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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

TEGO RC 711

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**TEGO RC 711****1. APPLICANT**

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

2. IDENTITY OF THE CHEMICAL

TEGO RC 711 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 711

Number-average molecular weight: 1257

Weight-average molecular weight: 2023

Maximum percentage of low molecular weight species (molecular weight < 1000): 18.1%

Method of detection and determination:

IR and NMR spectroscopy, GC, GPC

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: Greenish liquid

Odour: Ester-like

Boiling Point: Not measured as the substance is a viscous liquid

Density: 1050 kg/m³

Vapour Pressure: Not expected to be significant for a polymer

Water Solubility: < 42 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 pK_a: Not applicable

Flash Point:	> 100°C
Flammability Limits:	Not applicable
Combustion Products:	SiO ₂ , CO ₂ , H ₂ O
Reactivity/Stability:	Stable under normal conditions and does not degrade

Comments on Physico-chemical Properties

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

The water solubility was determined according to the analytical procedure THG-AL.022- 14 (which according to the company corresponds to the OECD Guideline 105) and was based on the silicone 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 two types of ester groups, but is not expected under environmentally relevant conditions (ie. pH range 4 - 9).

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: 99%

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

Non-hazardous impurities (> 1% by weight): None

Maximum content of residual monomers: 0.4%

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 of about 2.5 tonnes for the first year increasing to about 12 tonnes for the fifth year. It will be decanted into mixing vessels where it is added to another polymer, TEGO RC 726, 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 711 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 711 will arise from handling adhesive release sheets. However, prolonged dermal contact with the coated surface is unlikely, and by this stage TEGO RC 711 will have been incorporated into the polymer matrix.

8. ENVIRONMENTAL EXPOSURE

. Release

The company has indicated that during the roller 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 wastes 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 711 is a polymer with low water solubility, therefore leaching from landfill sites is not expected. Incineration of the 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 toxicological data for polymers of number average molecular weight greater than 1,000. However, some studies were available for TEGO RC 711 and are evaluated below.

Table 1 Summary of the acute toxicity of TEGO RC 711

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD ₅₀ > 2000 mg/kg	2
Skin irritation	Rabbit	slight 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 2000 mg/kg followed by a 14-day observation period.

No mortality was observed, there were no clinical signs and no macroscopic findings were noted at necropsy.

It can be concluded that the oral LD₅₀ for TEGO RC 711 is > 2000 mg/kg.

9.1.2 Skin Irritation (3)

TEGO RC 711 was tested for its potential as a skin irritant on the intact and abraded skin of 6 New Zealand White rabbits.

A semioclusive 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. 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 and at 24, 48 and 72 hours post-treatment.

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

For the intact skin, 1 rabbit exhibited no reaction, 2 rabbits exhibited very slight erythema at all time points, 1 rabbit exhibited very slight erythema at 30 - 60 minutes and 1 rabbit exhibited the same at 24, 48 and 72 hours. The remaining rabbit exhibited very slight erythema at 30 - 60 minutes and well defined erythema at 24, 48 and 72 hours.

For the abraded skin, very slight erythema was observed at all time points in 2 rabbits, at 30 - 60 minutes and 24 hours in 2 rabbits and at 24, 48 and 72 hours in 1 rabbit. The remaining rabbit exhibited very slight erythema at 30 - 60 minutes and well-defined erythema at the other time points.

It can be concluded that TEGO RC 711 is a slight skin irritant in rabbits.

9.1.3 Eye Irritation (4)

Into the conjunctival sac of the left eyes of 6 New Zealand White rabbits was placed 0.1 ml of TEGO RC 711. The right eye of each rabbit served as control.

For 3 of the rabbits, the treated eye was washed out. Readings of ocular reactions were made 1, 24, 48 and 72 hours after treatment. At the 24 and 72 hours times, potential eye lesions were examined by inserting 1 drop of 1% fluorescein for 60 seconds prior to washing with physiological saline.

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

For the 3 rabbits where the eyes remained unwashed, slight conjunctival redness were observed at 1 hour and in 2 of these rabbits also at 24 hours post treatment. Slight chemosis was observed in 1 rabbit at 1 hour post treatment. For chemosis the same results were observed for the rabbits whose treated eyes were washed following treatment. Slight conjunctival redness was observed in all 3 of these rabbits at 1 and 24 hours post treatment.

It can be concluded that TEGO RC 711 is a slight eye irritant in rabbits.

9.1.6 Skin Sensitisation (5)

TEGO RC 711 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, at 10% in arachid oil, was injected in 50 microlitre amounts intradermally in the craniodorsal area and below. Freund's adjuvant (FCA) was also injected. Control injections were of FCA, 10% aqueous FCA and distilled water.

2nd Induction

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

Challenge

Three weeks after the 1st induction, either undiluted test substance or arachid oil as control was applied to the clipped flank of the animals under a semiocclusive 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 711 is not a skin sensitiser in guinea pigs.

9.4 Overall Assessment of Toxicological Data

TEGO RC 711 was shown to be of low acute oral toxicity in rats, was a slight skin and 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. Given the low solubility and high molecular weight the polymer should not display 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 number average molecular weight of TEGO RC 711 is greater than 1000, which makes adverse health effects arising from absorption across biological membranes unlikely. This is supported by the toxicological profile of the notified polymer, which suggests it may be a slight skin and eye irritant but is unlikely to be a skin sensitiser and is unlikely to exhibit acute toxic effects following ingestion. However, there is a relatively high proportion of low molecular weight species (18%) which may be biologically available. Therefore, precautions should be taken to avoid exposure of the skin in view of the fact that the notified polymer is a component of an adhesive which could remain in contact with the skin for an extended period of time following exposure.

The notified polymer has a relatively low level of residual monomers.

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 under local exhaust ventilation 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 711 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 711 the following guidelines and precautions should be observed:

- . if engineering controls and work practices are insufficient to reduce exposure to TEGO RC 711 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;

a copy of the Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for TEGO RC 711 attached to this report 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*, secondary notification of TEGO RC 711 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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2. *Tego-Siliconacrylate RC 705 Acute Oral Toxicity in Rats*, Data on File, International Bio Research, Hanover, Germany. Project No.: 1-4-420-88, 1988.
3. *Test for Primary Irritation of Tego-Siliconacrylate RC 705 in Rabbits*, Data on File, International Bio Research, Hanover, Germany. Project No.: 1-3-421-88, 1988.
4. *Test for Eye Irritation of Tego-Siliconacrylate RC 705 in Rabbits*, Data on File, International Bio Research, Hanover, Germany. Project No.: 1-3-422-88, 1988.
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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.
8. Australian Standard 1337-1984, *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, 1984.
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