

File No: NA/326

Date: March 1996

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

BYK-331

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), 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**BYK-331****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, BYK-331.

2. IDENTITY OF THE CHEMICAL

BYK-331 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.

Trade names: BYK-331 or 42307

Number-average molecular weight: > 1000

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

fractions < 1000:	8.4%
fractions < 500	1.3%

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 the notified polymer, BYK-331.

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

Odour: no characteristic odour

Melting Point: not determined

Specific Gravity: 1.04 g/cm³ DIN 51757

Vapour Pressure: < 0.1 kPa

Water Solubility:	soluble
Partition Co-efficient (n-octanol/water) log P_{ow}:	not applicable (surface active substance)
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. The company states the chemical to be completely water soluble based on it's structure. This is acceptable.

Hydrolysis as a function of pH was not determined. There are no readily identifiable groups in the polymer structure to suggest hydrolysis would occur.

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

The notified polymer 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.

Degree of purity : ~74%

Maximum content of residual monomers/reactants: ~37%

5. USE, VOLUME AND FORMULATION

The notified polymer, BYK-331, is manufactured in Germany and will be imported into Australia in an undiluted form. The polymer will be used to improve surface slip and levelling in solvent-free, solvent based and aqueous automotive paints.

It is expected that the initial sales volume of polymer will be 300 kg per annum. In 5 years the volume is expected to be 2 tonnes per annum.

6. OCCUPATIONAL EXPOSURE

The imported polymer, BYK-331, will be imported in steel containers and distributed to customers by road. It is possible that the polymer 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 manufacturing plants) BYK-331 will be formulated into automotive paint products with a typical polymer concentration of < 1%. BYK-331 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 car manufacturers and resprayers. Workers involved in handling BYK-331 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 end users will apply the paint 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-331 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-331 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 car manufacturers and resprayers. 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 public will come in contact with painted automotive surfaces, the polymer is non-volatile and at 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-331 is imported in two drum sizes, 25 kg and 200 kg with the 25 kg unit being predominant. Even with the 2 tonnes per annum being imported, the notifier estimates over half would still be imported in the smaller drum size. There are around four end customers in Australia, located in major cities. Once imported, the chemical is shipped directly to these customers for reformulating into automotive paints. With the exception of accidental spillage, no release or exposure to the environment is expected from this chemical during transportation. There are adequate instructions on the chemical's Material Safety Data Sheet (MSDS) to cope with accidental spillage.

Once with customers the chemical will face exposure to the environment during paint manufacture and application. Throughout manufacture of the paint, the chemical will be exposed during 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 through sampling and filling operations is expected to be insignificant.

The paint is applied as a spray. Any release to the environment will be as a result of overspray, and through any volatility resulting from the paint itself. Application will be either through conventional spraying in booths where overspray could be higher than 50%, or by electrostatic application, where losses are somewhat lower. 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, although the significant quantities captured by pollution control technology would be disposed of by 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. 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), biodegradation 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 in the dry 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. Even though this particular silicone fluid is soluble in water, should any accidental spillage, or disposal to the sewer occur, it would still be expected that, because of the hydrophobic nature of the chemical, it will be removed from solution by adsorption onto sludge with little 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 BYK-331

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD ₅₀ = 8900 mg/kg	(5)
skin irritation	rabbit	non-irritant	(6)
eye irritation	rabbit	non-irritant	(7)

9.1.1 Oral Toxicity (5)

Species/strain: rats, Wistar

Method of administration (vehicle): Administered undiluted by non-flexible stomach tube (2000, 5000 or 10000 mg/kg).

Number and sex of animals: 5/sex/dose

Clinical observations: In low and mid dosage groups the preparation did not cause remarkable symptoms which were due to the test compound; high dose animals showed a slight decrease in reflexes, bristly coat and increased respiration leading to coma and death within 4 hours (7 animals)

Mortality: 7/10 (5 males, 2 females; high dose only)

Morphological findings: no abnormalities were noted at necroscopy in any of the groups

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

Result: LD₅₀ = 8900 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 (intact and abraded) and covered with a cellulose patch (2.5 x 2.5 cm) for 24 hours

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

Draize (9) Scoresⁱ:

Animal	Time after application					
	24 hours		72 hours		7 days	
ERYTHEMA	Intact	Abraded	Intact	Abraded	Intact	Abraded
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	0	0	0	0	0	0
OEDEMA						
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	0	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		7 days		6 days		7 days		
CORNEA:	opacity area		opacity area		opacity area		opacity area		opacity area		opacity area		opacity area		
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
IRIS															
1	0		0		0		0		0		0		0		
2	0		0		0		0		0		0		0		
3	0		0		0		0		0		0		0		
4	0		0		0		0		0		0		0		
5	0		0		0		0		0		0		0		
6	0		0		0		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	r ^a	c ^b	d ^c
1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	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 in rats 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* (10) 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 was 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 was to be applied with 50% losses, around 4.5 kg of the chemical would be released each day (if the maximum 2 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 1 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 (8.4% with NAMW < 1000). It also contains a number of hazardous impurities. These however are not present at levels great enough to classify the polymer as hazardous (10).

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-331 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.

Workers will be required to wear personal protective equipment (including protective clothing, gloves and eye protection) during paint formulation and application. 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 automotive 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 BYK-331 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 (11) to comply with AS/NZS 1337 (12).

Industrial clothing must conform to the specifications detailed in AS 2919 (13) and AS 3765.1 (14).

Impermeable gloves or mittens conforming to AS 2161 (15) and AS 3765.1 (14).

All occupational footwear should conform to AS/NZS 2210 (16).

- . 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 42307 (product code for the notified polymer) was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (17).

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. Sax N. I. and Lewis R. J. *Dangerous Properties of Industrial Materials*, Van Nostrand Reinhold, New York, 1989.
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: 1-4-165-88, *Acute Toxicological Study of BYK-331 After Oral Application on the Rat (OECD-Guidelines No. 401)*, Pharmatox, Hannover, 1988.
6. Report No: 1-3-164-88, *Irritant Effects of BYK-331 on Rabbit Skin According Guidelines No. 404*, Pharmatox, Hannover, 1988.
7. Report No: 1-3-163-88, *Irritant Effects of Compound BYK-331 on Rabbit Eye According Guidelines No. 405*, Pharmatox, Hannover, 1988.
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. National Occupational Health and Safety Commission, *Approved Criteria for Classifying Hazardous Substances*, Australian Government Publishing Service, Canberra, 1994.
11. Standards Australia, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, Australia, 1994
12. 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.
13. Standards Australia, *Australian Standard 2919 - 1987 Industrial Clothing*, Standards Association of Australia Publ., Sydney, Australia, 1987.
14. 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.
15. Standards Australia, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, Australia, 1978.
16. 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.
17. 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