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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

R-22586

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989, as amended* 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.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

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1. APPLICANT

3M Australia Pty Ltd, 2-74 Dunheved Circuit, St Marys NSW 2760

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, , is considered to be non-hazardous. Therefore, the chemical name, CAS number, molecular formula, structural formula, molecular weight, spectral data and monomer composition have been exempted from publication in the Full Public Report and the Summary Report.

Other names: T-5546; T-5330; R-22586

**Maximum percentage of low
molecular weight species
(molecular weight < 1000):** <0.01%

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer will be imported as a 5-20% solution in isopropanol. The following physico-chemical properties relate to the pure polymer except where indicated. The test substance was prepared from a large plastic sheet which was ground to form a fine powder and dried to remove any solvents.

Appearance at 20°C and 101.3 kPa: yellow solid
colourless liquid
(polymer solution)

Odour: alcoholic (polymer solution)

Melting Point/Boiling Point:	150 - 260°C @ 101.3 kPa (tacky solid at 150 °C, colour change observed above 200°C, viscous amber liquid at 260°C)
Density:	1053 kg/m ³ @ 20°C
Vapour Pressure:	2.9 x 10 ⁻⁹ kPa at 25°C
Water Solubility:	2.26 - 2.94 x 10 ⁻³ g/L @ 20°C and pH 5.89 - 6.13
Partition Co-efficient (n-octanol/water) log P_{O/W}:	>4.39 @ 20°C
Flammability Limits:	not flammable
Autoignition Temperature:	not autoflammable when tested up to 450°C
Pyrolysis/Combustion Products:	the polymer solution will decompose to toxic fumes of ammonia, hydrogen cyanide and oxides of carbon, silicon and nitrogen upon combustion
Explosive Properties:	the polymer was not explosive when subjected to flame, shock or friction
Particle size distribution:	not applicable as the chemical will be imported in solution only

Comments on missing data:

Data for hydrolysis, dissociation constant and adsorption/desorption of the notified polymer were not provided due to the low water solubility and lack of suitably sensitive analytical procedures. Although the structure of the notified

polymer is unclear, terminal amine groups are likely to be present. No other readily hydrolysable functional groups are expected in the polymer structure. Significant hydrolysis or dissociation is not expected under environmentally relevant conditions. The low water solubility and high partition coefficient suggest that the notified substance is likely to be sorbed onto soil or sediment particles.

4. PURITY OF THE CHEMICAL

Degree of purity: 100%

Toxic or hazardous impurity/impurities: none

Non-hazardous impurity/impurities: none

Maximum content of residual monomers: <0.1%

Additives/Adjuvants:

. **Chemical name:** isopropanol
 CAS No.: 67-63-0
 Weight percentage: 80-95%

5. INDUSTRIAL USE

The notified polymer will be imported as a 5-20% solution in isopropanol, to be used as a release surface on the backing of adhesive tape. As the notified chemical is considered non-hazardous, exemption from publication has been granted for the volume of import.

6. OCCUPATIONAL EXPOSURE

Storage, formulation and processing of the notified polymer will occur at the one site. The resultant adhesive tape will be distributed to several other manufacturers for attachment to the product. The product will be distributed Australia wide.

Approximately 30 workers will be involved in handling the material, including warehouse personnel, forklift drivers, process workers, foremen, quality control personnel, process

engineers and managers. Warehouse personnel (6-8) will unload the drums from the truck and place them on pallets as required (~15 minutes, up to 2 times a month); fork lift drivers (~4) will unload the pallets and transfer them to the flammable store as required and later to the processing area (involving ~15 minutes, up to 2 times a month); process workers (~13) will formulate the polymer solution and manufacture the tape (~8 hours/month); and quality control personnel (~2) will check the finished tape. Process engineers (~1) and managers (~1) may also be involved in checking the finished tape, however foremen (~3) will be in the vicinity but will not directly handle the product. The notifier states that workers will wear impervious gloves and chemical safety glasses or a full face shield if splashing is possible, and that vapours will be controlled around open containers and during transfer operations by local exhaust ventilation. In cases where solvent vapour control is not possible, workers will be instructed to wear an organic vapour respirator.

7. PUBLIC EXPOSURE

Articles containing R-22586 will be sold to the public. However, under normal use conditions exposure to R-22586 will be limited.

The notified chemical, R-22586, will be transported by road in drums; public exposure to R-22586 during transportation may occur during accidental spillages, but is unlikely to lead to significant exposure.

Waste products which cannot be reused will be disposed with normal liquid waste and processed at the local water treatment plant or processed to solids and disposed to landfills. Used product containing R-22586 will also be disposed to landfills.

It is envisaged that the potential for public exposure to R-22586 is low.

8. ENVIRONMENTAL EXPOSURE

. Release

It has been indicated by the notifier that residues resulting from the coater application are collected and returned to the

storage hoppers of the coater for reapplication. The expected total polymer wastage factor resulting from unused residues in the polymer containers, equipment washings, batch residues and spillage has been estimated at < 0.5% per annum. Potential wastage is minimised as formulation and processing is likely to occur at a maximum of twice per month. Liquid wastes containing the polymer will be collected with other solvent wastes and transported to a liquid waste treatment facility for processing and disposal.

Wastage due to off-cuts of the cured polymer is expected to be approximately 2%. These wastes will be consigned to landfill.

The notified polymer is only intended for use in the manufacture of adhesive tape backing. Release of the notified polymer to the environment, resulting from this application, is only expected in its cured form and will ultimately be consigned to landfill.

. **Fate**

R-22586 is a polymer with low water solubility, therefore, leaching from landfill sites is not expected. Incineration of the notified substance is expected to produce oxides of carbon, silicon and nitrogen, and other possibly 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 a solid polymer matrix. The resultant matrix structure should limit the biodegradation of the polymer. Bioaccumulation of the polymer is unlikely due to its high molecular weight (~28000) of the polymer even before curing.

9. **EVALUATION OF TOXICOLOGICAL DATA**

Toxicological data were provided for R-22586 although they are not required for polymers of number-average molecular weight (NAMW) > 1000 under the *Industrial Chemicals (Notification and Assessment) Act 1989, as amended* (the Act). These data are evaluated below.

9.1 Skin Sensitisation (1)

A human repeated insult patch test was provided for the silicone coated film.

The test material, a 1" x 1" piece of silicone coated film, was applied, shiny non-adhesive side up, to the upper arm of 224 human volunteers of both sexes by occlusive, adhesive overlay. Nine volunteers did not complete the study.

Induction consisted of 9 repeated applications (3 patches per week) to a single induction site. Challenge patches were applied 12 to 24 days after the final induction application to the induction site as well as to a naive site (directly adjacent to the induction site). Forty eight and 96 hours after challenge application the test sites were evaluated for allergic contact dermatitis. There were no visible responses reported over the duration of the study.

The results of this study, therefore, indicate that R-22586 is not a skin sensitiser in humans.

9.2 Genotoxicity: Bacterial Mutation Assay (2)

This study was conducted in accordance with OECD guideline Nos: 471 (3) and 472 (4).

R-22586 in isopropanol, at concentrations of 0, 156.25, 312.5, 625, 1250, 2500 and 5000 µl/plate, was tested for gene mutation according to the direct plate incorporation method using *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538, and *Escherichia coli* strain WP2 *uvrA*, both in the presence and absence of microsomal activation.

Positive controls used were 2-aminoanthracene (for all strains) in the presence of S-9 fraction and 9-aminoacridine (for TA 1537), 2-nitrofluorene (for TA 98 and TA 1538) and N-ethyl-N'-nitro-N-nitrosoguanidine (for TA 100, TA 1535 and WP2 *uvrA*) in the absence of S-9 fraction. No dose-dependant increase in the number of revertant colonies was observed in any of the strains exposed to R-22586, both in the presence and absence of microsomal activation. Marked increases in the number of revertant colonies were induced by positive controls.

The results of this study suggest that R-22586 is not mutagenic under the experimental conditions reported.

9.4 Overall Assessment of Toxicological Data

A repeated insult patch test in humans has shown R-22586 to be non-sensitising to skin.

R-22586 was negative in both the *Salmonella typhimurium* and *Escherichia coli* reverse mutation assays.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No aquatic toxicity data were provided, which is acceptable according to the Act, since the notified polymer has a > 1000 . The literature indicates that polymers which contain amine functional groups, have a MW greater than 1000 and are water soluble may have a potential for environmental toxicity (5). However, as the notified polymer has low water solubility its toxicity is not expected to be significant.

Due to its high NAMW the polymer is not expected to cross biological membranes.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The polymer is unlikely to present a hazard to the environment at any stage of its use. Of the original quantity of polymer imported (< 320 kg) it is expected that $> 99\%$ will remain at the processing site until it has been cured. The ultimate fate of all cured polymer is landfill. Off-cuts resulting from manufacture will be sent directly, while commercial products containing the polymer will be consigned to landfill after use. Leaching of the cured polymer from landfill is not expected due to the chemical and physical bonding which occurs during the surface coating process.

Non-polymerised polymer wastes are expected to be $< 0.5\%$ (or 1.6 kg p.a.) and will occur in solvent solution. These wastes will be collected with other solvent wastes from the company and transferred to a liquid waste treatment facility prior to treatment, disposal and discharge. Therefore the potential for release to the aquatic compartment is minimal and the associated aquatic hazard negligible.

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

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer R-22586 has a NAMW > 1000 and is therefore unlikely to cross biological membranes and cause significant systemic effects. The polymer contains <0.01% (w/w) low molecular weight (<1000) species and <0.1% residual monomers. At these concentrations, the monomer and the low molecular weight component of the notified polymer should not pose a significant risk to workers. It is stable at room temperature, non-flammable, not explosive and has low vapour pressure and water solubility.

The polymer was found to be non-sensitising to human skin and non-mutagenic in bacterial mutation assays.

Given the low concentration of R-22586 in the formulated polymer solution, with adequate engineering controls and personal protective equipment in place, exposure to R-22586 should be minimal.

Under normal use conditions, with appropriate control measures and/or precautions to minimise contact, the notified polymer is not expected to present any significant health or safety hazard to workers.

Under normal use conditions, R-22586 is not expected to lead to significant exposure or present a significant health hazard to the public.

13. RECOMMENDATIONS

To minimise occupational exposure (and public/environmental if recommendations have been made by these agencies) to R-22586 the following guidelines and precautions should be observed:

- . If engineering controls are insufficient to reduce exposure to a safe level during mixing processes or filling and

transfer operations, as well as during product application, the following personal protection equipment should be worn :

- . respiratory protection conforming to AS 1715 (6) and AS 1716 (7);
 - . goggles, or full face shield where splashing is possible, conforming to AS 1336 (8) and AS 1337 (9); and
 - . impervious gloves conforming to AS 2161 (10);
 - . protective clothing conforming to AS 3765.1 () or AS 3765.2 ().
- . Good work practices should be implemented to avoid spillages or splashings.
 - . Good personal hygiene practices, such as washing of hands prior to eating food, should be observed.
 - . A copy of the Material Safety Data sheet for Silicon Polymer Solution R-22586 and products containing it should be easily accessible to workers.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Silicon Polymer Solution R-22586 was provided in Worksafe Australia format (11). This MSDS was provided by 3M Australia Pty Ltd as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of 3M Australia Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989, as amended* (the Act), secondary notification of R-22586 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

1. Keyline Research Report No. L23 33T 1H. *A Human Repeated Insult Patch Test of Sample H (T-5330 DPD-036 Silicone coated film)*. Keyline Research, Ohio, 1991.
2. Report No. MIN 117A/930244. *T-5546 Bacterial Mutation Assay*. Huntingdon Research Centre, Cambridgeshire, 1993.
3. OECD Guidelines for Testing of Chemicals - *Genetic Toxicology: Salmonella typhymurium, Reverse Mutation Assay* No: 471, 1983.
4. OECD Guidelines for Testing of Chemicals - *Genetic Toxicology: Escherichia coli, Reverse Mutation Assay* No: 472, 1983.
5. *EPA Proposed Revision to Expand Criteria for Exempting Polymers from Premanufacture Notification* [58 FR 7679, Feb 8, 1993], Chemical Regulation Reporter, p2226, 12 February 1993.
6. Australian Standard 1715- 1991 *Selection, use and maintenance of Respiratory Protective Devices*, Standards Association of Australia Publ., Sydney 1991.
7. Australian Standard 1716-1991 *Respiratory Protective Devices*, Standards Association of Australia Publ., Sydney, 1991.
8. Australian Standard 1336-1982 *Eye protection in the Industrial Environment*, Standard Association of Australia Publ., Sydney, 1982.
9. Australian Standard 1337-1984 *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, 1984.
10. Australian Standard 2161-1978 *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, 1978.

10. Australian Standard 3765.1-1990 *Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals* Standards Association of Australia Publ., Sydney, 1990.
11. Australian Standard 3765.2-1990 *Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals.* Standards Association of Australia Publ., Sydney, 1990.
11. National Occupational Health and Safety Commission, *Guidance Note for Completion of a Material Safety Data Sheet*, 3rd Edition, Australian Government Publishing Service Publ., Canberra, 1991.