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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

X-31-1550

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Admil Adhesives Pty Ltd (ABN 85 092 730 562) of 5 Alimar Road, Glen Waverley, VIC, 3150.

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 identity
- Purity
- Spectral data
- Import volumes

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

- Dissociation constant
- Particle size
- Flammability limits
- Explosive properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (TSCA) EPA, P-89-0250 (1989)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
X-31-1550, KC-1A-5

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	UV, IR, ^{1}H NMR and LC/MS Spectroscopy
Remarks	Spectra provided. In the High Performance Liquid Chromatography (HPLC) analysis, four component peaks are typically observed. The dominant peak (component 2) was identified as the notified chemical.

3. COMPOSITION

DEGREE OF PURITY
>60%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is to be imported as a component (0.1-1% wt) of a silicone sealant.

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

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

USE
The notified chemical is imported as a curing agent present in silicone sealants at a concentration of 0.1-1%. The silicone sealants are widely used for many industries such as the electronics and construction industry.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not specified

IDENTITY OF MANUFACTURER/RECIPIENTS
The silicone sealant is repackaged at Admil Adhesives, Glen Waverley before being distributed to customers.

TRANSPORTATION AND PACKAGING
The silicone sealant containing the notified chemical is imported in 200 L drums. The sealant is repackaged into 300 g cartridges before being distributed to customers.

5.2. Operation description

Repacking
The sealant is repacked from 200 L drums to cartridges by automatic charge equipment. The cartridges are sealed by the automatic insertion of a plastic plunger on the same machine. The cartridges then roll off into boxes ready for distribution.

End Use
The silicone sealants primary application in the construction industry is to seal windows, roofs etc., to prevent ingress of water. The sealant is expected to be applied directly from cartridges using a caulking gun, although the uncured sealant may be worked using trowels or similar implements.

In the case of the use in electronics, again the silicone is applied with a caulking gun and left to cure.

5.3. Occupational exposure

Exposure Details
Repacking
It is estimated that 30 workers will be involved in repackaging and storage of the notified chemical. The repacking process is automated, therefore, worker exposure to the notified chemical is not expected except in the event of an accident. Workers will wear gloves, chemical protective clothing and eye protection. Local exhaust systems are in place to control inhalation exposure.

End Use
Although operators do not normally have any contact with the uncured silicone, incidental dermal exposure could occur during application of the silicone. Exposure to the cured product is most likely through dermal contact. Once cured it is expected that the notified chemical will not be bioavailable.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Since the notified chemical will not be manufactured or reformulated in Australia, it may potentially

only be released to the environment during importation, transportation, re-packaging, use and disposal of the chemical.

Environmental release of the notified chemical is unlikely during importation, storage and transportation, and accidental spills, leaks and catastrophic mechanical failure during a transport accident are the most likely reasons for environmental release. Engineering controls (eg. steel drum specifications, polythene bag liner) and emergency clean-up procedures (i.e. spill response instructions on Material Safety Data Sheet and label) will limit the impact on the environment of such incidents. Imported product will contain only 0.1-1% (w/w) of the notified chemical.

Drums holding the notified chemical will be transported directly from the Port facility to industrial facilities in Australia for storage prior to repackaging into 300 g cartridges using an automated pumping system.

Environmental release of the notified chemical due to spills and leaks or during the repackaging operation is expected to be negligible. Periodically, repackaging equipment will be cleaned using organic solvents (toluene, industrial gasoline).

Waste streams containing the notified chemical include residues in equipment cleaning solvents (up to 5 kg/year) and residues attached to imported drum liners (up to 25 kg/yr). On exposure to air, residues will cure to form an inert polymeric material.

RELEASE OF CHEMICAL FROM USE
The finished product will be used mostly in the field of electronics and building construction as a water sealant (eg. around windows). The sealant will be applied by caulking guns and left to cure.

On exposure to air, the cured and polymerised product is not expected to release the notified chemical. Tests conducted under AS4020:1999 indicate no leaching of the notified chemical from the polymer matrix into water (test report not provided).

Eventually, the majority of the notified chemical will be disposed of in landfill bound within the chemical matrix in the articles into which it has been cast at the end of their useful lifetime.

5.5. Disposal

Wastes containing the notified chemical generated from equipment washing (up to 5 kg/year) will be collected by a waste management firm for incineration.

Drum liners will be sent to landfill or incinerator for disposal.

Residues of notified chemical in emptied cartridges (<60 kg/yr) will be sent to landfill for disposal and/or incinerated.

Most of the notified chemical will eventually be disposed of in landfill bound within the chemical matrix in the articles into which it has been cast at the end of their useful lifetime.

5.6. Public exposure

The silicone sealant containing the notified chemical will only be sold to industry and therefore will not be available to consumers. Public exposure to the cured product is most likely to be through dermal contact. Once cured it is expected that the chemical will not be bioavailable.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa	Pale yellow viscous liquid
Pour Point	-11ºC

METHOD	OECD TG 102 Melting Point/Melting Range – Pour Point.
Remarks	No significant protocol deviations.

TEST FACILITY SafePharm Laboratories (2003a)

Boiling Point >252ºC at 101.3 kPa

METHOD OECD TG 103 Boiling Point – Differential Scanning Calorimetry (DSC)
Remarks No significant protocol deviations
The test material decomposed from approximately 252ºC without boiling. The boiling point has been estimated as >360ºC using an adaptation of the Stein Brown method.
TEST FACILITY SafePharm Laboratories (2003a)

Density 1310 kg/m^3 at 20ºC

METHOD OECD TG 109 Density of Liquids and Solids-Pycnometer method
Remarks No significant protocol deviations. Solvent used: Distilled water.
TEST FACILITY SafePharm Laboratories (2003a)

Vapour Pressure <8.6 x 10^{-8} kPa at 25ºC (estimation)

METHOD OECD TG 104 Vapour Pressure -Vapour Pressure Balance.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Consistent results could not be obtained using a Vapour Pressure Balance Method. (Subsequent attempts to obtain data by performing a relative reduced pressure boiling point determination were also unsuccessful due to decomposition of the sample.) A theoretical value based on the structure was calculated.
TEST FACILITY SafePharm Laboratories (2003b)

Water Solubility 1.26 g/L at 20ºC

METHOD OECD TG 105 Water Solubility - Flask Method.
EC Directive 92/69/EEC A.6 Water Solubility - Flask Method.
Remarks Analytical method: HPLC.
Four component peaks were observed and measured in the test; however, the dominant peak (component 2) was identified as the notified chemical. The absence of relative percentage composition data prevented the calculation of definitive water solubilities for each of the four components. Therefore, although each component was monitored individually, the results calculated are with respect to the test material as a whole. The solubilities of these four components are reported as $\geq$89.5, 1.26, $\geq$94.9 and 2.95 x10^{-2} equivalent grams of test substance per litre of solution respectively.

Limited hydrolysis of the notified chemical was unavoidable during testing.

TEST FACILITY SafePharm Laboratories (2003a)

Hydrolysis as a Function of pH The half-life times at 25ºC are ~36-215 days at environmentally relevant pH range of 4-9.

METHOD OECD TG 111: Hydrolysis as a Function of pH.

pH	*Rate Constant*	*Estimated half-life 25 ºC*
4	2.20x10^{-7}	36.4 days
7	3.73x10^{-8}	215 days
9	9.63x10^{-8}	83.3 days

Remarks A preliminary test only was performed in the dark at 50, 60 and 70±0.5ºC at pH 4, 7 and 9 to estimate the rate constant and half-life. An additional test was performed at pH 1.2 (37±0.5°C; half life 37.1 hours). Sample solutions were prepared at a nominal concentration of 0.40 g/L in 3 buffered solutions. A 1% co-

solvent of acetonitrile was used to aid solubility.
TEST FACILITY SafePharm Laboratories (2003b)

Partition Coefficient (n-octanol/water) log Pow <0.3–3.55, potentially 5.91

METHOD OECD TG 117 Partition Coefficient
Remarks HPLC Method. Preliminary and definitive tests were performed. An aliquot of test material (0.0625 g) was diluted to 100 mL with acetonitrile. The dead time was determined by measuring the retention time of thiourea in acetonitrile. A series of solution references were prepared in acetonitrile. Tests were conducted in duplicate. Results by component were: Component 1 log Pow: <0.3, Component 2 (notified chemical) log Pow: 0.542, Component 3 log Pow: 2.88, and Component 4 log Pow: 3.55. SafePharm Laboratories (2003b) indicate that the HPLC test method probably underestimates the actual log Pow value. Using the software KOWWIN (version 1.66, Syracuse Research Corporation), a log Pow of 5.91 was obtained.
TEST FACILITY SafePharm Laboratories (2003b)

Adsorption/Desorption Log Koc <1.25-3.22, potentially 4.09

METHOD OECD Method 121: Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).
Remarks Test material (0.0486 g) was diluted to 100 mL with acetonitrile. Dead time was determined by measuring the retention time of formamide. A series of reference standards were prepared in acetonitrile and analysed by HPLC. SafePharm Laboratories indicate that the HPLC test method probably underestimates the actual log Koc value and a log Koc of 4.09 was derived by QSAR.
TEST FACILITY SafePharm Laboratories (2003b)

Dissociation Constant Not determined

Remarks No testing was carried out using OECD Method 112. The chemical structure of the main component of the chemical presents no mode of dissociation in water.
TEST FACILITY SafePharm Laboratories (2003a)

Particle Size Not applicable

Remarks Notified chemical is a liquid.

Flash Point 113ºC at 101.325 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point- equilibrium closed cup.
Remarks No significant protocol deviations.
TEST FACILITY SafePharm Laboratories (2003b)

Flammability Limits Not determined

Remarks There is no standard test method for determining the flammability limits for liquids. The notified chemical is considered to be not highly flammable.

Autoignition Temperature >400ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY SafePharm Laboratories (2003b)

Explosive Properties Non Explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks From examination of the structure, there are no chemical groups that would infer explosive properties, therefore the result has been predicted negative.
TEST FACILITY SafePharm Laboratories (2003b)

Reactivity

Remarks	Expected to be stable under normal conditions of use. Contact with oxidising materials should be avoided.

ADDITIONAL TESTS

Oxidizing Properties Non Oxidizing

Remarks	From examination of the structure, there are no chemical groups that would infer oxidising properties, therefore the result has been predicted negative.
TEST FACILITY	SafePharm Laboratories (2003b)

7. TOXICOLOGICAL INVESTIGATIONS

No toxicity data were submitted

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted for the notified chemical. Structurally similar chemicals express aquatic ecotoxicity.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

There is a low potential for environmental release of the notified chemical during repackaging activities or use of the notified chemical.

The sealant containing the notified chemical will cure and polymerise to an inert matrix and environmental release of the notified chemical is unlikely to occur following its use or disposal of drum liners and cartridges.

Eventually, the majority of the notified chemical will be disposed of in landfill bound within the chemical matrix in the articles into which it has been cast at the end of their useful lifetime.

In landfill, it is anticipated that the cured chemical will not be mobile and will undergo slow abiotic or biotic degradation. The notified chemical will be destroyed if incinerated, releasing oxides of tin and carbon, and water.

The notified chemical is not volatile and volatilisation to the atmosphere is not likely to be a major migration pathway. The main components of the notified chemical are readily soluble in water and it will hydrolyse in environmental waters over time. With an estimated log Pow range for components of the notified chemical of <0.3–3.55 (potentially 5.91), the notified chemical has an affinity for lipids and may potentially bioaccumulate in exposed organisms. An adsorption co-efficient (Log Koc) range of <1.25-3.22 (potentially 4.09) indicates that the notified chemical is probably immobile in soils and has an affinity to sediments.

9.1.2. Environment – effects assessment

No data were provided for the notified chemical. Results provided for a structurally similar analogue indicate the notified chemical is not likely to be toxic up to the limit of its solubility in water. No details of the test methods or structure of this analogue have been provided.

9.1.3. Environment – risk characterisation

The notified chemical is an additive in composite resins, and as such, most of the chemical will be incorporated into the inert sealant matrix when cured, posing little risk to the environment. Most waste sealant generated during use and in container residues will cure, binding the chemical within the polymer matrix in an inert manner. Given the low volume usage and the low aquatic exposure of the notified chemical, the notified chemical is unlikely to pose an unacceptable risk to the environment. In landfills the notified chemical is likely to remain immobile and leaching is unlikely to occur.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Repacking

Due to the automated nature of the repacking process exposure to the notified chemical is not expected to occur except in the event of an accident or machine malfunction. Even in these cases, exposure is expected to be low due to the low concentration of the notified chemical (0.1-1%) and the expected use of personal protective equipment.

End Use

Exposure to the notified chemical at a concentration of 0.1-1% could occur during application of the sealant, before the sealant cures. Exposure would be dependent on the size of the application area and the accuracy of, and care taken by, the worker. It is anticipated that the potential for exposure is greater in the construction industry than the electronic industry.

Once the sealant is cured, the notified chemical will not be bioavailable and therefore exposure is expected to be negligible.

9.2.2. Public health – exposure assessment

The public will only have contact with the sealant containing the notified chemical once it has cured. Once the sealant is cured, the notified chemical will not be bioavailable and therefore exposure is expected to be negligible.

9.2.3. Human health - effects assessment

No toxicological data have been provided for the notified chemical. The notified chemical is a dibutyltin dicarboxylate. Information provided below relates to other dibutyltin dicarboxylates or other dibutyltin compounds and indicates the likely human health effects of the notified chemical. Only summary data has been used (ACGIH (2001), IPCS (1980), Kirk-Othmer (1997), RTECS (2004)), no study reports have been evaluated.

Acute toxicity.
Acute oral toxicity LD50 values in rats have been reported for various dibutyltin dicarboxylates in the range 100 – 250 mg/kg bw. There was no apparent relationship between the lethal dose and the number of carbons in the ester group. Dermal and inhalation acute toxicity data is less available. For one dibutyltin dicarboxylate the dermal and inhalation LD50 values were >2000 mg/kg bw in rabbit and 150 mg/m3/hour in mouse respectively.

Based on this information, the notified chemical is likely to be harmful or toxic if swallowed.

Irritation and Sensitisation.
Skin irritation ranging from severe to non irritating was reported after contact with various dibutyltin compounds. Moderate eye irritation was reported for one dibutyltin dicarboxylate. Some dibutyltin compounds are known to produce gastrointestinal irritation. There were no discussions of sensitisation properties.

Based on this information, the notified chemical may be irritating skin, eyes and the respiratory system.

Subchronic Toxicity
Dibutyltin dichloride is a potent thymolytic agent in rats exposed orally or by parenteral injection which causes severe, reversible thymic atrophy. Alkyltin-induced thymic atrophy has been associated with the impairment of T-cell-dependent immunity.

Based on this information, the notified chemical may have an adverse effect on immune function.

Genotoxicity
A dibutyltin dicarboxylate was negative in a bacterial mutation assay with *Salmonella typhimurium* in the presence and absence of metabolic activation and negative in a sex-linked recessive lethal mutation assay in *Drosopohila melanogaster.*

Exposure Guidelines
Relevant exposure standards for atmospheric contaminants in the occupational environment (NOHSC, 1995) are:
Tin, organic compounds (as Sn) 0.1 mg/m3 (TWA) and 0.2 mg/m3 (STEL)

ACGIH is the document source for this standard. ACGIH base their decision mainly on toxicological data for both trialkyltin and dialkyltin compounds.

The threshold limit value (TLV) –TWA is intended to minimize the potential for adverse effects on the immune function and central nervous system. The TLV-STEL was recommended to minimize acute symptoms such as eye and upper respiratory tract irritation, headache and nausea.
A skin notation (meaning absorption through the skin may be a significant source of exposure) was assigned, based on animal data and the potential danger of enhanced absorption due to the damaged skin.
Because studies in rats and mice demonstrated no carcinogenic effects, the A4 ‘not classifiable as a human carcinogen’ notation was assigned.

Health effects of notified chemical
Based on analogue data, the notified chemical is likely to be acutely and chronically toxic and has the potential to cause irritation to the skin, eyes and respiratory tract. Organotin compounds are also absorbed through the skin; the notified chemical has a relatively high molecular weight (> 500), however, smaller organotin molecules generated through degradation, particularly hydrolysis, may be absorbed.

Hazard classification for health effects
Although some dibutyltin compounds are listed in the NOHSC *List of Designated Hazardous Substances* (the List) (NOHSC, 2003) there is no listing for dibutyltin compounds as a whole. However, as organotin compounds have a NOHSC exposure standard and are therefore included on the List, members of this class of chemicals are considered to be hazardous substances.

No toxicological data were provided for the notified chemical and therefore a detailed hazard classification, with relevant risk phrases, is not possible in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is likely to be acutely and chronically toxic and has the potential to cause irritation to the skin, eyes and respiratory tract. It may also be absorbed through the skin. However, the notified chemical is only introduced in Australia as a 0.1-1% component of a sealant product. Therefore, although exposure to the notified chemical may occur during application of the sealant, the risk to workers is expected to be low due to the low concentration of the notified chemical.

The exposure standard for tin, organic compounds is unlikely to be exceeded due to the low concentration of the notified chemical as introduced, the predicted low vapour pressure of the notified chemical and the fact that aerosol formation will not occur during use.

Exposure to the notified chemical during repacking is expected to be low and therefore the risk to workers involved in the repacking process is also expected to be low.

Exposure to the notified chemical from contact with the cured sealant is expected to be negligible and therefore the risk to workers from such contact is also expected to be negligible.

9.2.5. Public health – risk characterisation

Exposure to the notified chemical is expected to be negligible and therefore the risk to public health from the proposed use is expected to be negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

As the notified chemical is an organotin compound, it is subject to the NOHSC exposure standard for this class of chemicals and is therefore included on the List as a hazardous substance.

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the

occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the product containing the chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification

- The notified chemical is a hazardous substance and all necessary controls and precautions under Australian hazardous substances legislations must be implemented.

AICS Listing

- When the notified chemical is added to the Australian Inventory of Chemical Substances (AICS), it should be annotated with the following condition of use:
  - 'for use in imported sealants at less than 3%'.

- For all other types of introduction the notified chemical will be regarded under the Act as a new chemical, and therefore subject to notification and assessment.

CONTROL MEASURES

Occupational Health and Safety

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

- No specific engineering controls or personal protective equipment are required for the safe use of the notified chemical as introduced (<1% in product), however, these should be selected on the basis of all ingredients in the formulation.

  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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
  - Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

- The notified chemical should be incinerated in a suitable incineration plant observing local authority regulations.
- The waste material containing the notified chemical should be disposed of to landfill.

Emergency procedures

- In case of spill, contain the spill or leak. Scrape up with rag or dry inert material (e.g. sand, vermiculite) and place into appropriately labelled drums for disposal as chemical waste.

AICS

- When the notified chemical is added to the Australian Inventory of Chemical Substances (AICS), it should be annotated with the following condition of use:
  - 'for use in imported sealants at less than 3%'.
- For all other types of introduction the notified chemical will be regarded under the Act as a new chemical, and therefore subject to notification and assessment.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under subsection 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical; or
  - the notified chemical is introduced at a concentration $\geq$ 3%

or

(2) Under subsection 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required. For secondary notification a full suite of toxicological and ecotoxicological data for the notified chemical will be required.

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