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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Acrylates/ Stearyl Acrylate/ Ethylamine Oxide Methacrylate Copolymer

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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Clariant (Australia) Pty Ltd (ABN: 30 069 435 552)
Brandon Office Park, Building 5, Level 2
530-540 Springvale Road Glen
Waverley VIC 3150

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Molecular Formulae, Molecular Weight, Purity, Impurities, Additives/adjuvants, Import Volume, Use Details

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Hydrolysis as a function of pH, Partition coefficient, Absorption/desorption.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

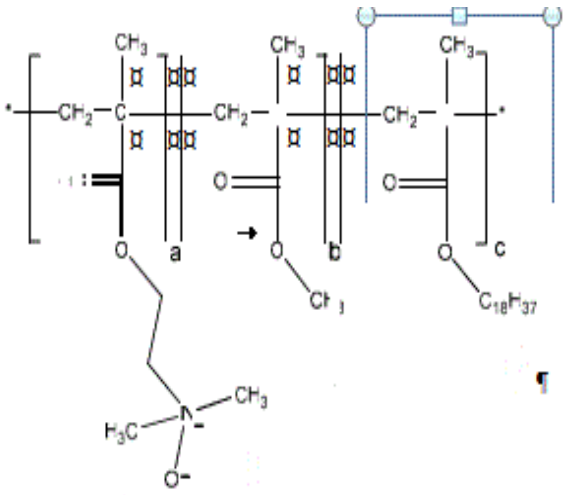
NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

CAS NUMBER
896465-76-2

CHEMICAL NAME
2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymer with methyl 2-methyl-2-propenoate and octadecyl 2-methyl-2-propenoate, N-oxides

STRUCTURAL FORMULA



MARKETING NAME(S)

Diaformer Z 632 N (containing < 40% notified polymer)

OTHER NAME(S)
Acrylates/ Stearyl Acrylate/ Ethylamine Oxide Methacrylate Copolymer (INCI name)
Amine oxide-methacrylate copolymer

MOLECULAR WEIGHT
Mn >10000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Not expected to occur during normal usage.

DEGRADATION PRODUCTS
Thermal degradation will result in the formation of carbon monoxide and nitrogen oxides.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Slightly viscous, yellowish liquid (Diaformer Z 632 N)
The notified polymer is likely to be white solid (based on Analogue Polymer 1)

Property	Value	Data Source/Justification
Melting Point	Glass transition temperature of notified polymer: 23°C Melting point of Diaformer Z 632 N: <-20 °C	Measured/MSDS
Density	910 kg/m^3 at 20°C (Diaformer Z 632 N)	MSDS
Vapour Pressure	< 1.3x10^{-9} kPa	Estimated based on high molecular weight (> 1000 Da) (USEPA, 2007).
Water Solubility	9.2 g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined. The notified polymer is expected to be hydrolytically stable.	The notified polymer is not separated from the aqueous solvent in which it is manufactured.
Partition Coefficient (n-octanol/water)	Log P_{ow} < -1	Estimated
Adsorption/Desorption	Not determined, but expected to be low based on the water solubility.	The notified polymer is not separated from the aqueous solvent in which it is manufactured.
Dissociation Constant	pKa = 3.8	Measured
Particle Size	Not determined	The notified polymer is imported in solvent.
Flash Point	Not determined	Low vapour pressure solid.
Flammability	Not determined	Not expected to be flammable and imported in solution.
Autoignition Temperature	Not determined	Imported in solution. Not expected to undergo autoignition under normal conditions of use.
Explosive Properties	Not expected to be explosive	Contains no groups with known explosive properties.

DISCUSSION OF PROPERTIES

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

Reactivity
The notified polymer is stable under normal use and storage conditions. Thermal decomposition of Diaformer Z 632 N may occur at temperatures > 150°C.

Dangerous Goods classification
Due to its solvent content, the product containing the notified polymer (Diaformer Z 632 N) is classified as a Class 3 Flammable liquid according to the Australian Dangerous Goods Code (NTC, 2007).

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported at concentrations of < 40% in the product Diaformer Z 632 N.

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

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

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Clariant (Australia) Pty Ltd
Formulators of hair styling products

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 180 kg drums and transported by road from the port of entry to Clariant and subsequently to formulators. The formulated product will be packaged into 125, 150, 200 or 250mL screw cap or push-on cap plastic bottles and jars. The containers will be packed in cardboard cartons and transported by road to distribution warehouses and then to retail outlets for consumer use.

USE
Used as a component of hair styling formulations. It will not be applied by spraying.

OPERATION DESCRIPTION
Formulation
At customer sites, drums containing the notified polymer at concentrations of < 40% will be opened by workers and the appropriate quantity manually dispensed into a mixing vessel. Other ingredients will be added to the vessel and the mixture blended in the closed mixing vessel using automated procedures.

Sampling and quality control testing of the formulated product (< 2.5% notified polymer) may take place following mixing. Packaging may occur directly from the mixing vessel or from a storage tank to which the product had been pumped from the mixing vessel. The formulated product will be automatically dispensed through a multiple head filling machine into end use plastic bottles and jars. The finished hair care products containing up to 2.5% of the notified polymer will be purchased by consumers at retail outlets.

End use - Hair salons
Hairdressing salons may also purchase the finished hair care products containing the notified polymer. Application of the product is likely to involve the hairdresser rubbing a small amount of the product between their hands and transferring it to the hair of customers.

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)*
Stores personnel	6	0.5	20
Laboratory technicians	5	1	30
Manufacturing operators	10	2	30
Line setters	6	1	30
Hairdressers	>100	2	200

EXPOSURE DETAILS

Formulation

Dermal and ocular exposure of workers to the notified polymer (at concentrations of < 40%) may occur during manual dispensing of the imported product containing the notified polymer to the mixing vessel, and cleaning and maintenance operations. Dermal and ocular exposure may also occur to concentrations of up to 2.5% of the notified polymer during quality control and sampling operations, pumping of the formulated product between the mixing vessel and storage vessel, and dispensing of the formulated product into end use containers.

Exposure is expected to be lowered by the enclosed mixing vessel, the automated systems used for dispensing, and the wearing of personal protective equipment (PPE), including overalls, safety glasses, safety shoes, masks and gloves for formulation processes, and laboratory coats, safety glasses and rubber gloves during quality control and sampling.

Retail sales

Retail workers will only be exposed to products containing up to 2.5% of the notified polymer in the event of damage or leakage of containers.

End use - Hair salons

As the products containing the notified polymer are intended for the retail market, a relatively small number of professional salon workers are expected to use these products. Such workers may be repeatedly exposed to the notified polymer (< 2.5%) by application of formulated hair styling products to the hair of customers. Exposure will primarily be via skin contact, with potential for eye contact by inadvertent transfer from the hands and an estimated up to ~0.1g of notified chemical per application. Good occupational hygiene practices would minimise exposure, such as the wearing of gloves during application or washing/rinsing of hands following application. However, it is unlikely that salon workers will wear gloves during the use of hair styling products and not all workers will wash or rinse hands following application to the hair of customers.

6.1.2. Public exposure

There will be widespread and repeated exposure of the public to the notified polymer (< 2.5%) as a component of hair styling products. Dermal and accidental ocular exposure of consumers to the notified polymer may occur when members of the public dispense small amounts of the hair styling product from jars or bottles into the hands and apply to the hair. Such products are not expected to be applied directly to the scalp. The notified polymer does not bond permanently to the hair and will be washed off during routine hair washing. During such rinsing, dermal exposure to other parts of the body and accidental ocular exposure may occur.

6.2. Human health effects assessment

The results from toxicological investigations conducted on a close analogue of the notified polymer (Analogue Polymer 1) are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	low oral toxicity LD50 > 2000 mg/kg bw
Rabbit, skin irritation	slightly irritating

Continuous dermal irritation	non-irritating
Phototoxic potential	no evidence of phototoxicity
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test.	no evidence of sensitisation
Guinea pig, skin photosensitisation – adjuvant test.	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

By analogy, the results of testing on Analogue Polymer 1 are considered to be indicative of the toxicological properties of the notified polymer.

Toxicokinetics.
The notified polymer is not expected to be significantly dermally absorbed due to its high molecular weight (Mn > 10000 Da), low proportion of low molecular weight species, and low partition coefficient (Log P_{ow} < -1). As such, systemic toxicity following dermal exposure to the notified polymer is expected to be low.

Acute toxicity.
Analogue Polymer 1 was found to be of low acute oral toxicity (LD50 > 2000 mg/kg bw).

Irritation and Sensitisation.
Analogue Polymer 1 was found to be slightly irritating to the skin of rabbits. The irritancy effects observed were mild and were not sufficient to warrant hazard classification. Analogue Polymer 1 was found to be non-irritating to the skin of guinea pigs in a continuous dermal irritation study that involved evaluation of skin reactions following repeated application of the test substance over a period of 12 days.

Conjunctival irritation (up to moderate severity) was observed in a study conducted on rabbits with Analogue Polymer 1; however the effects were resolved in all treated animals within 7 days. These irritations were not severe enough to warrant hazard classification.

Analogue Polymer 1 was found to produce no evidence of phototoxicity, skin sensitisation or photosensitisation under the conditions of the tests that were performed.

Mutagenicity and Carcinogenicity.
Analogue Polymer 1 was found to be non-mutagenic in bacteria.

It is considered that, in principle, alkyldimethyl-N-oxides (similar to one of the functional groups of the notified polymer) are potential precursors of carcinogenic nitrosamines (SCCNFP 2001, Kamp 1991, Morrison 1983, Morrison 1982, Hecht 1982). Thus the presence of nitrosamines in mixtures containing the notified polymer (as byproducts of reactions with nitrosating agents in the products or as impurities) cannot be excluded. However, given the high molecular weight of the notified polymer and the low level of low molecular weight species, there is not likely to be significant amounts of bioavailable nitrosamines.

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
The notified polymer was found to be a slight skin and eye irritant. At the concentrations that will be present in products handled by formulation workers (< 40%) and hairdressers (< 2.5%) the notified polymer is not expected to cause skin or eye irritancy effects.

The potential for the notified polymer to form carcinogenic nitrosamine impurities under certain conditions cannot be ruled out. The potential for formation of these impurities may be significantly reduced by appropriate precautions taken during manufacture, formulation, packaging and by monitoring their levels in products.

Dermal and ocular exposure to the notified polymer at concentrations of up to 40% (formulation workers) or up to 2.5% (hairdressers) may occur during handling of the notified polymer. While the potential for formation of carcinogenic nitrosamines cannot be ruled out, the risk is expected to be lowered by the measures

taken to minimise nitrosamine levels (as discussed above). The notifier has stated that appropriate precautions, including the use of high purity reagents, are currently being taken by the overseas manufacturer to minimise nitrosamine levels. In addition the risk for formulation workers exposed to the higher concentrations will be further minimised by the use of personal protective equipment to reduce exposure.

In conclusion, the occupational health and safety risk associated with the notified polymer is not considered to be unacceptable if appropriate precautions are taken to minimise the levels of nitrosamines in products containing the notified polymer.

6.3.2. Public health

Members of the public may be repeatedly exposed via the dermal and perhaps ocular routes during use of hair styling products containing the notified polymer at concentrations < 2.5%. The risk of skin or eye irritancy effects is not considered to be unacceptable, given the relatively low concentrations of the notified polymer in products. The risk associated with the potential for formation of carcinogenic nitrosamine impurities may be of concern, however this risk may be significantly lowered by appropriate precautions taken to minimise the levels of nitrosamines in products containing the notified polymer (as discussed above).

In conclusion, the public health risk associated with the use of the notified polymer in hair styling products is not considered to be unacceptable if appropriate precautions are taken to minimise the levels of nitrosamines in products containing the notified polymer.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be formulated into hair styling products at manufacturers' sites in Australia. Release volumes from the formation will be low.

During the formulation process, the estimated annual losses of the notified polymer are:

Spills: less than 1% (< 100 kg)
Equipment cleaning: 3% maximum (< 300 kg)
Container Residuals: less than 1% (< 100 kg)
Total Annual Loss: < 500 kg

All formulation waste will be treated in on-site treatment plants. The waste will be neutralized, with the solids removed for landfill and the liquid effluent discharged to trade waste.

RELEASE OF CHEMICAL FROM USE

Following application of the hair styling products, almost all of the notified polymer will be washed from the hair and released to sewer.

The end use containers are expected to be disposed of with normal household kerbside recycling. The residues of the notified polymer remaining in these bottles are expected to be up to 2% or up to 200 kg per annum.

RELEASE OF CHEMICAL FROM DISPOSAL

It is intended that all of the notified polymer will be incorporated into haircare products. The need for disposal of the new chemical will be limited and would only be required if spillage occurred.

Disposal of the polymer product should be in accordance with government regulations. It is recommended that disposal should be through a licensed waste disposal contractor to an approved landfill site or by thermal decomposition in an approved facility.

7.1.2 Environmental fate

The notified polymer may be released from sewage treatment works as it is water soluble and not expected to be

readily biodegradable based on analogue data, although some removal with sludge can be expected based on the surface activity. It is not expected to bioconcentrate in fish because of the water solubility and high molecular weight. For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC can be estimated as tabulated below based on the worst case assumption of complete passage through sewage treatment works into receiving waters.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	< 10000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	< 10000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.4	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.374	million
Removal within STP	0%	
Daily effluent production:	4,275	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	< 6.4	µg/L
PEC - Ocean:	< 0.64	µg/L

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical and an analogue polymer (Analogue Polymer 2) are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 > 100 mg/L	Not harmful
Daphnia Toxicity	EC50 > 100 mg/L	Not harmful
Algal Toxicity	EC50 > 100 mg/L	Not harmful
Inhibition of Bacterial Respiration	EC50 = 4100 mg/L	Not harmful

The fish and bacterial tests were conducted on an analogue of the notified polymer. While the analogue is acceptable, based on its structure, it is less soluble than the notified polymer. Results tabulated above are expressed as nominal concentrations. Actual exposure concentrations in the fish and bacterial tests are likely to have been lower than nominal, as test media were obtained by centrifugation and filtration, respectively. Strictly speaking, the analogue polymer should be described as showing no toxicity to fish up to the limit of water solubility.

7.2.1 Predicted No-Effect Concentration

The PNEC can be calculated as outlined below by application of a 100-fold assessment factor to the lower limit of 100 mg/L for daphnia and algal toxicity, as specific data are available for these two trophic levels, and analogue data for a third.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Daphnia and algal toxicity	> 100	mg/L
Assessment Factor	100	
PNEC:	> 1000	µg/L

7.3. Environmental risk assessment

The Risk Quotients (Q = PEC/PNEC) are tabulated below.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	6.4	> 1000	**< 0.00064**
Q - Ocean	0.64	> 1000	**< 0.000064**

The notified polymer is not considered to pose a risk to the environment, as risk quotients are well below one, even when estimated under worst case assumptions of complete release to sewer and subsequently to receiving waters.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified polymer cannot be 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 if appropriate precautions are taken to minimise the levels of nitrosamines in products containing the notified polymer.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health if appropriate precautions are taken to minimise the levels of nitrosamines in products containing the notified polymer.

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 safe work practices to minimise occupational exposure during handling of products containing the notified polymer:
  - Avoid contact with eyes and skin.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to products containing the notified chemical:
  - Gloves, safety glasses, protective clothing.

  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.

Control of impurities

- Preventive measures should be taken to ensure control of any nitrosamine contamination and other hazardous impurities in products containing the notified polymer. Such measures would include, where appropriate:

- Monitoring of levels of impurities including nitrosamines in the imported mixture and hair styling products. Monitoring should cover any changes during storage.
- Avoidance of nitrosating agents in formulation and handling.
- Use of suitable inhibitors.
- Packaging in nitrite-free containers.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by 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:

(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 component of hair styling formulations, 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;
- 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 of the imported product containing 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 9.2 g/L at 20°C

Method In house method
Remarks Flask Method. The notified polymer was isolated by vacuum drying and ground to a powder before stirring with water at a nominal 10 g/L for 24 hours. Solubility was determined gravimetrically after filtration and evaporation of the filtrate, and remained constant at pH 2, 7 and 9.
Test Facility Mitsubishi (2008)

Hydrolysis as a Function of pH

Remarks The test was not conducted as the notified polymer is manufactured in aqueous ethanolic solution. Hydrolytic stability is expected based on the structure of the notified polymer and its shelf-life in aqueous-based products.

Partition Coefficient (n-octanol/water) log Pow < -1

Remarks The partition coefficient was estimated based on increments for the monomer components, and the assumption that the partitioning behaviour of the polymer will mainly be determined by the amine oxide content.
Test Facility Clariant (2009a)

Adsorption/Desorption

Remarks The test was not conducted as the notified polymer is manufactured in aqueous ethanolic solution. Sorption to soil would arguably be weak based on the water solubility, but some sorption can be expected because of the surface active and cationic properties of the notified polymer.

Dissociation Constant pKa = 3.8

Method In house method
Remarks The pKa was determined as the pH at the half neutralisation point of the titration curve with hydrochloric acid and sodium hydroxide.
Test Facility Clariant (2009b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Analogue Polymer 1

METHOD: Similar to OECD TG 401 Acute Oral Toxicity – Limit Test.
- Species/Strain: Rat/Sprague-Dawley CD strain
- Vehicle: Suspension in arachis oil BP
- Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
Range finding study	1M, 1F	2000	0
Main study	5M, 5F	2000	0

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: None
- Effects in Organs: None

CONCLUSION: The analogue polymer is of low toxicity via the oral route.

TEST FACILITY: Safepharm (1996a)

B.2. Irritation – skin

TEST SUBSTANCE: Analogue Polymer 1

METHOD: Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3
- Vehicle: Distilled water
- Observation Period: 72 hr
- Type of Dressing: Semi-occlusive.
- Remarks - Method: The exposure period was 24 hours.

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	0.3	0	0	1	< 48 hr	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: Very slight erythema was noted at all treated sites at the one hour observation and at one treated skin site at the 24h observation.

CONCLUSION: The analogue polymer is slightly irritating to the skin.

TEST FACILITY: Safepharm (1996b)

B.3. Continuous dermal irritation

TEST SUBSTANCE	Analogue Polymer 1
METHOD	Continuous dermal irritation (internal test method)
Species/Strain	Hartley-derived albino guinea pigs
Number of Animals	20 Females (5 per dose group)
Vehicle	Distilled water
Observation Period	14 days
Type of Dressing	None
Remarks – Method	Samples were prepared at concentrations of 20%, 10% and 5%. Approximately 20 mg of the sample was applied to the left flank of each animal in a circle of 2cm diameter. Application was repeated once daily 12 times (6 times/week, ie. missing Sunday) with skin reactions evaluated 24 hours after application (or 48hr when applied on Saturday).
RESULTS	
Remarks – Results	There was no erythema, eschar or edema observed in any animals during the test period.
CONCLUSION	The analogue polymer is not irritating to skin.
TEST FACILITY	Drug Safety Testing Center (1997)

B.4. Irritation – skin (Phototoxic potential)

TEST SUBSTANCE	Analogue Polymer 1
METHOD	Phototoxic potential (internal test method)
Species/Strain	Dunkin Hartley albino guinea pigs
Number of Animals	5 males
Vehicle	95% aqueous ethanol
Observation Period	48 hours
Remarks – Method	A preliminary study was used to select the concentration for the main study, with the maximum non-irritant concentration chosen. In the main study, 25% w/w test material in vehicle was applied to 2 skin sites on each animal. Positive phototoxic material (0.005% w/v 8-methoxypsoralen) and vehicle control were also applied to 2 sites on each animal. Approximately 30 minutes after application, the skin sites on one side of the animals were occluded with aluminium foil and the sites on the other side were irradiated with UV light. Following irradiation, the occlusive dressings were removed and each site was examined 4, 24 and 48 hours after the end of the irradiation period. The degree of erythema and oedema were evaluated according to the Draize scale. Any skin reactions at an irradiated site of greater severity than those at a non-irradiated site were attributed to phototoxicity.

RESULTS

Lesion	*Mean Score**			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	4hr	*24hr*	*48hr*			
Erythema/Eschar						
- *Irradiated*	1.0	0.2	0.2	1	> 48h	1
- *Non-irradiated*	1.6	0.6	0.6	2	> 48h	1
Oedema						
- *Irradiated*	0.2	0	0	1	< 24h	0
- *Non-irradiated*	0.8	0.3	0.2	1	> 48h	1

*Calculated on the basis of the scores for ALL animals.

Remarks – Results

Irradiated sites
At the 4-hour observation very slight erythema was noted in all animals, with one incident of very slight oedema. The positive control substance displayed no skin reactions at this observation time.

At the 24 hour observation desquamation was noted in two animals together with very slight erythema in one of these animals. The positive control substance showed well-defined erythema and incidents of very slight oedema at this time point.

At the 48 hour observation one animal displayed desquamation and very slight erythema. The positive control substance showed well-defined erythema and incidents of very slight oedema at this time point.

Non-irradiated sites
Well-defined or very slight erythema was noted in all animals at the 4 hour observation, together with very slight oedema in most animals.

At the 24 hour observation, 3/5 animals displayed very slight erythema and 2/5 displayed very slight oedema.

At the 48 hour observation, 3/5 animals displayed desquamation and very slight erythema and 1/5 displayed very slight oedema.

No skin reactions were noted on the irradiated sites that had been treated with the positive control substance.

Evaluation
Whilst the test material produced higher grade skin reactions than that caused by the positive control substance 4 hours following irradiation, this was not considered to be indicative of phototoxicity as such reactions were not of significant severity and were not noted at later observations.

CONCLUSION The analogue polymer produced no evidence of phototoxicity under the conditions of the study.

TEST FACILITY Safepharm (1998a)

B.5. Irritation – eye

TEST SUBSTANCE Analogue Polymer 1

METHOD Similar to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 7 days
Remarks - Method No significant protocol deviations.

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	0.7	1.0	1.3	2	< 7 days	0
Conjunctiva: chemosis	1.0	0.3	1.0	2	< 72 hr	0
Conjunctiva: discharge	0.7	0.3	0.3	2	< 72 hr	0
Corneal opacity	0	0	0.3	1	< 48 hr	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 Dulling of the normal lustre of the cornea was observed in one treated eye one hour after treatment. Diffuse corneal opacity was noted in one treated eye at 24 hour observation. No other corneal effects were noted.

Moderate conjunctival irritation was noted in all eyes at the 1 hour observation. In 2/3 animals, the redness and chemosis remained moderate at the 24 hour observation and minimal in 1/3, whilst the discharge was minimal in all animals at this time point. Conjunctival irritation subsequently reduced to minimal, with redness then clearing by 72 hours (2/3) or 7 days (1/3), chemosis clearing by 48 hours (1/3) or 72 hours (2/3), and discharge clearing by 48 hours (2/3) or 72 hours (1/3).

CONCLUSION The analogue polymer is slightly irritating to the eye.

TEST FACILITY Safepharm (1996c)

B.6. Skin sensitisation

TEST SUBSTANCE Analogue Polymer 1

METHOD Similar to OECD TG 406 Skin Sensitisation - Magnusson and Kligman Maximisation Test.
Species/Strain Guinea pig/Albino Dunkin Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 10%
topical: 25%
MAIN STUDY
Number of Animals Test Group: 20 Control Group: 10
INDUCTION PHASE Induction Concentration:
intradermal: 10% in distilled water
topical: 25% in distilled water

Signs of Irritation	Very slight erythema was observed at the intradermal induction sites of all test group animals at 24 and 48 hours. Four of the control group animals displayed very slight erythema at the 24 hour observation only. Following topical induction, very slight to well-defined erythema and very slight or nil oedema were observed in test animals at the 1 and 24 hour observations. In control animals at the 1 hour observation, very slight to well-defined erythema was observed and very slight or nil oedema. In control animals at the 24 hour observation, very slight erythema was noted in most animals, with isolated incidences of very slight oedema.
CHALLENGE PHASE	
1st challenge	topical: 10% and 25% in distilled water
Remarks - Method	The maximum attainable concentration suitable for topical application was 25%. Due to the lack of irritation at this dose, sodium laurylsulphate (10% in petrolatum) was applied prior to topical induction application to provoke irritation.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: Challenge*	
		24 h	*48 h*
Test Group	10%	0	0
	25%	0	0
Control Group	10%	0	0
	25%	0	0

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the analogue polymer under the conditions of the test.
TEST FACILITY	Safepharm (1996d)

B.7. Photosensitisation

TEST SUBSTANCE	Analogue Polymer 1
METHOD	Photosensitisation Magnusson and Kligman Maximisation Test (internal method).
Species/Strain	Guinea pig/Albino Dunkin Hartley
MAIN STUDY	
Number of Animals	Test Group: 5 Control Group: 5 Positive Control Group: 5
Induction phase	Induction Concentration: Topical: 10% w/w in 95% aqueous ethanol
Signs of Irritation	Not reported
CHALLENGE PHASE	
1st challenge	Topical: 10% and 5% w/w in 95% aqueous ethanol
Remarks – Method	The results of the phototoxicity study were used to select the test concentration for this study. Irritation was noted at 25% during the phototoxicity study and therefore 10% concentration was chosen as the maximum non-irritant concentration for the present study. However, this was not actually demonstrated to be a non-irritating concentration under the occlusive conditions of the present study. In addition, the skin was not abraded during the phototoxicity study, though it was in the present study. Therefore the lack of irritation at 10% under abraded conditions is

unknown.

Procedures were similar for animals treated with the positive photosensitisation material (6-methylcoumarin) and vehicle control.

Induction
Intradermal injections of Freund's Complete Adjuvant (1:1 with distilled water) were made followed by abrasion of the stratum corneum, to which was topically applied the test substance (10%). Approximately 30 minutes after application, the skin sites were irradiated with UV light. These induction procedures were performed a total of five times on successive days. Results of evaluation of the skin reactions following induction are not given in the test report.

Challenge
On day 28, the test material was applied to separate sites on skin that had been abraded the previous day at concentrations of 10% and 5%. Approximately 30 minutes after application, the skin sites were irradiated with UV light.

Any skin reactions at an irradiated site of greater severity than those at a non-irradiated site were attributed to phototoxicity.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	10% non-irradiated	4/5 erythema (very slight)	0/5
	5% non-irradiated	0/5	0/5
	10% irradiated	1/5 erythema (very slight)	0/5
	5% irradiated	0/5	0/5
Positive control	5% non-irradiated	1/5 erythema (very slight)	1/5 erythema (very slight)
	5% irradiated	1/5 erythema (very slight) 4/5 erythema (well defined) 2/5 oedema (very slight) 2/5 oedema (well defined)	5/5 erythema (well defined) 3/5 oedema (very slight) 1/5 oedema (slight)
Control Group		0/5	0/5

Remarks - Results

Irritancy effects (slight erythema) were observed on the non-irradiated skin of four of the five test animals 24 hours after challenge with 10% test substance (Analogue Polymer 1). Such effects are unlikely to be due to sensitisation for the following reasons:

- They do not remain at the 48 hour observation
- Similar effects were observed in the phototoxicity test on non-irradiated skin (25% concentration, 3/5 test animals at 24 and 48 hours). Also, in the skin sensitisation study irritation was observed after topical induction at 25%. Thus the effects in the photosensitisation test may be due to skin irritation.
- Irritation may have been enhanced by the abrasion and occlusion that was utilised in the photosensitisation study. Occlusion was

not used in the sighting study of the phototoxicity test and abrasion was not used in the sighting or the main study of the phototoxicity study. It is uncertain whether the highest challenge concentration chosen for the photosensitisation test (10%) would be non-irritating under the conditions of abrasion and occlusion.
- The high molecular weight of the notified polymer suggests that sensitisation effects are unlikely, given that dermal absorption is expected to be very low.

The cause of the effects cannot be confirmed, however, based on the weight of evidence they are not considered to be due to contact sensitisation.

CONCLUSION The analogue polymer was considered to produce no evidence of photosensitization to guinea pig skin under the conditions of the study.

TEST FACILITY Safepharm (1998b)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Analogue Polymer 1

METHOD Similar to OECD TG 471 Bacterial Reverse Mutation Test.
Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbital and 5,6-benzoflavone-induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 313-5000 µg/plate b) Without metabolic activation: 313-5000 µg/plate
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	> 5000	Negative
Present				
Test 1	> 5000	> 5000	> 5000	Negative

CONCLUSION The analogue polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Genetic Laboratory (1996)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Analogue Polymer 2

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
- Inoculum: Aqueous phase of non-adapted activated sludge
- Exposure Period: 28 days
- Auxiliary Solvent: -
- Analytical Monitoring: Residual $Ba(OH)_2$

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
4	1	4	33
14	9	14	78
28	12	28	89

Remarks - Results: The toxicity control did not reveal any toxic effects from the test substance. The analogue polymer reached the 10% degradation level in one replicate after an adaptation phase of 7 days, but did not reach this level in the other replicate.

CONCLUSION: The analogue polymer, and by analogy the notified polymer, cannot be considered to be readily biodegradable.

TEST FACILITY: Noack Laboratorium (2002a)

C.1.2. Bioaccumulation

REMARKS: Bioaccumulation was not tested as the notified polymer is manufactured in aqueous ethanolic solution. The notified polymer would not be expected to bioconcentrate in fish because of its water solubility and high molecular weight.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE: Analogue Polymer 2

METHOD: OECD TG 203 Fish, Acute Toxicity Test - static.
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - static.
- Species: Zebra fish (*Danio rerio*)
- Exposure Period: 96 hours
- Auxiliary Solvent: None
- Water Hardness: 58 mg $CaCO_3$/L
- Analytical Monitoring: DOC
- Remarks – Method: Analysis found 30.9 mg/L DOC in the test solution, which was obtained by centrifugation of a suspension (nominally 100 mg/L analogue polymer).

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0.9 (DOC)	7	0	0	0	0	0
100	31 (DOC)	7	0	0	0	0	0

LC50	> Water solubility at 96 hours.
NOEC	Water solubility at 96 hours.
Remarks – Results	All fish exhibited normal behaviour

CONCLUSION The analogue polymer showed no toxicity to fish at the limit of water solubility.

TEST FACILITY Noack Laboratorium (2002b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	271 mg $CaCO_3$/L
Analytical Monitoring	DOC
Remarks - Method	The mean DOC level was 55.9 mg/L at test initiation and 61.6 mg/L at termination.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		20	0	0
100	58.8 (DOC)	20	0	0

LC50	> 100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	The response (EC50 = 1.66 mg/L) to the reference substance potassium dichromate was within the prescribed range (0.6-2.1 mg/L).

CONCLUSION The notified polymer is not harmful to daphnids

TEST FACILITY Noack Laboratorien (2009a)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L
Auxiliary Solvent	None
Water Hardness	Typical algal culture medium (soft water)

Analytical Monitoring	DOC
Remarks - Method	The measured concentration was 49 mg/L DOC before introduction of the algae.

RESULTS

Yield		*Growth*	
E_yC50 mg/L at 72 h	*NOEC mg/L*	*E_rC50 mg/L at 72 h*	*NOEC mg/L*
> 100	100	> 100	100

Remarks - Results	The average yield and growth rate from six replicates increased by 5.5% and 0.9% relative to controls,

CONCLUSION The notified polymer is not harmful to green algae

TEST FACILITY Noack Laboratorien (2009b)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE Analogue Polymer 2

METHOD ISO 11348-2 Determination of the inhibitory effect of water samples on the light emission of *Vibrio fischeri* (luminescent bacteria test)

Inoculum	-
Exposure Period	0.5 hours
Concentration Range	Nominal: 0.04-10 mg/L
Remarks – Method	The test was performed with serial dilutions of the filtered solution (nominally 20 g/L analogue polymer)

RESULTS

IC50	4100 mg/L
NOEC	Not determined (6.5% inhibition at 0.04 g/L)

CONCLUSION The analogue polymer is not harmful to luminescent bacteria.

TEST FACILITY Clariant (2002)

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