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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component 1 in CYCOM 5250-4 RTM Resin

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:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cytec Australia Holdings Pty Ltd (ABN: 45 081 148 629)
Suite 1, Level 1 Norwest Quay
21 Solent Circuit
Norwest Business Park
Baulkham Hills NSW 2153

Huntsman Advanced Materials Australia Pty Limited (ABN: 93 091 627 879)
Gate 3
Ballarat Road
Deer Park, VIC 3023

Boeing Aerostructures Australia Pty Limited (ABN: 15 103 165 466)
226 Lorimer St
Port Melbourne VIC 3207

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 and structural formulae, molecular weight, purity, impurities and use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: boiling point, melting point, density, vapour pressure, water solubility, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, flash point, flammability and autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC/681 and CER/18

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CYCOM 5250-4 RTM Resin (contains < 40% of the notified chemical)

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY ≥ 90%

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid at ambient temperatures.
Boiling Point	> 445.2°C at 101.3 kPa	Calculated
Density	1080 kg/m^3 at 20°C	MSDS
Vapour Pressure	5×10^{-8} kPa at 20°C	MSDS
Water Solubility	0.14 x 10^{-3} g/L at 20°C	Estimated by WSKOW v 1.41
Hydrolysis as a Function of pH	Not determined	The notified chemical does not contain any groups that are likely to undergo hydrolysis.
Partition Coefficient (n-octanol/water)	log P_{ow} = 6.43 at 20°C	Estimated by KOWWIN v1.67
Adsorption/Desorption	log K_{oc} = 4.8-6.3	Estimated by KOCWIN v 2.00
Dissociation Constant	pKa_1 = 10.68; pKa_2 = 9.96	Dissociation constants (two dissociable moieties) estimated by ACD/I-Lab service.
Flash Point	> 200°C (closed cup)	MSDS
Flammability	Not expected to be highly flammable.	Based on flash point.
Autoignition Temperature	Not determined	Expected to be high based on flash point.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores.

DISCUSSION OF PROPERTIES

Reactivity

The notified chemical is not expected to be stable at temperatures significantly above room temperature based on its use in the manufacture of heat-cured composite structures.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured within Australia.

The notified chemical will be imported as a resin (CYCOM 5250-4RTM) at up to 40% concentration.

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

Sydney and Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS

Cytec Australia Holdings Pty Ltd
Suite 1, Level 1 Norwest Quay
21 Solent Circuit
Norwest Business Park
Baulkham Hills, NSW 2153

Huntsman Advanced Materials Australia Pty Limited
Gate 3
Ballarat Road
Deer Park, VIC 3023

Boeing Aerostructures Australia Pty Limited
226 Lorimer St
Port Melbourne, VIC 3207

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 20 L sealed pails as a resin it is anticipated that it may also be introduced in 4 L pails. The pails will be transported by road from the wharf to the customer's warehouse.

USE
The notified chemical will be imported as a component of resin for the manufacture of composite materials.

OPERATION DESCRIPTION
The notified chemical will not be manufactured or reformulated within Australia.

Truck drivers will transport the sealed CYCOM 5250-4 RTM resin (up to 40% notified chemical) containers by road from the wharf to the customer's warehouse and then used as needed. Two incoming goods receiving personnel will unload the containers of CYCOM 5250-4 RTM resin for storage in designated refrigeration equipment.

The CYCOM 5250-4 RTM resin containing the notified chemical will be moulded into articles at the customer's manufacturing site. CYCOM 5250-4 RTM resin will be used in a closed mould process known to the aerospace industry as Resin Transfer Moulding (RTM). In this process the resin will be removed from refrigeration (the resin is a one part, self catalysed system and will undergo slow, non facile curing at room temperature and above, thus requiring cold temperature storage) and allowed to warm to room temperature. The resin, in a solid state after refrigerated storage, will be transferred manually to a sealed pressure pot (4 L capacity) of the injection moulding system, which extrudes the resin into the mould under heat and pressure conditions. The resin will be then injected into the mould at a temperature range of 90°C – 120°C. The mould will be sealed from atmosphere and internal pressure maintained while the temperature is elevated to a cure temperature of 190ºC for 3 hours. After this initial cure process the matrix is near fully cross-linked. An in-situ post cure is then performed at 210ºC for 4 hours. The post cure stage increases the glass transition temperature (Tg) of the polymer matrix to allow continuous service of the finished part in operating temperatures of 180°C. The above processes will be carried out under local exhaust ventilation.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage			
Transporting from dock to customer's site for warehousing.	2	2-3	10 – 15
Manufacture of parts			
Workers involved in introducing CYCOM® 5259-4 RTM resin to resin moulding machine	2-4	0.5 – 6	30
Quality control/chemists and technical service	4-8	1	30
Workers involved in packaging of parts	4	3	30
End-use in Aerospace industry			
Assembly of aircrafts	10-15	6-8	50

EXPOSURE DETAILS
Transport and Storage

Waterfront, transport and warehouse workers will not be exposed to the notified chemical (at up to 40% in CYCOM 5250-4 RTM resin) except in the case of an accident.

Manufacture of articles
Dermal and ocular exposure to the notified chemical will be possible when manually transferring the resin (up to 40% notified chemical) to the pressure pot, during equipment maintenance or quality control testing. Exposure is expected to be minimised by the use of PPE including coveralls, goggles and gloves. Inhalation exposure to the notified chemical is likely to be negligible due to the very low vapour pressure (5×10^{-8} kPa at 20ºC) of the notified chemical, the enclosed systems and the use of exhaust ventilation.

End use -in aerospace parts
Exposure to notified chemical during end use is expected to be negligible. Once cured the notified chemical will be bound within a polymer matrix and will not be bioavailable.

6.1.2. Public exposure
There is negligible potential for public exposure to the notified chemical as it will only be used within the aerospace industry and once cured the notified chemical will be bound within a polymer matrix and will not be bioavailable.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix A.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50> 5000 mg/kg bw for males oral LD50 > 2000 and < 5000 mg/kg bw for females oral LD50 > 2000 and < 5000 mg/kg bw combined low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw low toxicity
Rabbit, skin irritation	corrosive

Toxicokinetics, metabolism and distribution.
Based on the low molecular weight (< 500 Da) and the lipophilicity of the notified chemical (water solubility 0.14×10^{-3} g/L at 20ºC; log Pow = 6.43 at 20ºC) dermal absorption may occur, but the transfer from the stratum corneum into the epidermis is expected to be slow.

Acute toxicity.
The notified chemical is considered to be of low acute toxicity via the oral and dermal routes based on tests conducted in rats.

Irritation and Sensitisation.
The notified chemical was found to be corrosive in a skin irritation test in rabbits, with effects still present at the end of the 14 day observation period.

Health hazard classification
Based on the skin irritation test the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:
R34 Causes burns

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Dermal and ocular exposure to the notified chemical (up to 40%) will be possible during the manufacture of articles. The notified chemical is corrosive and as such, good hygiene practices should be maintained and exposure to the skin and eyes minimised by the use of impervious gloves, safety glasses and protective clothing.

Given the risk of causing skin and eye damage, the risk to workers is likely to only be acceptable when used

under controlled conditions with the appropriate PPE.

6.3.2. Public health

There is negligible potential for public exposure to the notified chemical as it will only be used within the aerospace industry and once cured the notified chemical will not be bioavailable, as it will be bound in an inert polyurethane matrix. Therefore, the risk to public health is considered to be low, due to the expected negligible exposure.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The imported resin, in the end-use formulation, will be transported directly to customer's site for storage and use. Release of notified chemical would only arise from accidental spills during transport and handling operations.

RELEASE OF CHEMICAL FROM USE

Very little release of the notified chemical is anticipated during manufacture of parts for the aerospace industry. The closed mould process known as Resin Transfer Moulding (RTM) has a dedicated dispensing system and ≤0.5% of the annual introduction volume is expected to be released as a result of cleaning and maintenance operations. Spillage from pails during transfer operations is expected to account for ≤1% of the annual introduction volume. Residual within import containers may also account for ≤1% of the annual introduction volume. Any notified chemical that is not consumed in the manufacturing process is expected to react with other ingredients in the residual end-use formulation and cure under ambient environmental conditions prior to disposal.

RELEASE OF CHEMICAL FROM DISPOSAL

Resin collected from spillages, cleaning and maintenance operations and from residual within import containers is expected to be disposed of to landfill after curing, through reactions with other ingredients in the end-use formulation.

The majority of the notified chemical will share the fate of the manufactured composite components. Given their use in aircraft, it is expected that this will entail eventual disposal to landfill.

7.1.2 Environmental fate

No environmental fate data were submitted.

7.1.3 Predicted Environmental Concentration (PEC)

Release of the notified chemical to the aquatic environment is not expected to occur in any significant quantities at any stage in its lifecycle. Therefore, a Predicted Environmental Concentration cannot be estimated.

7.2. Environmental effects assessment

No ecotoxicity data were submitted.

7.3. Environmental risk assessment

The notified chemical will be imported into Australia in the end-use formulation. The notified chemical is expected to react with other ingredients in the end-use formulation and cross-link under ambient environmental conditions. During the reaction, the notified chemical will be consumed in the formation of an inherently stable cross-linked matrix. Release of the notified chemical to the aquatic environment is not expected under the proposed use pattern. Release of the notified chemical to atmosphere will not be significant due to its low vapour pressure, and the specific engineering practices employed. In landfill, cross-linked polymer matrix containing the notified chemical is expected to be stable, immobile and inert. Ultimately, it is expected that this will degrade via abiotic and biotic process to form simple organic compounds and water.

Therefore, the notified chemical is not considered to pose a risk to the aquatic environment under the proposed use and introduction volume.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the provided data the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The following risk phrase applies to the notified chemical:

- C: R34 Causes burns

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 2009) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Skin Corrosion/Irritation	Category 1	Causes severe skin burns and eye damage

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

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:
  - C: R34 Causes burns

- Use the following cut-off concentrations and risk phrases for products/mixtures containing the notified chemical:
  - Conc ≥ 10%: R34
  - ≥ 5% Conc < 10%: R36; R38

CONTROL MEASURES
Occupational Health and Safety

- Employers should ensure that the facilities are equipped such that operations involving the notified polymer are performed in a controlled manner. The following isolation and engineering controls should be in place to minimise occupational exposure to the notified polymer:
  - Automated processes
  - Sealed equipment

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in the product CYCOM 5250-4 RTM resin:
  - Avoid contact with skin and eyes

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the product CYCOM 5250-4 RTM resin:
  - impervious gloves
  - safety glasses
  - 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.

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;
  - the end use of notified chemical is not incorporation into articles.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of resin for the manufacture of composite materials, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 1 tonne, 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.

Material Safety Data Sheet

The MSDS of the notified chemical and products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Tif: RAIF(SPF), F3-hybrid of RII 1/Tif × RII 2/Tif
Vehicle	Arachis Oil
Remarks - Method	The test substance was administered via gavage. No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0
II	5 per sex	5000	5 females/2 males

LD50	> 5000 mg/kg bw for males > 2000 and < 5000 mg/kg bw for females > 2000 and < 5000 mg/kg bw for males and females combined
Signs of Toxicity	All female and 2 male rats in the 5000 mg/kg bw dose group died during the 14 day observation period. There was no mortality observed in the 2000 mg/kg bw dose group. Dyspnoea, ruffled fur, diarrhoea and a curved body position were symptoms noted in the 2000 mg/kg bw dose group with the same symptoms and also sedation noted in the 5000 mg/kg bw dose group.
Effects in Organs	There were no remarkable necropsy findings reported in the 2000 mg/kg bw dose group. In the 5000 mg/kg bw dose group dilation of the small intestine was seen in 1 male and 1 female with haemorrhagic lungs detected in the same female. No other findings were reported.
Remarks - Results	Body weight gains were as expected.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Ciba (1986a)

A.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/Tif: RAIF(SPF), F3-hybrid of RII 1/Tif × RII 2/Tif
Vehicle	Test substance administered as supplied
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Slight erythema and oedema seen in all animals which cleared by day 9 post exposure.
Signs of Toxicity - Systemic	Symptoms included dyspnoea, ruffled fur, a ventral body position and a

	curved body position.
Effects in Organs	There were no remarkable necropsy findings reported.
Remarks - Results	Body weight gains were as expected.

CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Ciba (1986b)

A.3. Irritation – skin

TEST SUBSTANCE	Notified chemical

METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 male
Vehicle	Test substance administered as supplied
Observation Period	14 days
Type of Dressing	Occlusive
Remarks - Method	No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	2.66	3.33	2.66	4	> 14 days	3
Oedema	2	2.33	2.33	4	> 14 days	2

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	There were no deaths during the course of the study. Body weight gains were as expected. The effects noted in the treated rabbits were not reversible within the 14 day observation period.
CONCLUSION	Although the irritation scores fall within the range for classification as a skin irritant, the study authors concluded that with the necrosis observed, full skin destruction is expected. Therefore, the notified chemical is corrosive to the skin.
TEST FACILITY	Ciba (1986c)

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