File No: STD/1155

June 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in BYK-411

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Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

Chemical in BYK-411

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Nuplex Industries (Australia) Pty Ltd (ABN 25 000 045 572)
49-61 Stephen Road
Botany NSW 2019

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

Chemical Name
Other Names
CAS Number
Molecular Formula
Structural Formula
Molecular Weight
Spectral Data
Purity
Impurities
Additives/Adjuvants
Introduction Volume
Identity of Sites
Exact Use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None reported.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Chemical in BYK-411

SPECTRAL DATA

METHOD	Infrared spectroscopy
Remarks	A reference spectrum was provided
TEST FACILITY	Not specified

METHODS OF DETECTION AND DETERMINATION

METHOD	Gel permeation chromatography
Remarks	A reference was provided
TEST FACILITY	Not specified

3. COMPOSITION

DEGREE OF PURITY
>95% (w/w)

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All hazardous impurities are below the cut-off concentrations for classification of the notified chemical as a hazardous substance.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported as a component (<30%) of the product BYK-411.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-10	1-10	1-10	1-10	1-10

USE
BYK-411 is a rheology additive that will be used to impart anti-settling and anti-sagging properties to formulated coatings for industrial and DIY applications.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Not specified.

IDENTITY OF MANUFACTURER/RECIPIENTS
Not yet known.

TRANSPORTATION AND PACKAGING
Imported in 200 L steel drums and transported by road to the notifier's warehouse and to customers for formulation.

5.2. Operation description

Transport & Warehousing
Imported steel drums of BYK-411 will be transported by road to the notifier's site and to customer sites for formulation.

Coatings Formulation
BYK-411 and other ingredients (such as pigment, resin, solvent etc.) will be subject to high speed dispersing and blending in a mixing vessel. QC testing and batch adjustment will occur during this process. The blended product will be filtered and filled into 200 L steel drums or 20 L steel pails for end use, then transported to the customer's warehouse for distribution

Industrial Application
End use coatings products will be stirred before being pumped into trays for roller application, into dipping equipment, or into spray application equipment.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration Hours/Day*	*Exposure Frequency Days/Year*
Transport & Warehousing	10	4	200
Mixing	40	4	30
Makeup (batch adjustment)	40	2	30
QC testing	10	8	30
End use – roller application	10	8	200
End use – spray application	20	8	200
End use – equipment cleaning	30	2	200

Exposure Details

Transport & Warehousing

The only potential for exposure during transport and warehousing will be in the event of an accident involving breach of imported steel drums. Engineering controls will include fully bunded facilities and appropriate training for carriers. Personal protective equipment (PPE) will include protective clothing and, in the case of spills, impervious gloves, goggles and organic vapour respirators if necessary.

Coatings Formulation

Dermal exposure is possible in the event of splashes or spills of BYK-411 or formulated products during mixing, QC testing, batch adjustment, filtration and filling of end use containers. Engineering controls will include local exhaust ventilation (LEV) fitted to mixing vessels, and PPE will include impervious gloves, coveralls and goggles. QC testing of coatings involving spray painting will be conducted in a spray booth. Coatings will be filled into containers under LEV.

Industrial Application

During roller coating or dipping application there is the potential for dermal exposure from splashes or spills. During spray application there is also the potential for ocular and inhalation exposure from overspray. Engineering controls will include LEV and, for spray application, spray booths. PPE will include protective clothing, impervious gloves and eye protection and, for spray application, a supplied air breathing mask. Exposure will also be limited by the low concentration (<1%) of the notified chemical in end use products.

5.4. Release

RELEASE OF CHEMICAL AT SITE

No release of neat notified chemical is expected as the notified chemical will not be manufactured in Australia. Coatings will be manufactured by a variety of companies throughout Australia. Spills may occur during coating formulation. In this event containment occurs through bunding. As the notified chemical is not volatile there would be negligible release to atmosphere. The notifier has estimated that due to the cleaning of process equipment, containers and spills, approximately 80 kg per year of the notified chemical will be wasted.

RELEASE OF CHEMICAL FROM USE

The coatings containing the notified chemical will be used for both industrial and DIY applications. It ia anticipated that the coatings will be applied by a variety of application techniques including spraying, dipping, rollers and brushes.

The notifier estimates that up to 2 tonnes per annum of the notified chemical may be disposed of through overspray. The majority (80%) of this waste will be generated through industrial application and will be filtered out on the spray booth filter pads and residual solids, including the notified chemical, will be disposed of to an authorised land fill site. The remaining 20% will be generated by DIY painters and it is expected that it will fall to the ground or drop cloths (such as newspaper) where it will harden prior to disposal with other domestic waste to landfill.

A small amount of the notified polymer (up to 75 kg per annum) will be disposed of during drum recycling. It is anticipated that these residues will be incinerated during the recycling process.

Waste generated during cleaning of DIY application equipment such as brushes and rollers will account for 50 kg per annum of the notified chemical. In the worst case this will find its way into waste water, though water is not expected to be the main method of cleaning.

5.5. Disposal

Waste notified chemical will be generated during the manufacture of coatings and during cleaning of coating equipment. This waste will largely be disposed of through licensed waste disposal contractors; generally this is likely to be landfilled but may be incinerated. It is expected that the recycling drums will be cleaned by incineration. Waste paint such as from overspray is also most likely to be land filled.

A small amount may be disposed of to domestic waste water as a result of the cleaning of DIY application equipment such as brushes and rollers.

5.6. Public exposure

The public will only be exposed to BYK-411 in the event of a transport accident involving breach of imported steel drums.

The public will be exposed to end use coatings products containing <1% notified chemical. Dermal exposure is possible during application of coatings, which will most likely be by brush or roller. Exposure will be limited by the low concentration of notified chemical in end use products. Once dried, the notified chemical will be biologically unavailable.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa The notified chemical is a white powder.

The imported product BYK-411 is a light yellow liquid.

Melting Point/Freezing Point 202°C

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Performed using a Differential Thermal Calorimeter.
TEST FACILITY	RCC (1996)

Boiling Point 748, 779 and 809°C

METHOD	Calculated using Meissner's method based on the relation between reference boiling points and chemical types for each component of the notified chemical.
Remarks	Conditions (i.e. pressure) not specified. Calculated for three separate species.
TEST FACILITY	RCC (1998)

Density 1104 kg/m^3 at 20°C

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Assessed with a gas comparison pycnometer.
TEST FACILITY	RCC (1999a)

Vapour Pressure 2.35 x 10^{-27}, 5.20 x 10^{-29} and 1.22 x 10^{-30} kPa

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Calculated for 3 separate species according to the Modified Watson Correlation in the appendix to the test guideline.

TEST FACILITY RCC (1998)

Water Solubility <0.0001 g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method.

Although in the preliminary test water solubility was estimated to be <0.01 g/L, column elution could not be conducted because there was no suitable analytical method for the notified chemical.

The standard flask method was used but the level of the test substance was determined by analysis of non purgable organic carbon (NPOC) using a total organic carbon. The solubility of the notified chemical was below the limit of detection (0.1 mg/L).
TEST FACILITY RCC (1999b)

Hydrolysis as a Function of pH Not determined.

Remarks Hydrolysis of the notified chemical was not investigated due to its low water solubility and the lack of availability of an appropriate method of analysis. The notified chemical does contain functional groups that are susceptible to hydrolysis, but only at extreme pH values.
TEST FACILITY RCC (1999c)

Fat (or n-octanol) Solubility 0.15-3 mg/mL coconut fat at 37.2°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks Analytical Method: Gel Permeation Chromatography (GPC).

Eleven test concentrations were prepared by adding various masses of the test substance to vials and adding coconut fat (warmed to 30-40°C). Vials were maintained at 41 ± 1°C for six days on a rotating table then transferred to an oven at 37°C for 36 days. Samples were then warmed to 40°C for one hour and filtered and analysed by GPC. The measured fat solubility indicates that the notified chemical is slightly soluble in coconut fat (Mensink 1995).
TEST FACILITY GlobalTox (2001)

Partition Coefficient (n-octanol/water) log Pow =12.1, 14.1, 16.0

METHOD OECD TG 107 Partition Coefficient (n-octanol/water).
OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks A simplified shake flask method was attempted but was found not suitable for the determination of partition coefficient for the notified chemical. Partition coefficients for three separate species were determined by using the fragmentation calculation methods described in the Appendix to OECD TG 117.
TEST FACILITY RCC (1999d)

Adsorption/Desorption log Koc = 7

METHOD Calculated using ACD Software
Remarks The Koc was determined for a surrogate compound using the ACD software. The surrogate was used because the notified chemical exceeded the program limit for the number of potential charged centres.
TEST FACILITY GlobalTox (2001)

Dissociation Constant pKa >10

METHOD Calculated using ACD Software
Remarks The dissociation constant for the notified chemical was estimated using the ACD Software. The results indicate that the notified chemical is not likely to dissociate within the environmental pH range (4-9).
TEST FACILITY GlobalTox (2001)

Particle Size Range 1-100 µm
Median Mass Diameter 33.23µm
Inspirable fraction 98.36%
Respirable fraction 12.6%

METHOD EC Directorate General XII-JRC, Science Research and Development-Joint Research Centre. "Particle Size Distribution, Fibre Length and Diameter Distribution" Guidance Document, ECB/TM/February 1996

Range (µm)	*Mass (%)*
<7.82	10
<33.23	50
<66.82	90

Remarks The laser scattering/diffraction method was used.
TEST FACILITY RCC (1999e)

Flash Point Not determined

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Flash point of the imported product BYK-411 is 91˚C
TEST FACILITY Not specified.

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical could not be ignited in the preliminary test.
TEST FACILITY RCC (1999f)

Autoignition Temperature Not auto-flammable

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The notified chemical melted during the test
TEST FACILITY RCC (1999g)

Explosive Properties

Remarks No explosive properties are predicted based on the structure of the notified chemical and other phyisco-chemical properties such as flammability and autoignition.

Reactivity

Remarks The notified chemical is expected to be stable under normal operating conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	LD50 >5000 mg/kg bw low toxicity
Rat, acute dermal	LD50 >2000 mg/kg bw low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence
Rat, repeat dose oral toxicity – 28 days.	NOEL 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 401 Acute Oral Toxicity-Limit Test.
Species/Strain Rat/Wistar (Winkelman strain)
Vehicle 1% Carboxymethylcellulose
Remarks - Method None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0/10
2	5/sex	5000	0/10

LD50 >5000 mg/kg bw
Signs of Toxicity No clinical symptoms of toxicity.

Quieter behaviour was observed in high dose animals after dosing. This was considered to be due to the high dose volume (5 mL/100 g bw), and had regressed within 24 hours.
Effects in Organs No anatomical or pathological changes were observed.
Remarks - Results None

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY Pharmatox (1998a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD OECD TG 402 Acute Dermal Toxicity.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain Rat/HanIbm: WIST (SPF)
Vehicle Polyethylene glycol (PEG) 300
Type of dressing Semi-occlusive
Remarks - Method None

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0/10

LD50 >2000 mg/kg bw
Signs of Toxicity - Local No signs of toxicity
Signs of Toxicity - Systemic No signs of toxicity
Effects in Organs No macroscopic changes were observed at necropsy
Remarks - Results None

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY RCC (1999h)

7.3. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Vehicle Water
Observation Period 7 days
Type of Dressing Semi-occlusive
Remarks - Method None

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0	-	0
Oedema	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results None

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY Pharmatox (1998b)

7.4. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 72 hours
Remarks - Method None

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0	0	2	8 hours	0
Conjunctiva: chemosis	0	0	0	0	-	0

Conjunctiva: discharge	0	0	0	2	8 hours	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results None

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Pharmatox (1998c)

7.5. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation Maximisation test
EC Directive 96/54/EC B.6 Skin Sensitisation – Maximisation test

Species/Strain Guinea pig/Himalayan spotted (SPF)

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: Signs of irritation at both concentrations tested, 1% and 3%
topical: Not reported

MAIN STUDY

Number of Animals Test Group: 10 Control Group: 5

INDUCTION PHASE Induction Concentration:
intradermal: 1%
topical: 50%

Signs of Irritation Erythema, oedema, necrotising dermatitis, encrustation and exfoliation of encrustation were observed in both test and control animals after intradermal induction.

Discrete/patchy to moderate/confluent erythema was observed in 9/10 test animals at 24 hours and in all test animals 48 hours after topical induction. No such symptoms were observed after topical induction in control animals.

CHALLENGE PHASE

1st challenge topical: 50%

Remarks - Method None

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after 1st challenge*	
		24 h	*48 h*
Test Group	50%	0/5	0/5
Control Group	50%	0/10	0/10

Remarks - Results Concurrent positive controls showed skin reactions in 100% of animals 48 hours after topical challenge.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY RCC (1999i)

7.6. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

METHOD	Not specified
Species/Strain	Rat/Wistar (SPF)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: None
Vehicle	Polyethylene glycol (PEG) 300
Remarks - Method	Similar to OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0/10
II (low dose)	5/sex	50	0/10
III (mid dose)	5/sex	200	0/10
IV (high dose)	5/sex	1000	0/10

Clinical Observations

No treatment-related clinical effects were observed.

Laboratory Findings – Clinical Chemistry, Haematology

No treatment-related effects were observed.

Effects in Organs

High dose males had statistically significantly lower (~10%) relative heart weights compared to controls. In the absence of other observed effects, this finding was considered incidental.

No other treatment-related macroscopic or histologic effects were observed.

Remarks – Results

No effects were observed that were considered to distinguish treated rats from controls.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day in this study, based on the absence of treatment-related effects in all treated groups.

TEST FACILITY RCC (1999j)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	Chemikaliengesetz (Chemicals Act) of the Federal Republic of Germany, Annex 1, July 25, 1994, last revision dated May 14, 1997.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Phenobarbital and beta-naphthoflavone induced rat S9 liver fraction
Concentration Range in Main Test	a) With metabolic activation: 33-5000 µg/plate b) Without metabolic activation: 33-5000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	Plate incorporation and pre-incubation tests used.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	None observed		None observed	None observed
Test 2		100	None observed	None observed
Present				
Test 1	None observed		None observed	None observed
Test 2		33	None observed	None observed

Remarks - Results: Positive controls showed markedly higher numbers of revertant colonies, and negative controls were within historical ranges.

CONCLUSION: The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: RCC (1999k)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE: Notified chemical

METHOD: Chemikaliengesetz (Chemicals Act) of the Federal Republic of Germany, Annex 1, July 25, 1994, last revision dated May 14, 1997.

Cell Type/Cell Line: Chinese hamster V79 cells
Metabolic Activation System: Phenobarbital and beta-naphthoflavone induced rat liver S9 fraction
Vehicle: Dimethyl sulfoxide
Remarks - Method: None

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	7.5, 15, 30*, 60*, 80, 100*	4 hours	18 hours
Test 2	3.1, 6.3, 12.5, 25*, 50*, 100*	18 hours	18 hours
	12.5, 25, 50, 100*	28 hours	28 hours
Present			
Test 1	3.1, 6.3, 12.5*, 25*, 50*, 100*	4 hours	18 hours
Test 2	3.1, 6.3, 12.5, 25*, 50*, 100*	4 hours	28 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	100*	None observed	None observed	None observed
Test 2		None observed	100	None observed
Present				
Test 1	6.25*	100*	25	None observed
Test 2		100*	50	None observed

*No dose clear dose dependent effects were observed.

Remarks - Results: Solvent controls were within the range of historical control data, and positive controls demonstrated the sensitivity of the assay.

CONCLUSION: The notified chemical was not clastogenic to Chinese hamster V79 cells treated in vitro under the conditions of the test.

TEST FACILITY	RCC (1999l)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Micro-organisms from a domestic wastewater treatment plant.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	No dissolved organic carbon measurements made due to the insoluble nature of the test material. pH measured on days 0 and 28.
Remarks - Method	Monitoring of daily oxygen consumption values throughout the study duration assessed degradation of the test material. Test concentration 20 mg/L, with culture medium in sealed containers tested in the dark at 21±0.9°C.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
14	-	14	81
28	4	28	88

Remarks - Results	The toxic control and sodium benzoate control satisfied validation criteria. Toxicity control experiment showed no inhibition of the microbial activity.
CONCLUSION	The notified chemical is not readily biodegradable.
TEST FACILITY	RCC (1999m)

8.1.2. Bioaccumulation

Data regarding the bioaccumulation potential of the notified chemical were not provided. The high partition coefficient and low water solubility of the notified chemical suggest potential for bioaccumulation. However, due to the relatively high NAMW and low aquatic exposure the notified chemical is unlikely to bioaccumulate (Connell, 1990).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test -static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish -static.
Species	Zebra Fish (*Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC Limit of detection (LOD) 1 mg/L.
Remarks – Method	Fish were exposed to a single supersaturated suspension of 100 mg/L. At the start of the study the test substance was finely divided and homogeneously suspended in the test media. After about 2 hours particles

of the test material were observed at the water surface. After one day the test media was more or less clear and test material was observed to be floating on the surface or lying on the bottom. Water quality parameters of pH (7.9-8.1), water temperature (21-22°C) and O_2 content (>8.4 mg/L) were within normal limits throughout study. Concentrations were measured for the whole of the suspension.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	-	7	0	0	0	0	0
100	90.4	7	0	0	0	0	0

LC50	> 100 mg/L at 96 hours (Nominal)
NOEC	100 mg/L at 96 hours (Nominal)
Remarks – Results	No mortalities or sublethal effects were observed at the test concentration.

CONCLUSION The notified chemical is non-toxic to fish up to the limit of its water solubility.

TEST FACILITY RCC (1999n)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC Limit of detection (LOD) 1 mg/L.
Remarks - Method	Daphnia were exposed to a single supersaturated suspension of 100 mg/L. At the start of the study the test substance was finely divided and homogeneously suspended in the test media. After about 1 hour particles of the test material were observed at the water surface. After one day the test media was clear and test material was observed to be floating on the surface or lying on the bottom. Water quality parameters of pH (7.8-8.2), water temperature (20-22°C) and O_2 content (>8.5 mg/L) were within normal limits throughout study. Concentrations were measured for the whole of the suspension.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
100	83-88	20	0	0

LC50	>100 mg/L at 48 hours (Nominal)
NOEC	100 mg/L at 48 hours (Nominal)
Remarks - Results	During the 48 h period no immobility, mortality or other signs of intoxication were observed.

CONCLUSION	The notified chemical is non-toxic to Daphnia up to the limit of its water solubility.
TEST FACILITY	RCC (1999o)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L Actual: 83-89 mg/L
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	HPLC Limit of detection (LOD) 1 mg/L.
Remarks - Method	Algae were exposed to a single supersaturated suspension of 100 mg/L, under constant illumination and aeration. At the start of the study the test substance was finely divided and homogeneously suspended in the test media. After about 1 hour particles of the test material were observed at the water surface. After one day test material was observed to be floating on the surface or lying on the bottom, so the test media was constantly stirred. The pH of the test media increased from 7.8 at the start of the test to 8.9 at the end. Concentrations were measured for the whole the suspension.
RESULTS	
	After 72 h, there was no significant inhibition of algal growth or biomass at the nominal concentration of 100 mg/L. Therefore, EC50 > 100 mg/L and NOEC is 100 mg/L.
Remarks - Results	None.
CONCLUSION	The ecotoxicity data indicates the notified chemical is practically non-toxic to algae.
TEST FACILITY	RCC (1999p)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The majority of the notified chemical will be formulated with other components to form a stable coating film that firmly adheres to the surfaces to which it is applied. The majority of waste generated during the reformulation process and end use will go to landfill or will be incinerated where it is unlikely to present a hazard to the environment, as it is not water soluble and thus will not be mobile in soils. The notified chemical is likely to become associated with the soil matrix and sediments and slowly degrade.

During use of the coating, it is estimated that 50 kg of the notified chemical per year will be disposed of to sewer by the general public due to cleaning of equipment and spills. A PEC for disposal to sewer can be calculated as follows:

Amount of notified chemical released	50 kg
Number of days coating possibly used	365 days
Population of Australia	20.1 million
Amount of water released per person to sewer	200 L
Predicted Environmental Concentration in effluent in STP	$\frac{50{,}000\times1000\times1000}{365\times200\times20{,}100{,}000}$ = 0.034 µg/L

Given the expected low water solubility and the widespread and diffuse use of the notified chemical, levels in the sewer are likely to be low. Any notified chemical in the sewer is likely to adhere to suspended organic material or sediments, thus the PEC in receiving waters would be much lower.

At the end of their useful lives, buildings or articles to which the coating has been applied will also be disposed of by landfill.

9.1.2. Environment – effects assessment

The notified chemical is non-toxic to fish, Daphnia and algae up to the level of its water solubility.

Acute results are available for 3 trophic levels. Applying an assessment factor of 100 to the ecotoxicity data, the predicted no effect concentration (PNEC) is > 1 mg/L.

9.1.3. Environment – risk characterisation

The majority of the notified chemical will be incorporated at a low concentration into coatings and, once applied and dried, poses little risk to the environment since an inert matrix will be formed. The major loss in coating application will be due to overspray, all of which will be disposed of by landfill.

Wastes will be mainly disposed of to landfill or it may be incinerated. In landfill, the notified chemical is expected to associate with soil and sediment and slowly degrade through biotic and abiotic processes to water and oxides of carbon and nitrogen. If wastes are incinerated then the notified chemical would be destroyed with the production of water vapour, and oxides of carbon and nitrogen.

With release to sewer, due to its expected low water solubility, the notified chemical is likely to become associated with sediment and degrade slowly through abiotic and biotic processes. The worst case PEC/PNEC ratio is calculated to be 0.034 µg/L/1 mg/L =0.000034, indicating that there is unlikely to be an environmental risk to the aquatic compartment.

Furthermore, the limited exposure of the notified chemical to the aquatic compartment due to its low water solubility, expected strong adsorption to sludge and the relatively high molecular weight, mean that it is unlikely to have an adverse effect on aquatic organisms.

The majority of the notified chemical will be applied to surfaces and either share the fate of the

surface at the end of its useful life (most likely to landfill) or be removed by sanding. If removed by sanding the coating containing the notified polymer will be broken up into solid particulate matter and most likely disposed to landfill or deposited on nearby ground.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport & Warehousing

Exposure is only likely in the event of a serious accident involving breach of imported steel drums. Exposure is expected to be infrequent and acute, and will be limited by personal protective equipment (PPE) and handling as specified in the MSDS. Hazards associated with exposure to the imported product BYK-411 will be due principally to the major ingredient, N-methyl-2-pyrrolidone, which is irritating to eyes and skin.

Coating Formulation

Exposure during mixing, QC testing, batch adjustment, filtration and filling of end use containers will most likely be via dermal contact. Dermal exposure will be limited by PPE including gloves and protective clothing.

Dermal exposure was estimated by EASE (HSE, 1994). Assuming non-dispersive use and intermittent direct handling, estimated dermal exposure is 0.1-1 mg/cm^2/day of BYK-411 containing up to 30% notified chemical. This equates to 0.03-0.3 mg/cm^2/day of notified chemical. Therefore, for a 70 kg worker with surface area for hands at 820 cm^2 and forearms at 1140 cm^2, and assuming 100% absorption, systemic exposure is estimated to be 0.84-8.4 mg/kg bw/day of the notified chemical.

Due to the very low predicted vapour pressure of the notified chemical, inhalation exposure is unlikely, except during spray painting for QC testing. Use of spray booths will contain overspray and substantially limit exposure.

Industrial Application

Dermal exposure is possible during roller and dipping application; this will be limited by PPE including gloves and protective clothing. Ocular and inhalation exposure is possible during spray application; this will be limited by use of spray booths and/or supplied breathing masks. Overall, exposure will be substantially limited by the low concentration (0.<1%) of the notified chemical in end use products.

9.2.2. Public health – exposure assessment

Public exposure may occur during application of end use coatings products. Dermal exposure is likely during application by brush or roller. PPE is not expected to be routinely employed; however exposure will be limited by the low concentration (<1%) of notified chemical in end use products. It is expected that public exposure will be negligible once the product has dried and the notified chemical is no longer biologically unavailable.

9.2.3. Human health – effects assessment

The notified chemical was of low acute oral and dermal toxicity in rats. Inhalation toxicity data were not provided, but the notified chemical has very low estimated vapour pressure, so inhalation is not expected to be a likely route of exposure.

The notified chemical was not irritating to rabbit skin and slightly irritating to rabbit eye. In a Guinea pig maximisation test there was no evidence of sensitisation to the notified chemical. The notified chemical was no mutagenic in a bacterial mutation test and not genotoxic in an in vitro mammalian chromosome aberration test.

In a 28-day repeat dose oral toxicity study in rats, the No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day, based on the absence of treatment-related effects in any of the treatment groups.

Based on the available data, the notified chemical is not classified as a hazardous substance in

accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is of low acute toxicity (LD50>2000 mg/kg bw/day for dermal route and >5000 mg/kg bw/day for oral route). The notified chemical is not an irritant or a sensitiser, nor has it been shown to have genotoxic effects.

Chronic dermal exposure during formulation was estimated to be 0.84-8.4 mg/kg bw/day. The margin of exposure (MOE) is based on a sub-chronic oral NOEL of 1000 mg/kg bw/day. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. For dermal exposure, the MOE is calculated as >110 during formulation. Therefore, based on available toxicological data, the risk of chronic systemic toxicity using modelled worker data is acceptable for formulation workers even where direct handling is assumed. Actual exposure is expected to be lower than this, when PPE such as gloves and protective clothing are employed.

Overall, the risk to workers is low, based on the proposed use patterns and the low hazard associated with the notified chemical.

9.2.5. Public health – risk characterisation

It is likely that there will be exposure to the notified chemical during application of end use products. However, no hazards to human health have been determined for the notified chemical, so overall the risk to public health is expected to be low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the notified chemical would be classified as Chronic 4 on environmental grounds using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003). This system is not mandated in Australia and carries no legal status but is presented for information purposes.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

the notified chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used as an ingredient in coatings products.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS for the imported product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the imported product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of to landfill or be incinerated.

Emergency procedures

- Spills/release of the notified chemical should be handled by soaking up with inert absorbent material and follow state or local regulation for the disposal of the waste.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
  – if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Connell DW, 1990. General characteristics of organic compounds which exhibit bioaccumulation. *In*: Connell DW, (Ed) *Bioaccumulation of Xenobiotic Compounds*. CRC Press, Boca Raton, USA

GlobalTox (2001) Schedule II Notification Related Studies for BYK-[Notified Chemical]. GlobalTox International Consultants Inc., Guelph, Canada (unpublished report provided by the notifier)

Mensink BJWG, Montforts M, Wijkhuizen-Maslankiewicz L, Tibosch H and Linders JBHJ (1995). Report no. 679101022: Manual for Summarising and Evaluating the Environmental Aspects of Pesticides. National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands.

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

Pharmatox (1998a) Acute Toxicological Study of Compound BYK-[Notified Chemical] After One Oral Application to the Rat: LD50-Approximately. Pharmatox Beratung und Forschung GmbH, Hannover, Germany

Pharmatox (1998b) Irritant Effects of BYK-[Notified Chemical] on Rabbit Skin Acc. To Draize (OECD-Guidelines No. 404) Pharmatox Beratung und Forschung, Hannover, Germany

Pharmatox (1998c) Irritant Effects of Compound BYK-[Notified Chemical] on Rabbit Eye (OECD-Guidelines No. 405), Pharmatox Beratung und Forschung GmbH, Hannover, Germany

RCC (1996) Determination of the Melting Point/Melting Range of [Notified Chemical], Study Project No.: 710291. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1998) Calculation of the Vapour Pressure of [Notified Chemical], Study Project No.: 710313. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999a) Determination of the Relative Density of [Notified Chemical], Study Project No.: 710302. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999b) Determination of the Water Solubility of [Notified Chemical], Study Project No.: 710324. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999c) Hydrolysis Determination of [Notified Chemical] at Difference pH Values, RCC Project No.: 710526. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999d) Determination of the Partition Coefficient (n-Octanol/Water) of [Notified Chemical], Study Project No.: 710335. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999e) Determination of the Particle Size Distribution of [Notified Chemical], Study Project No.: 732701. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999f) Determination of the Flammability of [Notified Chemical], Study Project No.: 710346. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999g) Determination of the Relative Self-Ignition Temperature of [Notified Chemical], Study Project No.: 710368. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999h) [Notified Chemical]: Acute Dermal Toxicity Study in Rat, RCC Project 710392. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999i) [Notified Chemical]: Contact Hypersensitivity in Albino Guinea Pigs Maximuzation-Test, RCC Project 710403. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999j) [Notified Chemical]: 28-Day Oral Toxicity (Gavage) Study in the Wistar Rat, RCC Project 710414. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999k) Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay with [Notified Chemical], RCC-CCR Projeect 623001. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999l) *In Vitro* Chromosome Aberration Assay in Chinese Hamster V79 Cells with [Notified Chemical], RCC Project 710447. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999m) Ready biodegradability of [Notified Chemical] in a manometric respirometry test, RCC Project 710515. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999n) Acute toxicity of [Notified Chemical] to zebra fish (*Brachydanio rerio*) in a 96-hour static test, RCC Project 710458. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999o) Acute toxicity of [Notified Chemical] to *Daphnia magna* in a 48-hour immobilization study, RCC Project 7104381 RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

RCC (1999p) Toxicity of [Notified Chemical]to *Scenedsmus suaspicatus* in a 72 –hour algal growth inhibition test, RCC Project 710414. RCC Ltd, Itingen, Switzerland (unpublished report provided by the notifier)

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.