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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer BYK-LP N 206XX

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

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

DIC Australia Pty Ltd (ABN 12 000 079 550)
323 Chisholm Road
AUBURN NSW 2144

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name, Molecular formula, Structural formula, Molecular weight, Spectral data, Methods of detection and determination, Impurities, Additives/Adjuvants, Import volume, Residual Monomers, Polymer Constituents, Identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Water solubility, Hydrolysis as a function of pH, Partition coefficient, Adsorption/Desorption, Dissociation constant, Flammability limits, Explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
BYK-LP N 20666
BYK-LP N 20667
BYK-LP N 20668

CAS NUMBER
The notified polymer covers three distinct polymers (i.e. BYK-LP N 20666, BYK-LP N 20667 and BYK-LP N 20668) that share the same CAS number.

MOLECULAR WEIGHT
Mn > 1000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Clear to light yellowish liquid

Property	*Value	Data Source/Justification
Melting Point	Not determined	Liquid at 20°C.
Density	BYK-LP N 20666: 1050 kg/m^3 at 20°C BYK-LP N 20667: 1030 kg/m^3 at 20°C BYK-LP N 20668: 1000 kg/m^3 at 20°C	MSDS
Vapour Pressure	< 0.1 kPa (temperature not reported)	MSDS
Water Solubility	BYK-LP N 20666: > 160 g/L at 20°C BYK-LP N 20667: 1-2 g/L at 20°C BYK-LP N 20668: immiscible	Measured (qualitative test) Measured (qualitative test) MSDS
Hydrolysis as a Function of pH	Not determined	No hydrolysable groups present.
Partition Coefficient (n-octanol/water)	Not determined	Determination of Partition Coefficient is difficult for polymers. Given the water solubility of each polymer, the value is expected to be the highest for BYK-LP N 20668, and the lowest (probably negative) for BYK-LP N 20666. The value for BYK-LP N 20667 is expected to be between those values.
Adsorption/Desorption	Not determined	The log Koc value for each polymer would vary according to its water solubility. The value for BYK-LP N 20668 is expected to be the highest. However, given their potential cationic nature, each polymer is expected to be highly adsorbed.
Dissociation Constant	Expected pKa ≥ 9.8, potentially cationic in environmental pH 4-9.	Estimated
Particle Size	Not determined	Liquid at 20°C.
Flash Point	> 100°C at 101.3 kPa	MSDS
Flammability	Not expected to be highly flammable	Estimated from the measured flash point
Autoignition Temperature	270°C	MSDS
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores

* The notified polymer covers three discrete polymers (BYK-LP N 20666, BYK-LP N 20667 and BYK-LP N 20668). Whenever a single value is provided, it is considered to be representative of all three.

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, please refer to Appendix A.

The notified polymer has a low vapour pressure. However, as the notified polymer covers three distinct polymers, the notified polymer ranges in water solubility and lipophilicity from highly soluble/poorly lipophilic (BYK-LP N 20666), to moderately soluble/slightly lipophilic (BYK-LP N 20667) through to insoluble/highly lipophilic (BYK-LP N 20668).

Reactivity

The notified polymer is expected to be stable under normal storage and handling conditions.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported in the neat form (> 99%) or as a component of finished coatings or ink products (1-90%).

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

PORT OF ENTRY
All major sea ports throughout Australia.

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in the neat form (> 99%) by sea in 25 kg or 200 kg sealed drums, or as a component of finished coatings or ink products (1-90%), and transported by road or rail to the notifier's storage warehouse or manufacturing sites. Prior to use, the drums will be stored in a dry, cool, bunded and well-ventilated area.

USE
The notified polymer will be used as a wetting and dispersive agent in industrial printing inks (30% of the total import volume) and industrial coatings (70% of the total import volume) at a concentration of 1-90%.

Of the 70% of the notified polymer to be used in paints/coatings, a predicted 80% of these paints will be solvent-based and 20% will be water-based. The coatings will be primarily used for Original Equipment Manufacturer applications.

OPERATION DESCRIPTION
There will be no reformulation or repackaging of the notified polymer when imported as a component of finished coatings or printing inks; the finished product will be directly sold to customers for industrial application.

Coating/Ink Formulation
The notified polymer in the neat form (> 99%) will be blended into finished coatings or inks in closed automated systems with dedicated transfer lines. The notified polymer will be directly pumped from the storage drum to the blending vessel and added to the millbase. Following complete incorporation, any further additives (solvents, resins, pigments or fillers) will be added.

After formulation, the finished product (1-90% notified polymer) will be transferred via pipes to a hopper, or similar device, where it will be emptied into metal containers that are subsequently sealed and labelled. These may be stored on-site prior to their distribution to end-use customers.

Occasionally the coatings and inks may be manufactured in batch mixers, where addition of the notified polymer is semi-automated. This process will involve workers opening the pails or drums, weighing the required amount of notified polymer and manually charging the blending vessels.

All processes will occur under exhaust ventilation.

The ink and coating formulations (1-90% notified polymer) will be sampled via taps in the blending vessel, and tested by laboratory technicians to ensure that they meet set specifications and pass quality control testing.

All manufacturing and application equipment will be cleaned by rinsing with either solvents or water, depending on the formulation. Solvent washings will be collected and reused in a subsequent batch, or will be incinerated. Water-based washings will be treated prior to release to sewer treatment plants, resulting in the collection and disposal of the notified polymer to landfill.

Coating Application:
The industrial coatings (1-90% notified polymer) will be applied by spray (75%), brush (20%) or roller (5%). Prior to application, the paint will be manually stirred and poured into trays or into the spray guns. Spray applications will be conducted in spray booths at industrial sites.

Printing Ink Application:
When used in printing inks, the ink formulation will be transferred to an enclosed vessel of the fully automated labelling machine equipment via transfer lines connected to the storage drums.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Waterside	10	4	50
Storage and transport	70	4	150
Formulation			
Production of coatings	40	5	200
Production of inks	40	5	200
Lab technicians	10	2	100
Application			
Coatings	100	6	250
Printing inks	20	8	250

EXPOSURE DETAILS

Transport and Storage
Exposure to the notified polymer (> 99%) by waterside and storage and transport workers is unlikely, except in the case of accidental spillage or breach of packaging.

Formulation
There is potential for dermal and ocular exposure to the neat (> 99%) and formulated (1-90%) notified polymer, when formulation workers connect or disconnect transfer lines, when manually weighing and charging the blending vessels, during routine cleaning and maintenance of equipment, when cleaning up spills or leaks and when taking samples for testing. Exposure from other sources is likely to be low during formulation, as the process will be enclosed and automated.

In all cases where exposure to the notified polymer may occur it is stated by the notifier that personal protective equipment, such as coveralls, safety goggles and gloves, will be used by workers to limit exposure. It is also stated that local exhaust ventilation will be employed when weighing and charging the blending vessels to limit inhalation exposure to the notified polymer.

End use
Printing Ink:
Exposure to the notified polymer (1-90%) when used in printing inks may result via the dermal or ocular routes when connecting and disconnecting transfer lines to the labelling machine. Further exposure is not anticipated as the labelling machine is fully automated and enclosed.

Coating Application:
Dermal and ocular exposure of application workers to the notified polymer (1-90%) may occur during manual addition of the coatings to the spray guns, spray application and when cleaning up equipment. Inhalation exposure is possible during spraying.

Dermal and ocular exposure of workers to the notified polymer may occur during brush and roller applications,

particularly during manual decanting and manual application, and when cleaning up equipment.

It is stated by the notifier that to limit exposure all end-users will wear eye protection, coveralls and impermeable gloves and, if necessary, an air respirator will also be worn. Furthermore, all spray applications will be conducted within spray booths at industrial manufacturing facilities to limit inhalation exposure.

Workers may make dermal contact with the notified polymer once the ink or coating formulation is dried to the substrate. Once dried, the coating or ink will form an inert film that will contain and immobilise the notified polymer, making it unavailable for dermal absorption.

6.1.2. Public exposure

The public may be exposed to the notified polymer through contact with the dried coatings or inks (1-90%) on substrates. However, given that the notified polymer will be trapped within a polymer matrix once the coatings or inks are dry, dermal absorption is unlikely.

6.2. Human health effects assessment

The results from a toxicological investigation conducted on BYK-LP N 20666 are summarised in the table below. Details of this study can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity (BYK-LP N 20666)	LD50 > 2500 mg/kg bw; low toxicity

The result from the one toxicological endpoint given shows that BYK-LP N 20666 is of low toxicity by the oral route. Given the lack of results for all other toxicological endpoints, the potential hazards of the notified polymer cannot be identified.

General toxicity.
Systemic toxicity is unlikely as polymers with Mn > 1000 Da are poorly absorbed across biological membranes.

Toxicological data submitted by the notifier for BYK-LP N 20666 indicates that it is of low toxicity by the oral route. Given that BYK-LP N 20666 is highly water soluble and has a Mn > 1000 Da, the low toxicity of BYK-LP N 20666 is not unexpected, as it would likely pass through and be excreted than be absorbed across the gastrointestinal tract. This result may not be indicative of the acute oral toxicity of the notified polymer as a whole, as the physicochemical properties (i.e. water solubility and lipophilicity) for each of the three discrete polymers that comprise the notified polymer vary considerably.

Of the three discrete polymers of the notified polymer, BYK-LP N 20667 has the most favourable physicochemical properties for absorption across the gastrointestinal tract, and therefore might be expected to present the highest hazard by the oral route. Given the high molecular weight and low percentage of low molecular weight species, toxicity by the oral route is not expected.

Irritation and Sensitisation.
The notified polymer is surface active and potentially cationic, both of which are structural alerts for irritants (Hulzebos, 2005). Therefore the notified polymer may possess some irritant character. BYK-LP N 20667 based on its physicochemical properties (i.e. moderately water soluble/slightly lipophilic) would be expected to have the highest potential for irritancy. However, given the high molecular weight and low percentage of low molecular weight species, the potential for irritancy may only be at most moderate.

As the vapour pressure of the notified polymer is low, it is not expected to pose an inhalation hazard. However, under conditions where mists can be formed it may present itself as a mild upper respiratory tract irritant.

The sensitisation potential of the notified polymer is unknown.

Health hazard classification
Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Due to the limited available information, the hazard of the notified polymer is uncertain. However, based on structural alerts, irritancy of unknown severity is possible.

Given the notified polymer is introduced in the neat form and the formulated products could contain high concentrations (up to 90%) of the notified polymer, all workers that are likely to be exposed to the notified polymer in any form are potentially at risk of irritation.

Given the proposed use of PPE by all workers, the engineering controls in place and that spray applications of coatings will only be conducted at industrial sites in spray booths, the risk to workers of the notified polymer is not considered to be unacceptable.

6.3.2. Public health

As the public will not be exposed to the notified polymer where it is bioavailable, the risk to the public from exposure to the notified polymer is not expected to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

During manufacture and blending of the coating products, an estimated 1% of the total importation volume of the notified polymer may be regarded as spilt wastes. The spills will be readily contained and collected for disposal to landfill or be incinerated.

At most, 1% of the total importation volume of the notified polymer is anticipated to remain in the storage containers as residues. The storage containers will be cured prior to disposal to landfill.

Thirty percent (30%) of the total introduction volume for the notified polymer is likely to be used in inks and the remaining 70% will be used in industrial paints/coatings.

No release of the notified polymer to sewers is expected from rinsing any equipment used to manufacture printing inks and solvent-based paints/coatings. The equipment will be rinsed with solvents, which are either reused in a subsequent formulation batch or will be incinerated.

Of the 70% of the notified polymer to be used in paints/coatings, a predicted 80% of these paints will be solvent-based and 20% will be water-based. For water-based formulations (14% of the import volume), it is predicted that < 1% of the notified polymer used (up to 14 kg of the annual importation volumes) may be lost due to cleaning the manufacturing equipment, as the equipment will be flushed with water and may be released to sewer treatment plants. These washes will undergo a process of flocculation during which time the notified polymer will be removed and disposed to landfill.

RELEASE OF CHEMICAL FROM USE

Release of the notified polymer from use as a printing ink will be negligible, as little waste would be generated. Waste may be generated when the finished ink formulation is transferred to the labelling equipment. Once in the machine, the ink is directly applied to the packaging (e.g. carton) substrate and immediately cured/dried.

When coating formulations containing the notified polymer are applied by spray techniques, it is anticipated that approximately 20-30% of the coating product will form overspray and be collected as waste material. As the application of coatings will be conducted at industrial sites in designated spray booths, the overspray will be captured in the spray booth and on kraft paper or newspaper. The product will then dry onto the paper and be disposed to landfill or be incinerated.

During industrial use of the notified polymer, it is estimated that < 1% of the notified polymer will be spilt. These spills will be contained and disposed to landfill or be incinerated. Less than 1% of the notified polymer may remain as residues in the product containers. These will be disposed to landfill or be incinerated.

Equipment used to apply the coating formulations may be rinsed with organic solvents or water depending on the type of formulation. For solvent-based formulations, the equipment may be rinsed with solvents that will be reused or incinerated. It is predicted that 1% of notified polymer used in water-based coatings (up to 14 kg of the annual importation volume) may be released to sewer treatment plants due to application equipment rinsing. These washes will undergo a process of flocculation during which time the notified polymer will be removed and disposed to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer will be disposed predominately to landfill or be incinerated. When used as solvent based coating/painting, all application equipment will be rinsed with solvents with the solvent reused in a subsequent batch or will be incinerated.

Washings collected from equipment cleaning during coating manufacture and use may be released to sewer treatment plants. This is assumed to be up to 28 kg of the notified polymer released annually (2% of the water based formulation) and will undergo a process of flocculation where the notified polymer is separated from the solution, and then disposed to landfill.

Products containing the notified polymer, e.g. packaging materials, are likely to end up in landfill at the end of their useful life. Residues of the notified polymer that remain in empty storage containers will ultimately be disposed to landfill.

7.1.2 Environmental fate

No environmental fate data were submitted.

The notified polymer will be disposed predominately to landfill or be incinerated.

Two per cent of the notified polymer used in water-based coating formulations (equivalent to 0.28% of total import volume) is predicted to be released to sewers. After flocculation processes, the notified polymer is expected to be collected at sewage treatment plants and disposed to landfill.

Thirty percent of the notified polymer used in ink is expected to be mostly applied to paper and cardboard that is likely to be recycled. During the recycling process, the waste paper will be repulped using chemical agents that enhance fibre separation and ink detachment. The aqueous wastes generated are expected to go to trade waste sewers. It is assumed that 1.5% of the notified polymer (5% of ink use) would partition to the supernatant water which is released to the sewer (due to the moderate to high water solubility of BYK-LP N 20666 and BYK-LP N 20667). Sludge generated during the washing process will be dried and incinerated or sent to landfill for disposal.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	1.8%	
Annual quantity of chemical released to sewer	180.000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.69	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.16	µg/L
PEC - Ocean:	0.02	µg/L

7.2. Environmental effects assessment

The result from one ecotoxicological investigation conducted on BYK-LP N 20666 is summarised in the table below. Details of this study can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	NOEC >100 mg/L	Low toxicity

BYK-LP N 20666 has the highest water solubility of the three discrete polymers of the notified polymer and would therefore be expected to exemplify the highest hazard to the aquatic compartment.

7.2.1 Predicted No-Effect Concentration

The notifier has presented the results of an ecotoxicological investigation to determine the acute toxicity of the notified chemical to fish.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
NOEC (Fish).	>100.00	mg/L
Assessment Factor	1,000.00	
Mitigation Factor	1.00	
PNEC:	>100.00	µg/L

7.3. Environmental risk assessment

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	0.16	>100	< 0.002
Q - Ocean:	0.02	>100	< 0.0002

As the Risk Quotient (Q) is considerably less than 0.1, the environmental risk is not considered to be unacceptable.

The notified polymer will be used as a component of ink and industrial coatings. Once these have been cured, the notified polymer is expected to remain within the product matrices. Hence, the majority of the notified polymer will share the fate of the articles into which it is incorporated. It is anticipated that these will be disposed of to landfill or incinerated at the end of their useful lifetime. In landfill, it is expected that the notified polymer will remain immobile within the soil. Incineration of the notified polymer will result in the formation of water vapour and oxides of carbon and nitrogen.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to the health of the public.

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer during spray application:
  - Use of spray paints containing the notified polymer should be in accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC, 1999)

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced and in the formulated products:
  - Coveralls
  - Gloves
  - Safety goggles
  - Air respirator where mists are likely to be generated

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- 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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of by landfill, or if present in solvent-based formulations, by recovery or by incineration where possible.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, whilst preventing entry to drains and waterways. Do not discharge to soil or subsoil. Collect spill with adsorbent material (eg sand, vermiculite or universal binder) and place in suitable containers for disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if

- the polymer has a number-average molecular weight of less than 1000;

or

(2) Under Section 64(2) of the Act; if

- the function or use of the chemical has changed from a wetting and dispersive agent in industrial printing inks and industrial coatings, or is likely to change significantly;
- the amount of chemical being introduced has increased from 10 tonnes per annum, or is likely to increase, significantly;
- if the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS for each component of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility BYK-LP N 20666: > 160 g/L at 20ºC
BYK-LP N 20667: 1-2 g/L at 20ºC

Method	In-house qualitative water solubility test not conducted to GLP. Visual inspection of water solubility.
Remarks	BYK-LP N 20666: completely water soluble up to 160 g/L BYK-LP N 20667: 1g/L (clear solution) 2 g/L (slightly turbid solution without observable precipitation or sediment) 3 g/L (obviously turbid solution without observable precipitation or sediment) 10 g/L (turbid solution without observable precipitation or sediment) 20 g/L (highly turbid solution without observable precipitation or sediment)
Test Facility	Nuplex Industries (Aust.) Pty Ltd (communication)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	BYK-LP N 20666
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/SPF-Wistar (Winkelmann, Paderborn)
Vehicle	Water
Remarks - Method	No significant protocol deviations. Non GLP conditions.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 F	2,500	0/3
2	3 M	2,500	0/3

LD50	> 2,500 mg/kg bw
Signs of Toxicity	No treatment related effects were observed.
Effects in Organs	No treatment related pathological or macroscopic effects were observed.
Remarks - Results	No mortality occurred in test animals throughout the duration of the test.

CONCLUSION	BYK-LP N 20666 is of low toxicity via the oral route.
TEST FACILITY	Pharmatox (2004)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	BYK-LP N 20666
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static.
Species	Golden orfe (*Leuciscus idus L.*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	200 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	No significant protocol deviation.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*				
		1 h	*24 h*	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0	0
100	10	0	0	0	0	0

LC50	> 100 mg/L at 96 hours.
NOEC	> 100 mg/L at 96 hours.
Remarks – Results	No mortality or sublethal effects observed at anytime.
CONCLUSION	BYK-LP N 20666 has low toxicity to the tested species.
TEST FACILITY	BioChem agrar (2004)

BIBLIOGRAPHY

BioChem agrar (2004) Acute toxicity of BYK-LP N 20666 to *Leuciscus idus* L. (Project number 04 10 48 505). BioChem agrar, Gerichshain, Germany. (unpublished report provided by notifier).

Hulzebos E, Walker JD, Gerner I and Schlegel K (2005) Use of Structural Alerts to Develop Rules for Identifying Chemical Substances with Skin Irritation or Skin Corrosion Potential. *QSAR Comb. Sci.* 24, 332-342.

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

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

Pharmatox (2004) Acute toxicological study on BYK-LP N 20666 after one oral application to the rat (Project Number 4-98-04), Pharmatox GmbH, Hanover, Germany (unpublished report submitted 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.