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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Polymer in Disperbyk 167

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 Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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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FULL PUBLIC REPORT**Polymer in Disperbyk 167****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

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

PPG Industries Australia Pty Ltd ABN 82 055 500 939
Mc Naughton Road,
CLAYTON, VIC 3168

Hewlett Packard Australia Pty Ltd ABN 74 004 394 763
353 Burwood Highway,
FOREST HILL, VIC 3131

Australian Graphic Supplies Pty Ltd ABN 81 082 517 691
1/38 Neumann Road,
CAPALABA QLD 4157

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: Chemical name, Other names, Molecular and structural formulae, Molecular weight, Spectral data, Polymer constituents, Residual monomers/impurities, Use details, import volume, and Site of manufacture/reformulation.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Melting point/Freezing point, Boiling point, Density, Vapour pressure, Water solubility, Hydrolysis as a function of pH, Partition coefficient (n-octanol/water), Adsorption/Desorption, Dissociation constant, Particle size, Flammability limits, Autoignition temperature, and Explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

United States of America, Canada, Korea and China

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

DISPERBYK-167 (notified polymer at concentration of < 60%)

CAS NUMBER

Not assigned

MOLECULAR WEIGHT

>1000 Da

ANALYTICAL DATA

Reference IR, and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)
None

ADDITIVES/ADJUVANTS
None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Stable under normal conditions of use.

The notified polymer and coatings containing it are rarely exposed to the atmosphere, as production and formulation operations take place in closed systems and storage is in sealed vessels. Losses of additives due to volatility are therefore likely to be minimal. The level of residual monomers of the notified polymer is expected to be low.

DEGRADATION PRODUCTS
None under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Light yellow solid

Property	Value	Data Source/Justification
Melting Point	> 20°C	Estimated
Boiling Point	>200°C at 101.3 kPa	Estimated (The notified polymer is expected to have high boiling temperature, based on its high molecular weight)
Vapour Pressure	<10 ⁻² kPa at 25°C (or 20°C)	Estimated. Based on the high molecular weight of the notified polymer, it is expected to have low vapour pressure <10 ⁻² kPa (US EPA, 2007).
Water Solubility	6.13 × 10 ⁻⁴ g at 20°C (pH 2) 1.86 × 10 ⁻⁴ g at 20°C (pH 7)	Measured
Hydrolysis as a Function of pH	Not determined	Test not conducted due to low water solubility of the notified polymer. The notified polymer contains linkages that hydrolyse very slowly in the environmental pH range (4–9).
Partition Coefficient (n-octanol/water)	Not determined	Due to its low water solubility, the notified polymer is expected to partition into the octanol fraction.
Adsorption/Desorption	Not determined	Expected to be immobile in soil due to its low water solubility and is expected to become associated with soil and sediment.
Dissociation Constant	Not determined	Has very low water solubility and is therefore unlikely to dissociate to any significant extent. However, it contains functionalities that are likely to become cationic at environmental pH (4–9).
Particle Size	Not determined	Expected to be 1-5 mm
Flash Point	>100°C at 101.3 kPa	MSDS
Flammability	Not determined	Not expected to be highly flammable
Autoignition Temperature	>200°C	Calculated
Explosive Properties	Not expected to be explosive.	No explosive functional groups.

DISCUSSION OF PROPERTIES

For full details of tests on vapour pressure and water solubility, refer to Appendix A.

Reactivity

The notified polymer is stable under normal conditions of use. Contact with strong oxidizing agents should be avoided when using or storing polymer in Disperbyk 167.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia, and will be imported into Australia as a component of a wetting and dispersing additive at <60% concentration for reformulation into paints. The notified polymer will also be imported as a component of ink preparations at <5% concentration.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	<5	<10	<10	<10	<10

PORT OF ENTRY

Melbourne, Sydney and Brisbane.

TRANSPORTATION AND PACKAGING

The notified polymer will be transported by road or rail in sealed 25 kg or 200 kg drums as a wetting and dispersing additive and in 1, 3 and 5 L plastic bottles as an ink preparation. The reformulated coating will be repackaged, stored and transported in 1L, 4 L, 10L and 20L steel cans and pails.

USE

The notified polymer will be used as a polymeric wetting and dispersing additive at <20% in industrial solvent-borne paints and pigment concentrates and also at <5% as additive in industrial printing inks for wide format commercial printers. The printing substrates can consist of vinyl, canvas, paper, shade cloth and a variety of other substrates which are capable of holding images.

OPERATION DESCRIPTION

Coating formulation

The notified polymer will be imported as a component of wetting and dispersing additive at <60% concentration.

At the coating manufacturing sites, the notified polymer at <60% concentration will be manually weighed or metered directly from the storage drums into a stainless steel blending tank and mixed with pigments and resin to form the mill base. The mill base will then be pumped into a large mixing vessel to which the remaining additives and resin will be added to form the finished product. Samples of the finished products containing <20% of notified polymer will be taken for quality control testing by laboratory technicians. The finished product will be fed into containers by gravity from the bottom of the mixing vessel through a filter and filling lines.

Occasionally, the coatings 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.

All manufacturing and application equipment will be cleaned by rinsing with water. The 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 with <20% of notified polymer will be applied by spray (75%), brush (20%) or roller (5%) painting. 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.

The used drums will be cleaned by filling with an appropriate cleaning solvent and the contents pumped to pits for storage prior to disposal by a licensed waste management company.

Printing ink applications

The notified polymer will be imported as a component of a series of ink preparations containing <5% notified polymer. The ink formulations containing notified polymer (<5%), will be transferred directly from the import containers to printing machines via automated lines. The printing machine will be fully automated. The printer is supplied with local fume extraction. The operator will connect and disconnect the ink bottles and will also handle the printed substrate, once the ink has been fully dried and cured.

6. HUMAN HEALTH IMPLICATIONS**6.1 Exposure assessment****6.1.1 Occupational exposure****NUMBER AND CATEGORY OF WORKERS – Coating formulation and application**

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport	6-8	2-3	10-15
Coating/Blending	4	8	50
Laboratory	2	1	20
Application	100	6	260

NUMBER AND CATEGORY OF WORKERS – printing ink application

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Waterside workers	6	2	12
Storage and transport personnel	20	4	50
Printer operators	20	6	200
Service technician	5	1	50

EXPOSURE DETAILS*Transport and storage*

Transport and storage workers are not expected to be exposed to the notified polymer at <5% or <60% except in the event of an accident where the packaging is breached.

Coating Formulation

Dermal and ocular exposure to the notified polymer at <60% and <20% concentrations may occur when manually weighing, connecting and disconnecting pumps, charging the blending vessels and when taking samples from the blending vessel by laboratory technicians. Similar exposure may also occur during routine cleaning and maintenance of equipment, and cleaning up of spills or leaks. Inhalation exposure to the vapours and aerosols of notified polymer is not likely during blending due to the relatively high molecular weight, low vapour pressure of the notified polymer, and any aerosols formed will be extracted by local ventilation and filters.

In all cases where potential exposure may occur, the use of personal protective equipment such as coveralls, safety glasses, and gloves used by workers will minimise exposure. Local exhaust ventilation will also be employed in areas where weighing and charging of the blending vessels occur to limit inhalation exposure to the notified polymer.

Coatings Applications

Dermal and ocular exposure to the notified polymer at <20% concentration may occur during the manual addition of coating to spray guns, spray application and when cleaning up equipment. Inhalation exposure is possible during spraying. Dermal and ocular exposure to the notified polymer at <20% may also occur during brush and roller applications, particularly during manual decanting and manual application and when cleaning

equipment.

The end users will wear an eye protection, coveralls, and gloves, and if necessary an air respirator to minimise exposure to the notified polymer. Furthermore, all spray applications will be conducted within spray booths at industrial manufacturing facilities to minimise inhalation exposure.

Workers may also make dermal contact with the notified polymer once the coating formulation at <20% notified polymer has been applied to the substrate. However, once cured, the coating will form an inert film that will contain and immobilise the notified polymer.

Printing Ink Applications

When used in industrial printing inks, exposure to the notified polymer at <5% will be unlikely due to the automated and enclosed processes.

However, exposure is possible via the dermal or ocular routes during connection and disconnection of lines from containers of ink formulation to the printing machine and during printer maintenance. Inhalation exposure is unlikely due to relatively high molecular weight, and low vapour pressure of the notified polymer. Any aerosols formed will be extracted by local ventilation and air filters to reduce exposure. Exposure to the notified polymer will be further minimised by PPE worn by workers such as overalls, impermeable gloves and eye protection.

After application to substrate and once cured/dried, the ink containing the notified polymer forms an inert matrix and hence the polymer is unavailable for exposure.

6.1.2. Public exposure

The notified polymer, as imported, will not be sold to the public. The general public is only expected to come into contact with the notified polymer after the ink or coating formulation is cured to the substrate and is not bioavailable. Therefore, public exposure is expected to be negligible.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 >2000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating

No data on toxicokinetics, metabolism and distribution were provided. The notified polymer will have limited absorption via skin due to low water solubility and high molecular weight. Absorption through inhalation will be limited due to low vapour pressure.

The notified polymer is of low acute oral toxicity and was found to be non irritating to the skin.

No data for the other toxicological end points were provided by the notifier.

Health hazard classification

Based on the limited data submitted, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Based on the limited toxicological data submitted, it is not possible to determine the health hazards of the notified polymer.

Dermal and ocular exposure to the notified polymer may occur during various processes involving the notified polymer. There is also potential for inhalation exposure during spraying. However, considering the engineering controls in place and the use of PPE, the risk to workers from the use of the notified polymer is not expected to be unacceptable.

6.3.2. Public health

The public will not be exposed to the notified polymer in a bioavailable form during its lifecycle. The Public health risk from exposure to the notified polymer is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

No manufacturing of the notified polymer will take place in Australia. The notified polymer will be imported as a component of a wetting and dispersing additive for reformulation into paints and also as a component of finished ink products. Environmental release of the notified polymer is unlikely to occur during importation, storage and transportation.

During the manufacture of coating formulations, an estimated 1% of the total importation volume of the notified polymer will be lost due to spills. The spills will be readily contained and collected for disposal to landfill. At most, 1% of the total import volume of the notified polymer is anticipated to remain in storage containers as residues. The storage containers will be cured prior to disposal to landfill. Manufacturing equipment will be rinsed with solvents and it is predicted that less than 1% of the annual importation volume of the notified polymer will be lost to washing the manufacturing equipment. These washings will be stored in holding tanks on-site for disposal by licensed waste contractors.

RELEASE OF CHEMICAL FROM USE

When coating formulations containing the notified polymer are applied by spray techniques, it is anticipated that up to 30% of the coating product will form overspray and be collected as waste material. As the application of coatings is conducted at industrial sites in designated spray booths, the overspray will be captured in the spray booth in filters and on kraft paper. The product will then dry onto the paper and filters and be disposed of to landfill. It is estimated that less than 1% of the notified polymer contained in coating products applied by brush or roller would be lost due to cleaning of the application equipment. Washings will be collected and disposed of by licensed waste contractors.

During use of the ink products containing the notified polymer, some release is expected to occur during the printing process via cleaning and maintenance operations and small spills. It is expected these residues will be disposed of to landfill. The inks containing the notified polymer will be applied to a variety of substrates including paper materials using industrial inkjet printers. The applied notified polymer is expected to be trapped in the ink matrix with other components of the ink.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer is expected to be disposed of to landfill and is expected to remain associated with the substrate to which it has been applied. Of the notified polymer applied to paper, 50% is expected to be recycled. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of toner from the fibres.

7.1.2 Environmental fate

No environmental fate data were submitted.

The filters and kraft paper capturing the overspray and the majority of articles to which the notified polymer will be applied will be disposed to landfill. In landfill, the notified polymer is expected to degrade slowly via biotic and abiotic processes over time to form water and oxides of carbon and nitrogen. Some of the notified polymer applied to metal articles will be thermally decomposed during metals reclamation.

A small fraction of the notified polymer is expected to be released to the sewerage system due to the recycling of paper to which the product containing the notified polymer will be applied. In the waste water treatment processes in sewage treatment plants, most of the notified polymer is expected to partition to sludge or to suspended solids due to its low water solubility where it will be removed for disposal to landfill or used on land for soil remediation. The notified polymer is not expected to bioaccumulate based on its low water solubility and relatively high molecular weight.

7.1.3 Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified polymer to the aquatic environment will be very limited based on its reported use pattern.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. The notified polymer is potentially cationic at environmental pH (4 – 9) and therefore may be toxic to algae. However, the notified polymer is only slightly soluble in water and limited aquatic exposure is expected.

7.2.1 Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has been not calculated for the notified chemical as no significant aquatic exposure is expected based on its reported use pattern.

7.3. Environmental risk assessment

The notified polymer is anticipated to be of concern to aquatic organisms due to its potentially cationic functional group. However, the potential for exposure of the notified polymer to the aquatic environment is very low because the majority will be disposed to landfill. The risk for harm to aquatic organisms due to washings to the sewer, as a result of paper recycling, is mitigated by the notified polymer's lack of potential to bioaccumulate (due to its high molecular weight), low solubility in water and high propensity to adsorb to particulate matter. Taking into account the low exposure to aquatic organisms, the notified polymer is therefore not expected to pose an unacceptable risk to the environment based on its proposed use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the limited data submitted, the notified polymer cannot be classified according to 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 public health.

Environmental risk assessment

On the basis of the reported use pattern, the notified polymer is not expected 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 preparation of coating formulations, coating/spray applications, and printing:
 - *Local exhaust ventilation*
- Due to the limited toxicological data provided, employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during preparation of coating formulation, coating/spray applications, and handling ink for printing:

- Gloves
- Goggles
- Coveralls

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

- Spray application should be carried out in accordance with the Safe Work Australia *National Guidance Materials for Spray Painting* [NOHSC (1999)].
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer 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 to landfill. Emergency procedures
- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe 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:

- (2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of industrial coatings and industrial printing inks, or is likely to change significantly;
 - the amount of polymer being introduced has increased more than 10 tonnes, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer 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 of the notified polymer and products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Vapour Pressure** <10⁻² kPa at 25°C (or 20°C)

Method	Estimated
Test Facility	US EPA, 2007

Water Solubility 6.13 × 10⁻⁴ g/L at pH 2, 20°C
1.86 × 10⁻⁴ g/L at pH 7, 20°C

Method	OECD TG 120 Solution/Extraction Behaviour of Polymers in Water
Remarks	Three replicates of the test material at pH 7 and another three replicates at pH 2 were prepared as follows: Approximately 2.5 g of test material was added to 250 mL of test media (pH adjusted, glass double distilled water) and shaken at 20°C for approximately 24 hours. After shaking the flasks were centrifuged at 6000 rpm for 15 minutes. An aliquot (200 mL) of the sample solution was frozen and freeze dried and the residue was redissolved in 2 mL of tetrahydrofuran. Gel permeation chromatography was used to determine the concentration of the test material in each sample.
Test Facility	Harlan (2009)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rats/Wistar strain CrI: (WI) BR
Vehicle	Corn oil
Remarks - Method	Oral gavage No significant protocol deviation

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	3/sex	2000	0/6
II	3/sex	2000	0/6

LD50	>2000 mg/kg bw
Signs of Toxicity	Lethargy and/or hunched posture were noted in all males and one female on day 1. Piloerection was noted in one female on day 2.
Effects in Organs	No abnormality was observed at necropsy examination.
Remarks - Results	No mortality occurred throughout the duration of the test. Body weight changes were normal.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
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TEST FACILITY	Notox, Netherlands (2001)
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B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 females
Vehicle	Deionised water
Observation Period	72 Hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	0	0	0	0	not applicable	0
<i>Oedema</i>	0	0	0	0	not applicable	0

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

Remarks - Results	No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.
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All areas to be treated with the test substance and all control areas were normal before the application and at each observation time.

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

TEST FACILITY ARC Seibersdorf (2006)

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