Other names; CAS Number; Molecular formula; Structural formula; Molecular weight; Purity; Identity of toxic or hazardous impurities; % Weight of toxic of hazardous impurities; Non-hazardous impurities; Identity of additives/adjuvants; % Weight of additives/adjuvants; Manufacture/import volume; Use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC/708 (2006)

NOTIFICATION IN OTHER COUNTRIES
US (2004)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Acrylate ester
Acrylic ester

MARKETING NAME(S)
Sartomer CD278 (up to 90% acrylate ester)

ANALYTICAL DATA
A reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
Up to 90 %

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Clear colourless liquid

Property	Value	Data Source/Justification
Freezing Point	<-20.1°C	Measured
Boiling Point	Not determined	The notified chemical is

		expected to polymerise before reaching its boiling point.
Density	981 kg/m^3 at 20 ± 0.5°C	Measured
Vapour Pressure	1.4 x 10^{-3} kPa at 25°C	Measured
Water Solubility	9.54 g/L at 20°C	Measured
Hydrolysis as a Function of pH	$t_{1/2}$ > 365 d (pH 4, 25 °C) $t_{1/2}$ = 445 d (pH 7, 25 °C) $t_{1/2}$ = 5.88 d (pH 9, 25 °C)	Measured
Partition Coefficient (n-octanol/water)	log P_{ow} = 2.57 at 30°C	Measured
Adsorption/Desorption	log K_{oc} = 1.67 at 30°C	Measured
Dissociation Constant	Not Determined	There are no chemical groups capable of ionisation in the pH range 4-9
Particle Size	Not applicable	
Flash Point	114 ± 2°C at 101.3kPa	Measured
Flammability	Not determined	Based on the flash point, the notified chemical would not be classified as flammable according to the Australian Dangerous Goods classification (FORS, 1998).
Autoignition Temperature	216 ± 5°C	Measured
Explosive Properties	Negative	Predicted

Discussion of Observed Effects

For full details of the physical-chemical properties tests please refer to Appendix A.

Reactivity

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

Dangerous Goods classification

Based on the available physico-chemical properties the notified chemical is not classified as a Dangerous Good according to the Australian Dangerous Goods Code (FORS, 1998). However, the notified chemical is classified as a C1 combustible liquid according to *National Standard for the Storage and Handling of Workplace Dangerous Goods* (NOHSC 2001).

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured in Australia and will be imported as a neat material for reformulation.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤1	≤1	≤1	≤1	≤1

PORT OF ENTRY

Melbourne airport or Sydney or Melbourne port

IDENTITY OF MANUFACTURER/RECIPIENTS

T.R. (Chemicals) Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The notified chemical will be imported in 208 L (lined) steel drums. It will be transported by ground transportation to the T.R. Chemicals warehouse and subsequently to customers. No repackaging will occur.

USE
The notified chemical will be used as an additive in the manufacture of printing plates.

OPERATION DESCRIPTION
Reformulation
At the customer site, the neat notified chemical will be manually transferred, using a vacuum wand transfer tool, from the import drums into a blending vessel. It will then be mixed with other components in the enclosed vessel. Quality control personnel obtain samples of the blended final product for testing. The final product (printing plate formula containing 6 – 9% notified chemical) will be manually packaged using a dispensing tool connected to the blending vessel. The final containers will typically be 18kg pails or 200kg drums.

End use
At the end user sites, the product containing 6-9% of the notified chemical will be manually added to a tray containing a printing plate. The resulting film will then be cured within curing equipment that is largely enclosed.

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 per day)*	*Exposure Frequency (days per year)*
TR Chemicals			
Warehouse employee (receive and ship drums of CD278)	1-2	0.5-1	10-20
Customer			
Production blender/mixer	1	2-3	52-104
QC chemist	1	1	52-104
Packaging	1	3-4	52-104
End users			
Production employees	2-4	2	52-104

Exposure Details
Transport and storage
Workers at the TR Chemicals warehouse are unlikely to be exposed to the notified chemical, except in the unlikely event of an accident.

Reformulation
Dermal and ocular exposure of workers to the neat notified chemical may occur during manual transfer into the blending vessel for reformulation. Inhalation exposure is expected to be low based on the low volatility and the expected low potential for formation of aerosols. Exposure should be minimised by the use of local exhaust ventilation and personal protective equipment such as gloves and safety goggles.

Dermal and ocular exposure of workers to the notified chemical at concentrations of 6-9% may also occur during QC testing and packaging operations. Exposure during such operations is likely to be minimised by the wearing of skin and eye protection, by performing QC testing in a laboratory fume hood, and by utilising local exhaust ventilation during packaging procedures.

End-Use
Dermal and ocular exposure of workers to the notified chemical may occur when manually transferring the product to a tray, during curing, and during cleaning/maintenance of casting equipment. Exposure

should be minimised by workers wearing skin and eye protection. During curing, inhalation exposure to the notified chemical may also occur, however, this should be minimised by the largely enclosed and ventilated nature of the casting equipment. After curing, the notified chemical will be bound within a matrix on the printing plate and be unavailable for exposure.

6.1.2. Public exposure

The notified chemical will not be sold to the public. The printing plates that are produced will be for industrial use only. Therefore, public exposure to the notified chemical is expected to be negligible.

6.2. Human health effects assessment

No toxicological data were provided for the notified chemical.

The notified chemical contains an acrylate functional group, which is considered to be of high concern, and is likely to cause skin and eye irritation (HSIS, 2007; TSCA, 2002), and skin sensitisation (TSCA, 2002; Barratt, 1994). In addition, high dermal absorption is expected, based upon the relatively low molecular weight of the notified chemical (MW<500), its water solubility (100-10,000 mg/L), and its partition coefficient (logPow = 1-4) (European Commission, 2003). Therefore, there is the potential for skin sensitisation to occur upon exposure to the notified chemical.

Based on the potential for skin irritation and sensitisation, and classification performed by the notifier, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).
R36/37/38: Irritating to eyes, respiratory system and skin
R43: May cause sensitisation by skin contact.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified chemical has not been tested for any toxicological properties but is likely to be a skin and eye irritant and skin sensitiser based on the presence of an acrylate functional group, its molecular weight, water solubility and partition coefficient.

The risk of these effects exists when handling the neat imported products, particularly during manual transfer into the blending vessel when reformulating into final products. However, the risk should be minimised by the short exposure duration to the neat imported product, and the use of local exhaust ventilation and PPE, such as gloves and eye protection.

The potential risk of skin sensitisation also exists during handling of the reformulated product containing 6-9% of the notified chemical, particularly during QC testing, manual packaging operations, and manual addition of the product to trays for the manufacture of printing plates.

All operations involving the notified chemical should take place under local exhaust ventilation and workers should wear PPE to minimise skin exposure. Overall the risk to workers can be considered acceptable if such controls are in place.

6.3.2. Public health

The notified chemical will not be sold to the public. The flexographic plates are for industrial purposes only. Therefore, the risk to the public from the notified chemical will be negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical is imported and stored in a warehouse at room temperature prior to shipping to the customer for formulation. No releases to the environment are expected through the import, storage and transport of the notified chemical. Accidental spills of the notified chemical will be contained and the spilled chemical adsorbed on an inert support and disposed of to landfill.

The notified chemical will be transported to another site for reformulation into the printing plate formula. The clean-up of processing equipment at this site will result in up to 0.6% of the notified chemical being disposed of to waste water treatment. Spilled material is disposed of by incineration and solid wastes are sent to landfill. Residual notified chemical in the import drums is immobilised and disposed to landfill with the container and no release to the aquatic environment is expected by this pathway.

RELEASE OF CHEMICAL FROM USE

The formula is cured to form the printing plate articles at the end-user sites. It is expected that clean-up of the curing equipment and unused formula will result in the release of up to 1.1% of the notified chemical to waste water treatment. A further 0.45% will be released to waste water treatment from the clean-up of residual formula in the product containers.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical is irreversibly combined with other ingredients in the printing plates. Ultimate disposal of the plates to land-fill is therefore not expected to lead to release of the notified chemical.

7.1.2 Environmental fate

No environmental fate data were submitted.

7.1.3 Predicted Environmental Concentration (PEC)

The notified chemical is expected to be released in limited quantities into the aquatic environment from the manufacture of the printing plate formula and the printing plate articles. The Predicted Environmental Concentration arising from the anticipated release pattern has been modelled for the worst case in which none of the chemical is removed by either on-site waste water treatment or sewage treatment plants. As the notified chemical is to be used in specialised commercial applications, it is anticipated that release will occur on 260 days per year into only 25% of the total Australian effluent volume. The details of the calculation are presented below:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer (maximum)	2.1	%
Annual quantity of chemical released to sewer	21.00	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.08	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Fraction of population	25	%
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.08	µg/L
PEC - Ocean:	0.01	µg/L

7.2. Environmental effects assessment

No eco-toxicity data were submitted with this notification. The aquatic eco-toxicity of the notified chemical data was therefore modelled using the EPIWIN suite of models. The modelling inputs included such relevant experimental data as were supplied with this notification. The results of this analysis are summarised below:

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) 2.6 mg/L	Toxic
Daphnia Toxicity	LC50 (48 h) 10.7 mg/L	Harmful
Algal Toxicity	EC50 (96 h) 1.1 mg/L	Toxic

These modelling results indicate that the notified chemical is potentially toxic to aquatic life.

7.2.1 Predicted No-Effect Concentration

The Predicted No-Effect Concentration has been calculated from the algal toxicity of the notified chemical. As all of the toxicity data have been derived from modelling, the maximum assessment factor of 1000 has been used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Algae)	1.1	mg/L
Assessment Factor	1000	
Mitigation Factor	1.00	
PNEC:	1.1	µg/L

7.3. Environmental risk assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.08	1.1	0.07
Q - Ocean:	0.01	1.1	0.01

The Risk Quotients are much less than 1 for both the river and ocean disposal scenarios. Therefore, the notified chemical is not expected to pose an unacceptable risk to the aquatic environment based on the current use pattern and at the current import volume.

8. CONCLUSIONS – SUMMARY OF RISK ASSESSMENT FOR THE ENVIRONMENT AND HUMAN HEALTH

8.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). The classification and labelling details are:
R36/37/38: Irritating to eyes, respiratory system and skin
R43: May cause sensitisation by skin contact.

8.2. Human health risk assessment

8.2.1. Occupational health and safety

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

8.2.2. Public health

When used in the proposed manner the risk to the public is considered to be acceptable.

8.3. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the chemical is not considered to pose a risk to the environment based on its reported use pattern.

9. MATERIAL SAFETY DATA SHEET

The MSDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS and is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant. The MSDS was found to be in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003).

10. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - R36/37/38: Irritating to eyes, respiratory system and skin
  - R43: May cause sensitisation by skin contact.

- The following safety phrases for the notified chemical are recommended:
  - S25: Avoid contact with eyes
  - S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
  - S24: Avoid contact with skin
  - S28: After contact with skin, wash immediately with plenty of water.

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - concentration ≥ 10%: R36/37/38 (based on Hazardous Substances Information System, 2007, listing for acrylates)
  - concentration ≥ 1%: R43

Health Surveillance

- As the notified chemical presents a sensitisation health hazard, employers should carry out health surveillance 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 chemical:
  - Local exhaust ventilation should be in place during all operations involving handling of the notified chemical.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid contact with eyes and skin.
  - Avoid aerosol formation.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Gloves.
  - Safety goggles.
  - Protective clothing.

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.

Environment

Disposal

- The notified chemical should be disposed of by incineration or to landfill.

Storage

- The following precautions should be taken regarding storage of the notified chemical:
  - Storage in accordance with the *National Standard for the Storage and Handling of Workplace Dangerous Goods* [NOHSC:1015 (2001)] for C1 combustible liquids.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

11. REGULATORY OBLIGATIONS

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 regardless of whether the notified chemical has been listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director 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

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the notified chemical has changed from use in the manufacture of printing plates, or is likely to change significantly;
  - if the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the notified 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.

12 . BIBLIOGRAPHY

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United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.

Appendix A: Physico-Chemical Properties

Freezing Point < -20.1°C

METHOD OECD TG 102 Melting Point/Melting Range.
TEST FACILITY SafePharm (2006a)

Density 981 kg/m^3 at 20.0 ± 0.5°C

METHOD OECD TG 109 Density of Liquids and Solids.
Remarks Pycnometer
TEST FACILITY SafePharm (2006a)

Vapour Pressure 1.4 x 10^{-3} kPa at 25°C

METHOD OECD TG 104 Vapour Pressure.
Remarks The vapour pressure was determined by the effusion method (vapour pressure balance). The vapour pressure at 25°C was extrapolated from the dependence of the vapour pressure of the notified chemical on temperature in the range 9-19°C (10 replicates).
TEST FACILITY SafePharm (2006b)

Water Solubility 9.54 g/L at 20°C

METHOD OECD TG 105 Water Solubility.
Remarks The water solubility was determined by the flask method. The notified chemical in solution was quantified by high-performance liquid chromatography on a reverse-phase column.
TEST FACILITY SafePharm (2006a)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*t½ <hours or days>*
4	25	> 365
7	25	445
9	25	5.88

Remarks The notified chemical was determined to be hydrolytically stable at pH 4 by preliminary tests carried at 50°C over 5 days. After further testing, the half life of the notified chemical at pH 7 was determined by extrapolation from the Arrhenius plot of the hydrolysis rate constants. The half-life at pH 9 was determined by interpolation from the corresponding Arrhenius plot. The concentration of the notified chemical in solution was quantified by high-performance liquid chromatography on a reverse-phase column.
TEST FACILITY SafePharm (2006a)

Partition Coefficient (n-octanol/water) log P_{ow} = 2.57 at 30°C

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks The logarithm of the partitioning constant was estimated to be > 3.21 based on the approximate solubilities of the notified chemical in the two solvents. The definitive determination of the partitioning constant was carried out by high-performance liquid chromatography on a reverse-phase column. The retention time of the notified chemical was bracketed by those for the reference chemicals, benzonitrile and toluene, under the test conditions.
TEST FACILITY SafePharm (2006a)

Adsorption/Desorption – screening test

log K_{oc} = 1.67 at 30°C

METHOD OECD TG 121 Adsorption - Desorption By Means of an HPLC Method.
Remarks The adsorption-desorption constant was determined by high-performance liquid chromatography on a nitrile column under neutral pH conditions. The retention time of the notified chemical was bracketed by those for the reference chemicals, phenol and atrazine, under the test conditions.
TEST FACILITY SafePharm (2006a)

Dissociation Constant

Not Determined

Remarks The notified chemical does not have a group capable of ionisation in the pH range 4-9.
TEST FACILITY SafePharm (2006a)

Flash Point

114 ± 2ºC at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Closed cup equilibrium method.
The notified chemical is classified as a C1 combustible liquid according to NOHSC *National Standard for the Storage and Handling of Workplace Dangerous Goods* (NOHSC 2001).
TEST FACILITY SafePharm (2006b)

Autoignition Temperature

216 ± 5ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY SafePharm (2006b)

Explosive Properties

Not predicted to be explosive

METHOD EC Directive 2004/73/EC A.14 Explosive Properties.
Remarks The notified chemical does not contain any functional groups that would imply explosive properties. In addition, the testing laboratory has stated that the calculated oxygen balance of the notified chemical (-207) also indicates that the notified chemical would not pose an explosive risk.
TEST FACILITY SafePharm (2006b)

Oxidizing Properties

Not predicted to be oxidising

METHOD EC Directive 92/69/EEC A.21 Oxidizing Properties (Liquids).
Remarks The notified chemical does not contain any functional groups that would imply oxidising properties.
TEST FACILITY SafePharm (2006b)