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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Intermedio S1

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**Intermedio S1****1. APPLICANT**

A.C. Hatrick Chemicals Pty Ltd of 49-61 Stephen Road BOTANY NSW 2019 has submitted a limited notification statement in support of their application for an assessment certificate for the new synthetic polymer, Intermedio S1.

2. IDENTITY OF THE CHEMICAL

Intermedio S1 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular formula, structural formula monomer composition and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Other name: Intermedio S1 (polymer alone)

Trade name: BYK-024 or 42288 (product containing 14.4% polymer)

Number-average molecular weight: > 1000

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

fractions < 1000:	3.0%
fractions < 500	0.5%

Method of detection and determination:

infrared spectroscopy; nuclear magnetic resonance spectroscopy; and gel permeation chromatography charts were provided for identification of the polymer

3. PHYSICAL AND CHEMICAL PROPERTIES

The following data were provided for Intermedio S1.

Appearance at 20°C and 101.3 kPa: colourless to light yellow liquid

Odour: no characteristic odour

Melting Point: not determined

Specific Gravity:	1.01 g/cm ³ DIN 51757
Vapour Pressure:	< 0.1 kPa
Water Solubility:	insoluble
Partition Co-efficient (n-octanol/water) log P_{ow}:	not applicable (insoluble in water)
Hydrolysis as a function of pH:	not determined
Adsorption/Desorption:	not determined
Dissociation Constant pKa:	not applicable (does not dissociate in water)
Flash Point:	> 100°C ISO 3679
Flammability Limits:	does not form flammable vapours
Decomposition Products:	CO ₂ , H ₂ O and SiO ₂ , typical decomposition products for polyoxyalkylenes
Autoignition Temperature:	not applicable
Explosive Properties:	does not form flammable vapours
Reactivity/Stability:	does not decompose at temperatures ≤ 150°C

Comments on Physico-Chemical Properties:

No test results were given for water solubility, but due to the hydrophobic nature of the polymer, solubility would be expected to be low (< 0.1%). The composition of the polymer also suggests a low solubility.

While hydrolysis was not determined, the structure of the polymer suggests there is a potential for hydrolysis. If hydrolysis occurs acetic acid will be produced. The rate of hydrolysis is expected to increase under basic conditions but is unlikely to occur in the environmental pH range due to low solubility.

The environmental properties of silicone fluids have been well reviewed by Hamelink (1). Silicone fluids are surface active as a result of flexible linkages between siloxanes and both the non-polar phase (algae, sediment etc.) and the polar phase (generally water). In aqueous environments, strong adsorption of high molecular weight silicone fluids to sediment may be assumed. Low solubility and low surface tension of organosilicons also tends to promote adsorption on particles (2)

4. PURITY OF THE CHEMICAL

Degree of purity: > 98%

The notified chemical contains no hazardous impurities at levels necessary to classify it as a hazardous substance (3). Therefore, information on the purity of the chemical has been exempted from publication in the Full Public Report and the Summary Report.

Maximum content of residual monomers: 1.8%

5. USE, VOLUME AND FORMULATION

The notified polymer is manufactured in Germany and imported into Australia in the product BYK-024 (containing 14.4% polymer). The product will be used as a defoamer for water-based paints for industrial use.

It is expected that the initial sales volume of polymer will be 1 tonne per annum. In 5 years the volume is expected to be 5 tonnes per annum.

6. OCCUPATIONAL EXPOSURE

The imported product, BYK-024, will be imported in steel containers and distributed to customers by road. It is possible that the product will be stored prior to distribution. The notifier has indicated 5 possible storage sites in Brisbane, Sydney, Melbourne, Adelaide and Perth. Each storage facility is expected to employ a warehouse worker and a forklift driver. Workers involved in transportation from the wharf to the supplier and/or customer will include one driver, a forklift driver at the supplier site and a forklift driver at the customer site. Exposure of transport and storage workers will only result in the event of accidental spillages.

At the customer sites (up to 20 paint manufacturing plants) BYK-024 will be formulated into industrial paint products with a typical polymer concentration of < 1%. BYK-024 will be blended with other ingredients in a mixer fitted with exhaust ventilation. Samples will be taken from the mixer during the blending operation for batch adjustment. Formulated paint will be filtered and filled into 200 L drums or 25 L pails under exhaust ventilation and later stored or distributed to industrial paint applicators. Workers involved in handling BYK-024 or formulated paint will be instructed to wear impervious gloves, coveralls and goggles. Spills will be contained through bunding, thus limiting exposure to clean-up personnel.

The types of end uses are not known yet but may include furnishings, furniture finishes and flooring. It is possible that a few methods of paint application will be employed including spray application, electrostatic and airless application as well as rolling. Spray application is expected to be conducted using automatic spray equipment in a spray booth fitted with a fume extraction system. Paint application rooms will be fitted with down draft ventilation. Workers involved in paint application and clean-up of spray equipment will be required to wear nylon overalls and rubber solvent resistant gloves.

Once the paint has been applied it will undergo a drying process and form a protective surface coating. In this form the potential for worker exposure will be negligible.

Disposal of used drums or containers will be conducted by up to 10 contracted waste disposal workers.

7. PUBLIC EXPOSURE

BYK-024 will be imported to Australia in steel drums and distributed by road to storage sites around Australia and then to paint manufacturing plants. No public exposure is expected to occur during the storage or distribution of the notified polymer.

Paint manufacturers will blend BYK-024 with other paint ingredients in a mixer which will be fitted with exhaust ventilation. The blended product will be packaged in 200 L drums or 25 L pails and then stored or distributed to industrial paint applicators. Paint will be applied by spray or by electrostatic and airless application methods in areas employing scrubber apparatus or filters. No public exposure to the notified polymer is expected to occur during the manufacture, storage, distribution or industrial use of paint products.

Disposal of any waste polymer produced during the manufacture of paints will be to secured landfill and is not expected to lead to public exposure.

Although the type of products to be painted are not yet known, it is anticipated that the paint will be applied to a number of surfaces to which the public will come in contact with (eg. furniture). However, given that the polymer is non-volatile and the concentration of the polymer in paints is low, exposure levels are expected to be low.

8. ENVIRONMENTAL EXPOSURE

Release

All manufacturing of the chemical is carried out in Germany. BYK-024 is imported in two drum sizes, 25 kg and 200 kg. It is not expected that the larger drum size will be used for some years unless demand for imports increases sharply. Even with the 5 tonnes per annum being imported, the notifier estimates over half would still be imported in the smaller drum size. Once imported, the chemical is shipped directly to end customers for reformulating into industrial paints. With the exception of accidental spillage, no release or exposure to the environment is expected from this chemical until it reaches the end customer. There are adequate instructions on the chemical's Material Safety Data Sheet (MSDS) to cope with accidental spillage.

Once the chemical has reached the customer, environmental exposure may occur during paint manufacture and application. During paint application, exposure is expected to be limited to sampling and filling operations. When formulated, paints may contain between 0.05% and 2%, but concentrations of the notified chemical are

typically between 0.1% and 1%. Due to the low vapour pressure of the chemical, and the simple mixing process when being incorporated into paints, overall release to the environment during sampling and filling operations is expected to be insignificant.

The paint is designed as a waterborne, industrial spray. Any release to the environment during application will be as a result of overspray, and through any volatility resulting from the paint itself. The release during application will be dependent on the method of application. BYK-024 is mainly applied to timber products such as furnishings, furniture finishes and flooring. Methods of application include electrostatic and airless application which are fairly efficient (upwards of 75%), or conventional spraying, which could have less than 50% efficiency. Other applications may be by rolling, as is the case with flooring, which is highly efficient, probably more than 90%. However, all applications are carried out in the confines of a factory and protection is provided by scrubber apparatus or by filters. This minimises any release to the environment during application operations, though the significant quantities captured by pollution control technology would be disposed of to landfill.

Fate

If disposal of the imported chemical is needed (prior to dilution in paints) it will be in approved landfill in accordance with local, state and Federal regulations. Due to the nature of organosiloxanes to adsorb strongly to sediment, and be insoluble in water, it is unlikely that the chemical will enter the aquatic system through disposal in this manner. In addition, research has suggested that, in all soils, siloxanes of this type degrade extensively to low-molecular weight, water soluble products (4). Because this rearrangement is much more rapid in dry soils (4), degradation within aquatic sediments would not be expected.

Excess paints, residues (from drums, cleaning of spray equipment, scrubber apparatus, and filters) and empty drums, will be disposed of by landfill where the polymer would be immobilised through incorporation in the dried paint.

After application the paint dries to form a protective coating. Any dry paint lost through chipping or flaking will be inert and form part of the sediments.

It is unlikely that the notified chemical will reach the sewer through any form of disposal, either as the imported raw material, or in any end use product. Should any accidental spillage, or disposal to the sewer occur, it is expected that, because of the hydrophobic nature of the chemical, it will be promptly removed from solution by adsorption onto sludge with little, if any, likely to be contained in treated waste water. Sludge containing the notified substance will be incinerated or landfilled. Incineration would destroy the silicones, and create typical decomposition products of oxides of carbon and silicon.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Toxicological data are not required for polymers of number-average molecular weight (NAMW) >1000 according to the Act. However, the following studies on acute oral toxicity, skin irritation and eye irritation were submitted for the notified polymer.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Intermedio S1

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD ₅₀ > 5000 mg/kg	(5)
skin irritation	rabbit	non-irritant	(6)
eye irritation	rabbit	non-irritant	(7)

9.1.1 Oral Toxicity (5)

Species/strain: rats, Winkelmann, Paderborn

Number and sex of animals: 5/sex

Method of administration (vehicle): Administered by non-flexible stomach tube (2000 mg/kg and 5000 mg/kg) in Tylose 0.25%

Clinical observations: In both dosage groups the preparation did not cause symptoms which were considered due to the test substance

Mortality: no deaths

Morphological findings:
no abnormalities were
noted at necroscopy

Test Method: in accordance with OECD Guidelines for Testing Chemicals (8)

Result: LD₅₀ > 5000 mg/kg

9.1.2 Skin Irritation (6)

Species/strain: New Zealand White rabbits

Number of animals: 5

Method of administration: 0.5 ml of undiluted test substance was applied to the skin and covered with gauze squares (2.5 x 2.5 cm) for 4 hours

Test Method: in accordance with OECD Guidelines for Testing Chemicals (8)

Draize (9) Scoresⁱ:

Animal	Time after patch removal				
	60 min	1 day	2 days	3 days	7days
ERYTHEMA					
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
5	0	0	0	0	0
OEDEMA					
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
5	0	0	0	0	0

ⁱ See Attachment 1 for Draize Scales

Result: non-irritant

9.1.3 Eye Irritation (7)

Species/strain: New Zealand White rabbits

Number of animals: 6

Method of administration: 0.1 ml of the compound was instilled into the conjunctival sac of the left eye of each animal. The right eye was untreated and served as control

Test Method: in accordance with OECD Guidelines for Testing Chemicals (8)

Draize (9) Scoresⁱ:

Animal	Time after instillation											
	1 day			2 days			3 days			4 days		
CORNEA:	opacity area			opacity area			opacity area			opacity area		
1	0	0		0	0		0	0		0	0	
2	0	0		0	0		0	0		0	0	
3	0	0		0	0		0	0		0	0	
4	0	0		0	0		0	0		0	0	
5	0	0		0	0		0	0		0	0	
6	0	0		0	0		0	0		0	0	
IRIS												
1	0			0			0			0		
2	0			0			0			0		
3	0			0			0			0		
4	0			0			0			0		
5	0			0			0			0		
6	0			0			0			0		
CONJUNCTIVA	r ^a	c ^b	d ^c	r ^a	c ^b	d ^c	r ^a	c ^b	d ^c	r ^a	c ^b	d ^c
1	1	0	0	0	0	0	0	0	0	0	0	0
2	1	0	0	0	0	0	0	0	0	0	0	0
3	1	0	0	0	0	0	0	0	0	0	0	0
4	1	0	0	0	0	0	0	0	0	0	0	0
5	1	0	0	0	0	0	0	0	0	0	0	0
6	1	0	0	0	0	0	0	0	0	0	0	0

^a redness ^b chemosis ^c discharge

ⁱ See Attachment 1 for Draize Scales

Result: non-irritant

9.4 Overall Assessment of Toxicological Data

The notified polymer has low acute oral toxicity and is not irritating to the skin or eye of rabbits.

The notified chemical is not classed as hazardous according to Worksafe Australia's *Approved Criteria for the Classifying of Hazardous Substances* (3) in relation to the toxicity data provided.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data are required for polymers of NAMW > 1000 according to the Act. The high molecular weight and low solubility of the substance suggest that it will not cross biological membranes, and will therefore be of low toxicity. The

surface active nature and ability of the polydimethylsiloxane to adsorb to sediments and other organic carbon material will favour precipitation of the notified substance with sediment.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The chemical is likely to be shipped to four customers around Australia. These paint manufacturers are only in the major cities of Sydney, Melbourne, Adelaide and Perth.

In the event of accidental spillage in a worst case, if a 200 kg drum of undiluted chemical were accidentally spilled, and entered the sewer in one of these cities in one day (with a nominated sewer output of 200 ML), the chemical would be diluted to a concentration of 1 ppm.

Within the formulated paint the notified chemical is typically present at a concentration of between 0.1% and 1%. Through the different application methods, it is difficult to gauge the amount of chemical lost as a result of overspray. In a worst case however, if all the prepared industrial paint were to be applied with 50% losses, 13.7 kg of the chemical would be released each day (if the maximum 5 tonnes per annum was being imported). If this were to be lost straight to the sewer in a large country town (5 ML sewage output), it would enter the waterway in a concentration of less than 3 ppm.

These calculations are not particularly meaningful for such strongly surface active compounds, which tend to undergo essentially complete removal through sorptive processes during waste water treatment. Secondly, with the overspray effectively being trapped, bagged and disposed of by landfill, because of the hydrophobic nature of the chemical and its ability to adsorb, it is unlikely to enter the waterways.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer has NAMW > 1000 and is therefore not expected to cross biological membranes and cause systemic effects. It contains low levels of low molecular weight species (3% with NAMW < 1000). It also contains a number of impurities and residual monomers/reactants with toxic properties. These however are not present at levels great enough to classify the polymer as hazardous (12).

The notified polymer showed low acute oral toxicity and no skin and eye irritancy potential in animals. It is therefore not expected to cause a significant toxicological concern to workers. Hazards associated with the polymer's physico-chemical properties (low vapour pressure, non-flammable) should also be low.

Potential for worker exposure will exist during paint manufacture (addition of BYK-024 to the blender, batch analysis and adjustment, filtration and filling of formulated product), paint application (loading and operating spray or roller equipment, equipment clean-up) and waste disposal. During these operations skin and eye

contact may occur. Inhalation of the polymer is not likely as spray application is expected to be conducted in closed spray booths.

The imported product, BYK-024, is classified as a hazardous substance (12) based on the high percentage of the irritant polypropylene glycol. Workers will be required to wear personal protective equipment (including protective clothing, gloves and eye protection) to protect themselves from this ingredient. The use of this equipment, as well as engineering controls, is expected to reduce the level of exposure to the notified polymer to safe levels.

Under normal use situations, the overall risk to workers is expected to be low considering the engineering controls and level of personal protective equipment employed, as well as the low levels of toxicity associated with the polymer.

Although public contact with painted surfaces containing the notified polymer may occur, the high NAMW for the polymer suggests that if contact were to occur, absorption would be unlikely, and there would therefore be negligible risk to public safety.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified polymer the following guidelines and precautions should be observed:

- . If engineering controls and work practices are insufficient to reduce exposure to Intermedio S1 to a safe level, then the following personal protective equipment which conforms to Australian Standard (AS) or Australian/New Zealand Standard (AS/NZS) should be worn:

Safety goggles should be selected and fitted in accordance to AS 1336 (10) to comply with AS/NZS 1337 (11).

Industrial clothing must conform to the specifications detailed in AS 2919 (12) and AS 3765.1 (13).

Impermeable gloves or mittens conforming to AS 2161 (14) and AS 3765.1 (13).

All occupational footwear should conform to AS/NZS 2210 (15).

- . Spillage of the notified polymer should be avoided.
- . Good personal hygiene should be practised to minimise the potential for ingestion.
- . A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for 42288, containing the notified polymer, was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (16).

This MSDS was provided by A.C. Hatrick Chemicals Pty Ltd as part of their notification statement. The accuracy of this information remains the responsibility of A.C. Hatrick Chemicals Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified polymer 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. Hamelink J. L. Silicones in the Handbook of Environmental Chemistry, Vol 3: Detergents, N.T. de Oude (ed), 1992.
2. World Health Organisation, Reports and Studies No 29. *Review of Potentially Harmful Substances: Organosilicon Compounds (Silanes and Siloxanes)*, 1986.
3. National Occupational Health and Safety Commission, *Approved Criteria for Classifying Hazardous Substances*, Australian Government Publishing Service, Canberra, 1994.
4. Lehmann, R. G. Varaprath, S. Annelin, R.B. Arndt, J. L. "Degradation of Silicone Polymer in a Variety of Soils." *Environmental Toxicology and Chemistry*, **14**, pp 1299-1305, 1995.
5. Report No: 1-4-163-90, *Acute Toxicological Study of Compound Intermedio S-1 After Oral Application to the Rat (OECD-Guidelines No. 401)*, Pharmatox, Hannover, 1990.
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7. Report No: 1-4-165-90, *Irritant Effects of Compound Intermedio S-1 on Rabbit Eye (OECD-Guidelines No. 405)*, Pharmatox, Hannover, 1990.
8. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris, France.

9. Draize J H. 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, **49**, 1959.
10. Standards Australia, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, Australia, 1994
11. Standards Australia, Standards New Zealand, *Australian/ New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand, 1992.
12. Standards Australia, *Australian Standard 2919 - 1987 Industrial Clothing*, Standards Association of Australia Publ., Sydney, Australia, 1987.
13. Standards Australia, *Australian Standard 3765-1990 Clothing for Protection Against Chemical Hazards, Part 1 Protection Against General or Specific Chemicals, Part 2 Limited Protection Against Specific Chemicals*, Standards Association of Australia Publ., Sydney, Australia, 1990.
14. Standards Australia, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, Australia, 1978.
15. Standards Australia, Standards New Zealand, *Australian/ New Zealand Standard 2210 - 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand, 1994.
16. National Occupational Health and Safety Commission, *Code of Practice for the Preparation of a Material Safety Data Sheets*, Australian Government Publishing Service, Canberra, 1994.

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	rating	Oedema Formation	rating
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising)	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA			
Opacity	rating	Area of Cornea involved	rating
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE					
Redness	rating	Chemosis	rating	Discharge	rating
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS	
Values	rating
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe