

File No: NA/150

Date: August 19, 1994

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

TEGO RC 726

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989*, and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Human Services and Health.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**TEGO RC 726****1. APPLICANT**

International Sales and Marketing Pty Ltd, 262 Highett Rd, Highett, Victoria, 3190

2. IDENTITY OF THE CHEMICAL

TEGO RC 726 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae have been exempted from publication in the Full Public Report and the Summary Report.

Trade name: TEGO RC 726

Number-average molecular weight: 9146

Weight-average molecular weight: 47530

Maximum percentage of low molecular weight species (molecular weight < 1000): 5%

Method of detection and determination:

IR and NMR spectroscopy, GC, GPC

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: Pale yellow liquid

Odour: Ester-like

Boiling Point: Not measured

Density: 1000 kg/m³ at 20°C

Vapour Pressure: Not expected to be significant for a polymer

Water Solubility: < 17 mg/L

Partition Co-efficient (n-octanol/water) log P_{O/W}: Not measured due to water insolubility

Hydrolysis as a function of pH: No hydrolysis is expected in the pH range of 4-9. However, at pH values less than 2 and greater than 11 above 90°C cleavage of Si-O-Si bonds of dimethyl polysiloxane will occur.

Dissociation Constant

pKa: Not applicable

Flash Point: > 100°C

Flammability Limits: Not applicable

Combustion Products: SiO₂, CO₂, H₂O

Reactivity/Stability: Stable under normal conditions and does not degrade

Comments on Physico-chemical Properties

Methods for determining boiling points are not appropriate for a polymer, and thus tests were not conducted. This is acceptable.

The water solubility was determined according to the analytical procedure THG.AL022-14 (which according to the company corresponds to the OECD Guideline 105) and was based on the silicon content in solution. High molecular weight silicones have a high affinity for the inter-facial surfaces between two media, and are noted for being extremely hydrophobic, and are generally completely insoluble (1).

Hydrolysis is possible, as the polymer contains ester groups, but is not expected under environmentally relevant conditions (ie. pH 4-9). However, at pH below 2 and over 11, and at > 90°C, cleavage of the Si-O-Si bonds of dimethyl polysiloxane may occur.

As the tests for partition co-efficients, dissociation constants and adsorption/desorption would not be applicable given the insoluble nature of the polymer, the omission of these tests is acceptable.

4. PURITY OF THE CHEMICAL

Degree of purity: 94%

Toxic or hazardous impurities (> 0.1% by weight): None

Non-hazardous impurities (> 1% by weight):

Chemical name:	Octamethylcyclotetrasiloxane
CAS No.:	556-67-2
Weight percentage:	1.4%

There are unidentified higher cyclic or linear dimethylpolysiloxanes at 2.4% by weight

Maximum content of residual reactants: 1.9%

Additives/Adjuvants: None

5. INDUSTRIAL USE

The notified chemical is to be used in a release coating for paper or plastic films.

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported in 50 and 200 kg open top drums at levels. It will be decanted into mixing vessels where it is added to another polymer, TEGO RC 711, the subject of another notification statement.

Primarily, two stores people will be handling containers of the notified chemical and rolls of coated product for about 30 hours per month.

Six people involved in mixing will be pouring ingredients into a mixing tank where they will be stirred by a propeller style motorised mixer. Mixing is carried out in a ventilated, flame-proof room with a separate exhaust system for the mixing tank. The duration of exposure is likely to be 8 hours per month.

Six people will be involved in operating a 3 roll coater which will be running for approximately 67 hours per month.

Two laboratory staff will perform various quality control tests to the finished product and monitor the incoming raw material quality for a maximum time of 3-4 hours per month.

7. PUBLIC EXPOSURE

There is low potential for public exposure to the uncured polymer during industrial blending and coating operations. TEGO RC 726 is not expected to exhibit significant mobility if accidentally released, being a viscous, water insoluble liquid with negligible vapour pressure. Spills are to be mixed with absorbant material and incinerated.

Widespread but intermittent public exposure to TEGO RC 726 will arise from handling adhesive release sheets. However, prolonged dermal contact with the coated surface is unlikely, and by this stage TEGO RC 726 will have been incorporated into the polymer matrix.

8. ENVIRONMENTAL EXPOSURE

. Release

The company has indicated that during the coating process, any spray or mists that may be produced are drawn into an extraction system. The company stated that wastes produced as a result of application should be incinerated. At present, the polymer is expected to be used at one site only, but the notifier expects that several customers will adopt the process over the next few years.

Although no estimates of waste are given in the submission, it would be expected that only minimal amounts of waste would be produced. Therefore, assuming that 1-2% of the polymer will be present as spills during the formulation and blending process, approximately 0.25 tonnes will be produced as wastes to be burnt per year.

The only other means of release of the polymer to the environment would be through products going to landfill. Again, exposure is expected to be low, as the polymer would be in a cured state when disposed of, and in a very dispersed manner.

Fate

TEGO RC 726 is a polymer with low water solubility, therefore leaching from landfill sites is not expected. Incineration of notified polymer is expected to produce oxides of carbon, silicon and nitrogen, and possible toxic gases depending on the conditions of pyrolysis.

The notified polymer is not expected to be released to the environment until it has been fully cured into release strips. The resultant matrix structure should limit the hydrolysis or biodegradation of the polymer. The high molecular weight should preclude any risk of bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

The Industrial Chemicals (Notification and Assessment) Act 1989 does not require the provision of toxicology data for polymers where the number average molecular weight exceeds 1,000. However, some studies were available for TEGO RC 726 and are evaluated below.

Table 1 Summary of the acute toxicity of TEGO RC 726

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD ₅₀ > 5000 mg/kg	2
Skin irritation	Rabbit	non-irritant	3
Eye irritation	Rabbit	slight irritant	4
Skin sensitisation	Guinea pig	non-sensitiser	5

9.1.1 Oral Toxicity (2)

The notified polymer was administered to Wistar rats (5/sex) by gavage at a dose level of 5000 mg/kg followed by a 14-day observation period.

No mortality was observed and no macroscopic findings were noted at necropsy. The only clinical signs observed were increased piloerection in some animals between 6 hours and 2 days after application.

It can be concluded that the oral LD₅₀ for TEGO RC 726 is > 5000 mg/kg.

9.1.2 Skin Irritation (3)

TEGO RC 726 was tested for its potential as a skin irritant on the intact and abraded skin of 6 New Zealand White rabbits.

A gauze pad containing 0.5 ml of the test substance was placed on the left side of the back of each rabbit. On the right side the skin was abraded prior to application of the gauze pad. Control areas were treated in the same way without test substance. The gauze pads were secured with sticking plaster and wrapped securely. After 4 hours the cuffs were removed and the residues of the test substance removed if necessary with lukewarm water. Skin reactions were evaluated at 30 - 60 minutes, 24, 48 and 72 hours post treatment.

No erythema or oedema was observed in any animal at any time point.

It can be concluded that TEGO RC 726 is not a skin irritant in rabbits.

9.1.3 Eye Irritation (4)

Into the conjunctival sac of each left eye of 6 New Zealand White rabbits was placed 0.1 ml of TEGO RC 726. The right eye of each rabbit served as control.

Readings of ocular reactions were made 1, 24, 48 and 72 hours after treatment with an ophthalmoscope.

No effects on the cornea or iris were observed for any animal at any time point.

At one hour post-treatment, slight conjunctival redness was observed in 4 animals and moderate conjunctival redness was observed in 2 animals. In one of these animals, slight conjunctival redness persisted to 24 hours.

It can be concluded that TEGO RC 726 is a slight eye irritant.

9.1.4 Skin Sensitisation (5)

TEGO RC 726 was tested for skin sensitisation in guinea pigs of the Pirbright strain using the method of Magnusson and Kligman (6).

Twenty animals were used in both test and control groups. The treatments were as follows:

1st Induction

The test compound (5% in peanut oil or Freund's complete adjuvant (FCA)) was injected in 100 microlitre amounts, intradermally, in the shoulder area. FCA (diluted 1:2 in water) was also injected alone. Control injections were of FCA (diluted 1:2 in water), vehicle alone and vehicle diluted 1:2 with FCA. Injections were in pairs on either side of the spine.

2nd Induction

Seven days after the 1st induction, either undiluted test substance or peanut oil as control was applied to the injection sites under a semioclusive patch for 48 hours.

Because the test article was non-irritating at all concentrations, the area to be treated was pretreated with 10% sodium lauryl sulfate in petrolatum. Treatment with test substance was conducted 24 hours later.

Challenge

Three weeks after the 1st induction, either undiluted test substance or peanut oil as control was applied to the clipped flank of the animals under a semioclusive patch. The patch was removed after 24 hour and scoring was conducted at 48 hours.

No erythema or oedema was found in any animal at either the 24 or 48 hour time points following challenge.

It can be concluded that TEGO RC 726 is not a skin sensitiser in guinea pigs.

9.4 Overall Assessment of Toxicological Data

TEGO RC 726 was shown to be of very low acute oral toxicity in rats, was not a skin irritant but was a slight eye irritant in rabbits and was not a skin sensitiser in guinea pigs.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were supplied, which is acceptable under the Act. However, given the low water solubility and the high molecular weight, the polymer should not display any markedly ecotoxicological properties.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The polymer is unlikely to present a hazard to the environment at any stage of its use. Very small amounts would be expected to be released as a consequence of blending or application to the paper products. Wastes produced will either be burnt (formulated product) or consigned to landfill (waste paper, nappies etc). Leaching of the cured polymer from landfill is not expected due to the chemical and physical bonding which occurs during the surface coating process.

The low environmental exposure of the polymer as a result of normal use indicates that the overall environmental hazard should be negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The toxicological profile of TEGO RC 726 suggests that it is unlikely to produce acute toxic effects upon ingestion and dermal contact and is not likely to irritate the skin or to provoke skin sensitisation in humans. However, it may be a slight eye irritant.

The high number average molecular weight of TEGO RC 726 suggests it is unlikely to be absorbed across biological membranes and is unlikely to be a health hazard. Residual monomers and reactants (some of which become modified in the polymer matrix) are at low levels and are unlikely to cause adverse health effects.

Exposure to the notified polymer as a mist is most likely to occur during mixing to produce the finished adhesive prior to its addition to the coating machine. However, mixing occurs infrequently and the fact that the polymer is a viscous liquid with a low vapour pressure makes contact easily prevented.

There is potential for widespread but intermittent public exposure to TEGO RC 726 when handling release sheets coated with the notified polymer. However, prolonged contact with the treated surface is unlikely, and the notified polymer will be in its cured state where absorption should be negligible.

It can be concluded that there is a low risk of adverse health effects to workers and the public under normal conditions of use.

13. RECOMMENDATIONS

To minimise occupational exposure to TEGO RC 726 the following guidelines and precautions should be observed:

- . if engineering controls and work practices are insufficient to reduce exposure to TEGO RC 726 to a safe level, then personal protective devices which conform to and are used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS 1337) (7,8), impermeable gloves (AS 2161) (9) should be worn. Overalls also should be worn;

- . good work practices should be implemented to avoid spillages and splashing;
- . good personal hygiene should be observed;
- . a copy of the Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The attached Material Safety Data Sheet (MSDS) for TEGO RC 726 was provided in Worksafe Australia format (10).

This MSDS was provided by International Sales and Marketing Pty Ltd as part of their notification statement. The accuracy of this information remains the responsibility of International Sales and Marketing Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of TEGO RC 726 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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3. *Primary Dermal Irritation Test of Tego-Siliconacrylate RC 725 in Rabbits*, Data on File, International Bio Research, Hanover, Germany. Project No.: 10-03-1871-89, 1990.
4. *Primary Eye Irritation of Tego-Siliconacrylate RC 725 in Rabbits*, Data on File, International Bio Research, Hanover, Germany. Project No.: 10-03-1872-89, 1990.
5. *Guinea Pig Maximisation Test of Skin Sensitisation with Tego-Siliconacrylate RC 725*, Data on File, International Bio Research, Hanover, Germany. Project No.: 10-05-1873-89, 1990.
6. Magnusson, B. and Kligman, A.M. *Allergic Contact Dermatitis in the Guinea-pig: Identification of Contact Allergens*. Thomas, C.C., Springfield, Illinois, USA, 1970.
7. Australian Standard 1336-1982, *Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, 1982.
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10. National Occupational Health and Safety Commission, *Guidance Note for the Completion of a Material Safety Data Sheet*, 2nd. edition, AGPS, Canberra, 1990.