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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Polymer in BYK-410

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer in BYK-410

1. APPLICANT

A C Hatrick Chemicals of 49-61 Stephen Road BOTANY NSW 2019 has submitted a limited notification statement in support of their application for an assessment certificate for Polymer in BYK-410.

2. IDENTITY OF THE CHEMICAL

Polymer in BYK-410 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, molecular weight, spectral data and details of the polymer composition have been exempted from publication in the Full Public Report and the Summary Report.

Trade Name: BYK-410, BYK-LP R 6237 (55% formulation in n-methyl-2-pyrrolidone, CAS no. 872-50-4)

Number-Average Molecular Weight: > 1 000

Maximum Percentage of Low Molecular Weight Species
Molecular Weight < 500: 0.1%
Molecular Weight < 1 000: 3.8%

3. PHYSICAL AND CHEMICAL PROPERTIES

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

Boiling Point: 163°C

Specific Gravity: not determined

Vapour Pressure: < 0.1 kPa

Water Solubility:	< 0.1 g/L
Partition Co-efficient (n-octanol/water):	not available as insoluble in both octanol and water
Hydrolysis as a Function of pH:	not available
Adsorption/Desorption:	not available
Dissociation Constant:	does not dissociate
Flash Point:	> 100°C
Flammability Limits:	does not form flammable vapours
Autoignition Temperature:	not applicable
Explosive Properties:	not explosive
Reactivity/Stability:	does not decompose < 170°C

Comments on Physico-Chemical Properties

An estimate of the water solubility of the polymer was attempted using the preliminary test in OECD Method 105 for the determination of water solubility. In the test it was observed that 0.1 g of polymer did not completely dissolve in 1 L of water, even after allowing 1 week for equilibration. This means that the polymer could have a solubility up to 100 ppm. How much lower the actual solubility would be is unclear, noting the significant proportion of hydrophilic units. Thus, the polymer has relatively low water solubility.

Hydrolysis, partition coefficient, adsorption/desorption and dissociation constant have not been determined due to the relatively low solubility of the polymer. This is acceptable for the following reasons:

- (i) Hydrolysis of certain linkages of the polymer would not be expected under environmental conditions;
- (ii) given the expected relatively low solubility in water it is anticipated that the partition coefficient for the polymer would be high; and
- (iii) on the basis of the polymer's relatively low water solubility it is likely to adsorb to, or be associated with soil/sediment and organic matter and be immobile in soil.

The polymer contains no acidic or basic functional groups that may dissociate in water.

4. PURITY OF THE CHEMICAL

Degree of Purity:	high
Toxic or Hazardous Impurities:	see residual monomers/other reactants
Non-hazardous Impurities (> 1% by weight):	see residual monomers/other reactants
Maximum Content of Residual Monomers/Other Reactants:	< 2.5%

One of the residual monomers is an irritant, respiratory sensitiser and toxin (1); but is below the threshold for hazardous classification according to Worksafe Australia's *List of Designated Hazardous Substances* (1) (the List). It is also a group 2B carcinogen according to the International Agency for Research in Cancer (IARC). Another residual monomer is not listed on (1), Toxline (2) or in Sax and Lewis (3). Another hazardous residual monomer according to the List, has no threshold listed although an exposure standard of time weighted average (TWA) of 0.1 g/m³ (4) has been assigned.

Additives/Adjuvants:	the imported formulation BYK-410 also contains the following:
Chemical name:	n-methyl-2-pyrrolidone
Synonyms:	methyl pyrrolidone
CAS No.:	872-50-4
Weight percentage:	45%
Toxic properties:	an irritant according to the List (1), threshold for classification of a mixture containing this chemical as hazardous is 10% (1); there is no exposure standard listed (4)

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia, it will be imported into Australia as a 55% formulation in n-methyl-2-pyrrolidone for use as a rheological (flow) additive in industrial paints. One tonne of the product, BYK-410, containing the notified polymer will be imported in the first year. This will rise to five tonnes per annum in the fifth year. This corresponds to the importation of 550 kg of the notified polymer in the first year rising to 2 750 kg per annum in the fifth year. The notified polymer is never isolated as a defined entity but always remains in solution in a mixture of organic solvents.

The notified polymer is intended for use as a rheological additive for paint. The commercial production of coatings made with BYK-410 will be carried out at a

variety of sites in Australia depending on the actual customer. Uses recommended by the manufacturer are: primers and surfacers; two component high build systems; traffic paints; zinc rich paints; pearlescent and/or aluminium pigments; and underbody paints. BYK-410 will be incorporated into the paints at 0.1 to 3.0% by weight.

6. OCCUPATIONAL EXPOSURE

The notified polymer will not be manufactured in Australia but imported in steel drums (either 25kg or 200 kg) as a 55% component of BYK-410 which also contains 45% of n-methyl-2-pyrrolidone. It is either transported direct to the notifier's customers or warehoused prior to distribution. Occupational exposure during transport and warehousing is unlikely and will only occur in the event of accidental spillage.

Occupational exposure can potentially occur during reformulation and during application of the final paint product. The imported formulation, BYK-410, contains 45% of n-methyl-2-pyrrolidone and is classified as hazardous due to its irritant potential. The threshold for hazardous classification according to the List (1) is 10%. Reformulation will take place in mixers fitted with exhaust ventilation and fume extraction. Staff who will be potentially exposed to the notified polymer include those involved with lab development and testing, paint formulation and packaging of the final products. The final paint products will contain between 0.55 and 1.65% of the notified polymer and 0.45 to 1.35% of the additive, n-methyl-2-pyrrolidone. The low concentration of both the polymer and additive in the final products will reduce exposure during packaging and final use of the product. Occupational exposure will be greatest during addition of the formulation BYK-410 to the paint mixers.

Inhalational exposure to the notified polymer may occur during spray application of the paint formulations containing the notified polymer. The paint will only be applied in industrial situations.

7. PUBLIC EXPOSURE

The potential for public exposure of the notified polymer is considered to be low given that the notified polymer will be incorporated into paints for industrial use.

8. ENVIRONMENTAL EXPOSURE

Release

No release or exposure to the environment is expected from this polymer during transportation, with the exception of accidental spillage. There are adequate instructions on the polymers Material Safety Data Sheet (MSDS) to cope with accidental spillage.

Once with customers, the polymer may be exposed to the environment during paint manufacture and application. Throughout manufacture of the paint, the polymer will be exposed during sampling and filling operations. When formulated, paints may contain between 0.1% and 3%, of the product, BYK-410, containing the notified polymer. Due to the low vapour pressure of the polymer, and the simple mixing process when being incorporated into paints, overall release to the environment through sampling and filling operations is expected to be low. The notifier has estimated that the maximum paint loss during manufacture would be 2%. This corresponds to the loss of approximately 55 kg of the polymer per annum, at the maximum rate of import. This waste polymer would be disposed of to landfill.

The most likely range of container sizes for the formulated paints would be 1 L, 4 L, 10 L and 20 L. 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 through conventional spraying in booths. Transfer efficiencies range from 35% to 75% depending on the application method. 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 to landfill.

Fate

Excess paints; residues from drums, cleaning of spray equipment, scrubber apparatus, and filters; and empty drums, will be disposed of to landfill where the polymer would be immobilised in the dry paint.

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

It is unlikely that the notified polymer will reach the sewer through any form of disposal, either as the imported raw material, or in any end use product. Given the relatively low water solubility of the polymer it would be expected that it will be removed from solution by adsorption onto sludge. Little, if any is likely to be contained in treated waste water. Sludge containing the notified substance will be incinerated or landfilled. Incineration would destroy the polymer, and create typical decomposition products of water and oxides of carbon and nitrogen.

9. EVALUATION OF TOXICOLOGICAL DATA

No ecotoxicology data is required to be submitted for polymers of number-average molecular weight (NAMW) greater than 1 000 according to the Act. However the following test data was submitted and evaluated.

9.1 Acute Toxicity

Summary of the acute toxicity of Polymer in BYK-410

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD ₅₀ > 5 000 mg/kg	5
skin irritation	rabbit	not an irritant	6
eye irritation	rabbit	not an irritant	7

9.1.1 Oral Toxicity (5)

Species/strain:	rat /Wistar
Number/sex of animals:	5 male, 5 female
Observation period:	14 days
Method of administration:	single oral dose of 5 000 mg/kg by gavage
Clinical observations:	nil
Mortality:	nil
Morphological findings:	nil
Test method:	according to OECD guidelines (8)
LD ₅₀ :	> 5 000 mg/kg
Result:	low acute oral toxicity

9.1.4 Skin Irritation (6)

Species/strain:	rabbit/ New Zealand white
Number/sex of animals:	5/not stated
Observation period:	7 days
Method of administration:	powdered material wetted with water 1:1 under gauze for 4 hours
Draize scores (9):	all zero
Test method:	according to OECD guidelines (8)
Result:	not an irritant

9.1.5 Eye Irritation (7)

<i>Species/strain:</i>	rabbit/New Zealand white
<i>Number/sex of animals:</i>	6/not stated
<i>Observation period:</i>	7 days
<i>Method of administration:</i>	powder in conjunctival sac of one eye
<i>Draize scores (9) of unirrigated eyes:</i>	conjunctival irritation apparent in all test animals up to 8 hours following application, resolved by 24 hours, scores were zero from day 1 to day 7
<i>Test method:</i>	according to OECD guidelines (8)
<i>Result:</i>	slight conjunctival irritation for 8 hours after application, resolved by 24 hours; not an irritant according to Worksafe criteria (10)

9.4 Overall Assessment of Toxicological Data

Although there is only limited toxicological data for the notified polymer it indicates that the polymer is of minimal toxicological concern. In an acute oral toxicity study using rats, no symptoms were apparent in the 14 day observation period after a single dose of 5 000 mg/kg. An eye irritation study in rabbits produced transitory conjunctival effects up to 8 hours following administration, these were resolved by 24 hours and the polymer was not classified as an irritant. A skin irritation study in rabbits gave a negative response.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicology data were provided, which is acceptable for polymers of NAMW greater than 1 000 according to the Act.

Biological membranes are not permeable to polymers of very large molecular size and therefore bioaccumulation of the notified polymer is not expected (11, 12).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The polymer is unlikely to present a hazard to the environment when it is incorporated into the paint and applied to solid substrates. Such painted objects will be consigned to landfill or recycled at the end of their useful life and the paint containing the notified substance will share their fate.

The main environmental exposure arises from landfill disposal of recovered waste paint (up to 60% of that imported) containing the resin. Such material will be bound to soil and remain immobile in the environment. Hence, the overall environmental hazard is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer will be imported as a 55% component of the formulation BYK-410. The notified polymer has a molecular weight in excess of 1 000 which would largely preclude transmission across biological membranes. It has a low level of low molecular weight species (3.8% below 1 000), a low level of residual monomers and a low volatility. The levels of residual monomers are below the thresholds requiring a hazardous classification. These attributes indicate that the polymer is unlikely to constitute a toxicological hazard and would not be classified as hazardous on this basis. This is confirmed by the limited toxicological data submitted by the notifier. The polymer has a low oral toxicity to the rat and is not classified as either an eye or skin irritant on the basis of studies using rabbits. There was some conjunctival irritation in the rabbit eye however this was transitory and indicated that the notified polymer has some eye irritation potential but this was limited.

The imported formulation is classified as hazardous as the solvent component, n-methyl-2-pyrrolidone (45%), is a respiratory irritant and exceeds the threshold for hazardous classification (1) of 10%. The final products contain between 0.45 and 1.35% of the solvent and would not be classified as hazardous on the basis of solvent content. Currently there is no assigned occupational atmospheric exposure standard for the solvent.

Occupational exposure to the imported formulation containing the notified polymer will be limited during reformulation into paints through the use of engineering controls such as exhaust ventilation and fume extraction. Occupational exposure may potentially occur during spray application of paints containing the notified polymer. These paints will contain only 0.55 to 1.65% of the notified polymer. This in conjunction with engineering controls and personal protective equipment will reduce actual exposure to the notified polymer to a low level. The negligible volatility of the polymer will further reduce inhalational exposure however there will be the possibility of dermal or ocular exposure particularly if splashing occurs on addition to the mixing vessel. Dermal exposure will be reduced by the use of protective clothing. The notifier has indicated that cartridge type respirators will be used during spraying. This personal protective equipment will also reduce inhalational exposure to the additive, n-methyl-2-pyrrolidone.

The risk associated with occupational exposure to the notified polymer will be low, however there is some risk associated with reformulation of the imported product containing the notified polymer, due to the hazardous solvent, n-methyl-2-pyrrolidone. This risk is reduced during application and use of the final paint formulations due to dilution with other components of the paint.

The potential for public exposure to the notified polymer in the form of the paint product is considered to be very low.

In the case of accidental spillage during transport, the public may be exposed to the notified polymer. Public exposure resulting from transport and disposal is expected to be negligible. The MSDS for BYK-410 provides cleanup procedures which should minimise any adverse effects.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer in BYK-410 the following guidelines and precautions should be observed when handling the imported formulation BYK-410:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (13) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (14);
- Industrial clothing should conform to the specifications detailed in AS 2919 (15) and AS 3765.1 (16);
- All occupational footwear should conform to AS/NZS 2210 (17);
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

Due to the presence of the hazardous solvent, n-methyl-2-pyrrolidone in the imported formulation, it is advisable that during formulation and spray application of paints containing the notified polymer, and where engineering controls are inadequate, to use the appropriate respiratory device. The respiratory device should be selected and used in accordance with AS/NZS 1715 (18) and should conform to AS/NZS 1716 (19).

14. MATERIAL SAFETY DATA SHEET

The MSDS for the imported formulation containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (20).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical 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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7. Dickhaus S. 1991. Irritant effects of BYK-LP-R-6075 on rabbit eye. Pharmatox report no. 1-3-26-91. Pharmatox Hannover, Germany.
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16. Standards Australia 1990, *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.
17. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves)*, Standards Association of Australia Publ., Sydney.
18. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.
19. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1715-1994, Selection, Use and Maintenance of Respiratory Protective Devices*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.
20. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.
21. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)], Australian Government Publishing Service, Canberra.

Attachment 1

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

<i>Erythema Formation</i>	<i>Rating</i>	<i>Oedema Formation</i>	<i>Rating</i>
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

<i>Opacity</i>	<i>Rating</i>	<i>Area of Cornea involved</i>	<i>Rating</i>
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

<i>Redness</i>	<i>Rating</i>	<i>Chemosis</i>	<i>Rating</i>	<i>Discharge</i>	<i>Rating</i>
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

<i>Values</i>	<i>Rating</i>
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