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April 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Synative ES 3345

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)
Cognis Australia Pty Ltd (ABN 87 006 374 456)
4 Saligna Drive
Tullamarine, VIC 3043

BP Australia Pty Ltd (trading as Castrol Australia Pty Ltd) (ABN 53 004 085 616)
132 McCredie Road
Guildford, NSW 2161

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, CAS number, other names, molecular formula, molecular weight, structural formula, spectral and identification data and methods, hazardous impurities, non-hazardous impurities (> 1%), import volumes, details of use and identity of analogues.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: dissociation constant, flammability limits, auto ignition, explosive properties and reactivity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Synative ES 3345
Castrol BioBar

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None under normal conditions of use.

DEGRADATION PRODUCTS
No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Liquid

Property	Value	Data Source/Justification
Glass transition temperature	-79 to -77°C	Measured
Boiling Point	≥ 406°C at 101.3 kPa	Measured
Density	954 kg/m^3	MSDS (DIN 51757)
Viscosity	105-120 mm^2/s at 40°C	MSDS (DIN 51562)
Vapour Pressure	≤ 1.3 × 10^{-6} kPa at 20°C	Estimated
Water Solubility	8.69 × 10^{-10} g/L	Estimated. EPI Suite (v3.20): WSKOW (v1.41)
Hydrolysis as a Function of pH	$t_{½}$ > 1 year at pH 4, 7 and 9, 25˚C	Measured. The notified polymer is expected to hydrolyse very slowly at environmental pH.
Partition Coefficient (n-octanol/water)	log Pow > 5.7	Measured
Adsorption/Desorption	Not determined	The notified polymer is expected to have a high K_{OC} and to strongly adsorb to carbon-rich sediment or suspended solids in water due to its mainly hydrophobic structure.
Dissociation Constant	Not determined	The notified polymer does not contain any functional groups that will dissociate under environmental conditions.
Flash Point	> 260°C	TDS (ISO 2592)
Flammability	Not expected to be highly flammable	Based on flash point
Autoignition Temperature	Not determined	Based on flash point
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores.
Stability Testing	Stable to 150°C (0.1 wt. % loss) where a slow increase in weight loss occurs up to 300°C (4.9 wt. % loss) followed by rapid increase to 450°C (98.6 wt. % loss).	Measured

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured within Australia. It will be imported as a component in finished automotive and industrial oils and as a raw material to be blended locally.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10	15	20	20	20

PORT OF ENTRY
Sydney and Melbourne.

TRANSPORTATION AND PACKAGING

The neat notified chemical will be imported in 20 L white polyethylene containers and in 208 L steel drums on pallets. The finished products containing the notified chemical will be imported in 208 L steel drum containers suitable for sale. These containers will be packed on pallets. The pallets will be transported in a container from the wharf, to the notifier's central warehouse.

USE
The notified chemical is a synthetic lubricant. It may be used in finished automotive and industrial oils at levels up to 100%.

OPERATION DESCRIPTION
Reformulation
The imported neat notified polymer will undergo quality assurance tests prior to being reformulated into automotive and industrial oils. The notified polymer will then be weighed before being added to the mixing tank. The notified polymer will be pumped from 208 L steel drums to the mixing tank via transfer hoses. For smaller batches where 20 L plastic drums of the notified polymer are used transfer will be manual. The mixing facilities are expected to be fully automated, well ventilated (local exhaust ventilation) and closed systems. After being reformulated, the oil products containing the polymer will undergo further quality assurance tests before being packaged into containers.

Use
The notified chemical at concentrations up to 100% will primarily be used by industry in marine hydraulic oils. Small quantities of the oil products containing the notified polymer may be sold to the public.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

EXPOSURE DETAILS
Storage and transportation
It is anticipated that waterside workers, transport drivers and warehouse workers would only be exposed to the material in the event of an accident.

Reformulation
Dermal and ocular exposure to the notified polymer (up to 100%) is possible when plant operators are connecting and disconnecting pump lines to mixing tanks. It is expected that negligible exposure will occur during the fully automatic and closed blending process. The opportunity also exists for dermal exposure when cleaning up spills or leaks and during maintenance of the mixing equipment. Workers involved in the reformulation process are expected to wear impermeable gloves, goggles or face shield and protective clothing to further minimise exposure. Negligible exposure is expected during transfer of the formulated product containing the notified polymer to packaging as this will be carried out using automated processes.

Inhalation exposure is expected to be negligible given the very low vapour pressure of the notified polymer ($\leq 1.3 \times 10^{-6}$ kPa at 20°C). In addition, blending and packaging facilities are expected to be well ventilated.

End use
There is potential for dermal and ocular exposure to the notified polymer (up to 100%) during the transfer of oils containing it into machinery and the maintenance of the machinery. Exposure is expected to be minimised by the use of gloves, goggles and protective clothing.

6.1.2. Public exposure
Products containing the notified polymer are primarily intended for use by industry and therefore public exposure to the notified polymer is expected to be low. However, exposure to the notified polymer (up to 100%) may occur during the use of oil products containing it or equipment to which it has been added by the public, although this is expected to be on an infrequent basis. Exposure will primarily be dermal, although ocular exposure is also possible. PPE is not expected to be worn by the public.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer or acceptable analogues 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	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation [analogue 1]	slightly irritating
Rabbit, eye irritation [analogue 1]	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test. [analogue 2]	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Chromosome Aberration Test [analogue 3]	non genotoxic

Toxicokinetics, metabolism and distribution.
The notified polymer is not expected to be absorbed across biological membranes, based on the high molecular weight (> 1,000 Da). As such, systemic toxicity following dermal exposure to the notified polymer is expected to be low.

Acute toxicity.
The notified polymer is considered to be of low acute toxicity via the oral routes based on a test conducted in rats. No acute dermal or inhalation toxicity data was provided for the notified polymer or the analogues.

Irritation and Sensitisation.
Based on a test conducted in rabbits an analogue chemical was found to be slightly irritating to the skin and eye. With a further analogue there was found to be no evidence of reactions indicative of skin sensitisation.

Mutagenicity.
The notified polymer was found to not be mutagenic using a bacterial reverse mutation test, and a further analogue was not clastogenic to V79 cells treated *in vitro*.

Health hazard classification
Based on the data provided, the notified polymer is not classified as hazardous 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 studies on an analogue chemical the notified polymer may be a slight eye and skin irritant. The risk of systemic effects is expected to be low based on the high molecular weight (> 1,000 Da) of the notified polymer and low acute oral toxicity. The notified polymer is not mutagenic and based on a study conducted on an analogue, is not genotoxic.

Although workers will handle the notified polymer at concentrations up to 100%, exposure is expected to be low given the proposed use of PPE and largely enclosed, automated processes.

Overall, the risk to occupational health and safety is not considered unacceptable, considering the expected low exposure and the low hazardous nature of the notified polymer.

6.3.2. Public health
Exposure to the notified polymer by the public will be limited as most consumers do not change engine oil in their vehicles. For DIY users changing their own engine oil the risk is not considered unacceptable, given that draining of engine oil is an infrequent event and the low hazardous nature of 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 imported as both a raw material and a component of finished products as lubricants for application in automotive and marine hydraulic oils at levels up to 100%. Further reformulation of neat notified polymer into automotive and industrial oils may be carried out. At the reformulation facilities, release during the fully-automated, closed-system blending process is not expected. Water cleaning of the equipment will be rare and it is expected it will be cleaned with oil and these washings will be used in the formulation of the next batch or another oil blend. No significant release of the notified polymer to the water environment is expected from transportation, storage and reformulation processes. It is estimated that < 1% of the notified polymer will be left in the imported drums that will be sent to landfill.

RELEASE OF CHEMICAL FROM USE

Applications as marine hydraulic oils

The main application of the notified polymer will be for use in topsides hydraulic systems, above the water line, where there is a risk of leakage or spillage into the marine environment. However, since professional operators are expected to be changing the oil, no significant release to the water environment (< 1%) is likely.

Applications as automotive oils

The minor application of the notified polymer will be as an automotive lubricant oil that will be used by both professionals and the public. A survey by the Australian Institute of Petroleum (AIP 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60% are potentially recoverable (i.e. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases is disposed of responsibly (e.g. oil recycling or incineration). Assuming this is the case, no significant release of the notified polymer should result from these professional activities. The remaining 14% of oil is removed by "do-it-yourself" (DIY) enthusiasts.

According to a survey tracing the fate of used lubricating oil in Australia (Snow 1997), only approximately 20% of used oil removed by DIY enthusiasts is collected for recycling, approximately 25% is buried or disposed of in landfill, 5% is disposed of into stormwater drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways. Therefore, significant release to the water environment through inappropriate disposal by DIY enthusiasts into the stormwater system is not expected (< 0.1%), especially given use by the public will be low.

RELEASE OF CHEMICAL FROM DISPOSAL

Hydraulic oil which has been used offshore will be drained from the systems where it has been used and will then be filled either into used drums or dedicated "Waste Oil" tanks. Dedicated tanks are commonly used where the offshore operation has a comprehensive support infrastructure available. Different types of hydraulic oil and lubricating oil will be mixed for shipment back onshore for disposal by waste oil contractors to landfill or it will be recycled as burner fuel.

Used oil drained from crankcases at specialised automotive service centres is expected to be disposed of to oil recycling centres (most likely to be re-used as burner oil).

7.1.2 Environmental fate

The notified polymer is considered to be readily biodegradable based on the provided study report. For the details of the environmental fate studies refer to Appendix C. The notified polymer is not expected to have potential for bioaccumulation or to be bioavailable to aquatic organisms due to its high molecular weight, ready biodegradability and low aquatic exposure.

Most of the notified polymer will either be thermally decomposed during re-use as burner fuel and burner oil or will be disposed to landfill to undergo further biotic or abiotic degradation. Either via thermal decomposition or via landfill degradation, the notified polymer will finally be transformed into small molecules or water and oxides of carbon.

7.1.3 Predicted Environmental Concentration (PEC)

Aquatic exposure is expected to be very low and therefore a PEC has not been determined. Any residues entering aquatic environments will partition to sediment and suspended solids, and degrade through biotic and abiotic processes.

7.2. Environmental effects assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LL50 > 10 000 mg/L (WAF)	Not harmful up to the limit of solubility in water
Daphnia Toxicity	EL50 > 100 mg/L (WAF)	Not harmful up to the limit of solubility in water
Inhibition of Bacterial Respiration	IC50 > 10 000 mg/L	Not harmful

The notified polymer is not harmful to fish, daphnids and sludge bacteria up to the limit of its solubility in water.

7.2.1 Predicted No-Effect Concentration

A PNEC has not been calculated due to both the expected low release to the water environment and the high ecotoxicological endpoints of the notified polymer to the aquatic organisms.

7.3. Environmental risk assessment

A Risk Quotient (Q=PEC/PNEC) has not been calculated since neither a PEC nor PNEC has been determined. The notified polymer is not expected to pose an unacceptable risk to the environment based on both its low toxicity and its low release expected from its reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the data provided, the notified polymer is not classified as hazardous 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 safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid contact with eyes and skin.

- 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 chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical 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:

(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 polymer has changed from a synthetic lubricant, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 20 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 chemical 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

Melting Point/Freezing Point Glass transition temperature at -77 to -79ºC

Method OECD TG 102 Melting Point/Melting Range.
Remarks No area of melting was seen between -150 and 40ºC in the DSC plot.
No significant protocol deviations.
Test Facility Henkel (2009a)

Boiling Point ≥ 406ºC at 101.3 kPa

Method OECD TG 103 Boiling Point.
Remarks A weight loss of only 9.1% was seen up to the boiling/decomposition point at 406ºC.
No significant protocol deviations.
Test Facility Henkel (2009b)

Vapour Pressure ≤ 1.3×10^{-6} kPa at 20ºC

Method OECD TG 104 Vapour Pressure.
Remarks The experimentally determined vapour pressure of the notified polymer at 20ºC was much smaller than 1 mbar, which is not in the recommended range of 1 to 1000 mbar for DSC measurement. Therefore, the vapour pressure of the notified polymer was estimated using Grain-Watson method to be ≤ 1.3×10^{-6} kPa at 20ºC.
Test Facility Henkel (2009c)

Water Solubility 8.69×10^{-10} g/L

Method EPI Suite (v3.20): WSKOW (v1.41)
Remarks The test was not performed. The water solubility was estimated from fragments. The notified polymer is expected to be insoluble in water based on its mainly hydrophobic structure.

Hydrolysis as a Function of pH $t_{½}$ > 1 year at 25˚C

Method OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$*
4	50	> 1 year
7	50	> 1 year
9	50	> 1 year

Remarks GPC/RI was used for concentration analyses of the notified polymer. The test item was stable and not prone to hydrolysis over 5 days at 50ºC when employing pH values of 4, 7 and 9. The determined average concentrations were all in the range of 95-101% (w/w). Based on the test results, the $t_{½}$ is considered to be > 1 year at 25˚C according to OECD TG 111.
Test Facility Henkel (2009d)

Partition Coefficient (n-octanol/water) log Pow > 5.7

Method EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks HPLC Method. Triphenylamine (log P_{OW} = 5.7) was used as a reference item for estimation of the log P_{OW} for the notified polymer. Since the notified polymer eluted after triphenylamine, the notified polymer is considered to have a log P_{OW} > 5.7.
Test Facility Henkel (2009e)

Stability Testing

Method Determination of Weight Loss by Thermogravimetric Analysis. The temperature was raised at the rate of 20 degrees Kelvin per minute from room temperature to 600ºC. Sample was 25.43mg. Purge gas was nitrogen at 3L/h.

Remarks Results showed weight loss from 150ºC.

Temp (^{O}C)	150	200	250	300	350	400	450	500
Weight Loss %	0.1	0.2	0.7	4.9	24.4	75.3	98.6	98.9

Test Facility Henkel (2009f)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 420 Acute Oral Toxicity - Fixed Dose Method.
Species/Strain	Rat/Wistar Crl:(Wi)BR
Vehicle	Test substance administered as supplied
Remarks - Method	No significant protocol deviations. All animals were dosed by gavage. The sighting study was conducted using 2 female animals dosed at 500 and 2000 mg/kg. As there was no mortality an additional 5 male and 5 female animals were dosed at 2000 mg/kg.

RESULTS

Discriminating Dose	> 2,000 mg/kg bw
Signs of Toxicity	There were no deaths. No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necroscopy
Remarks - Results	Body weight gains were as expected.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	ToxLabs (2008a)

B.2. Irritation – skin

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Kleinrussen Chbb:HM
Number of Animals	3
Vehicle	Test substance administered as supplied
Observation Period	72 h
Type of Dressing	Semi-occlusive.
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			
Erythema/Eschar	0.7	0.3	0.3	1	< 72 hours	0
Oedema	0	0	0	0	< 1 hour	0

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

Remarks - Results	A single 4-hour, semi-occluded application of the test material to the intact skin of the three rabbits produced slight erythema at the 24 hour observation. Slight erythema was noted in one rabbit at the 48 hour observation. All treated animals appeared normal at the 72 hour observation. No corrosive effects were noted.
CONCLUSION	Analogue 1 is slightly irritating to the skin.
TEST FACILITY	Henkel (1989a)

B.3. Irritation – eye

TEST SUBSTANCE Analogue 1

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Kleinrussen Chbb:HM
Number of Animals 3
Observation Period 72 h
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	0	0	1	< 24 hours	0
Conjunctiva: chemosis	0	0	0	0	< 1 hour	0
Conjunctiva: discharge	0	0	0	1	< 24 hours	0
Corneal opacity	0	0	0	0	< 1 hour	0
Iridial inflammation	0	0	0	0	< 1 hour	0

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

Remarks – Results A single application of the test material to the non-irrigated eye of three rabbits produced slight conjunctival irritation at the 1 hour observation. All symptoms had cleared by the 24 hour observation.

CONCLUSION Analogue 1 is slightly irritating to the eye.

TEST FACILITY Henkel (1989b)

B.4. Skin sensitisation

TEST SUBSTANCE Analogue 2

METHOD OECD TG 406 Skin Sensitisation – Buehler method
EC Directive 92/69/EEC B.6 Skin Sensitisation – Buehler method
Species/Strain Guinea pig/Pirbright white (Hsd/Win :DH)
PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 100%
MAIN STUDY
Number of Animals Test Group: 20 Control Group: 10
INDUCTION PHASE Induction Concentration:
topical: 100%
Signs of Irritation After triple (once per week) topical applications (occlusive/6 h) at 100% concentration none of the animals in the test or control groups showed any signs of irritation.
CHALLENGE PHASE
1st challenge topical: 100%
Remarks – Method No significant protocol deviations.
Only 1 challenge phase was performed.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*		
		24 h	*48 h*	*72 h*
Test Group	100%	0/20	0/20	0/20
Control Group	0%	0/10	0/10	0/10

Remarks - Results

In the test group 1 animal showed slight skin irritation at the 24 and 72 hour observations, with 5 animals showing slight skin irritation at the 48 hour observation. In the control group 1 animal showed slight skin irritation at the 24 and 48 hour observations. As slight dermal effects were observed in test and control animals the effects were not considered to be test substance related. Therefore, analogue 2 is not a skin sensitiser.

CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to analogue 2 under the conditions of the test.

TEST FACILITY

Henkel (1994)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Both plate incorporation procedure and pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Rat S9 fraction from phenobarbitone/β-napthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 33 – 5,000 µg/plate b) Without metabolic activation: 33 – 5,000 µg/plate
Vehicle	Dimethylformamide
Remarks - Method	No signs of toxicity were recorded in the preliminary test. Test I used the plate incorporation procedure and test II used the pre-incubation procedure. 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
Test 2		> 5000	> 5000	Negative
Present				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2		≥ 100	> 5000	Negative

Remarks - Results

The test material was tested up to the maximum recommended dose level of 5000 µg/plate. No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.

Slight toxic effects evident as a reduction in the number of revertants were observed in strain TA1535 in the presence of metabolic activation at 100, 1000, 2500 and 5000 µg/plate.

All the positive control chemicals used in the test induced marked

increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

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

TEST FACILITY RCC (2000)

B.6. Genotoxicity – in vitro

TEST SUBSTANCE Analogue 3

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line	V79
Metabolic Activation System	Rat S9 fraction from Aroclor 1254 induced rat liver
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	312.5, 625*, 1250*, 2500*, 5000*	4 hours	20 hours
Test 2	312.5, 625*, 1250*, 2500*, 5000*	20 hours	20 hours
Present			
Test 1	312.5, 625*, 1250*, 2500*, 5000*	4 hours	20 hours
Test 2	312.5, 625*, 1250*, 2500*, 5000*	4 hours	20 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2		> 5000	> 5000	Negative
Present				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2		> 5000	> 5000	Negative

Remarks - Results The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

The test material did not induce any statistically significant increases in the frequency of cells with aberrations, or in the numbers of polyploid cells.

CONCLUSION Analogue 3 was not clastogenic to V79 cells treated *in vitro* under the conditions of the test.

TEST FACILITY LPT (2009)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.

- Inoculum: Activated sludge from the municipal wastewater treatment plant Breisgauer Bucht with a concentration equivalent to 30 mg dry solid per litre
- Exposure Period: 28 days
- Auxiliary Solvent: None
- Analytical Monitoring: The carbon dioxide produced was absorbed in wash bottles filled with 200mL 0.2 M sodium hydroxide. The determined amount of CO_2 evolved is expressed as percentage of $ThCO_2$ (theoretical amount of carbon dioxide).
- Remarks - Method: The study was conducted at nominal 20 – 20.9 mg/L TOC of the notified polymer in duplicate at 22 - 24˚C. A blank control (triplicate) and a reference control (nominal 20.1 mg/L TOC, duplicate) with sodium benzoate were included.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
10	66.6	10	85.6
14	67.4	14	87.4
28	88.3	28	100.0

- Remarks - Results: A mean degradation value of 66.6% (64.8 – 68.4%) was achieved after 10 days and a mean of 88.3% (73.7 – 102.9%) was achieved after acidification at day 28. The test was considered valid since biodegradation of the reference chemical reached the pass level of 60% $ThCO_2$ in a 10 day window and by day 14, and the difference of extreme replicate values of the notified polymer at the end of the 10 day window was less than 20%.

CONCLUSION: The notified polymer is considered to be readily biodegradable

TEST FACILITY: Hydrotox (2003)

C.1.2. Bioaccumulation

CONCLUSION: A test for bioaccumulation of the notified polymer has not been conducted. Based on its high molecular weight and ready biodegradability, the notified polymer is not considered to have potential for bioaccumulation in aquatic organisms.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified polymer

METHOD: EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Semi-static.

- Species: Zebra fish (*Brachydanio rerio*)
- Exposure Period: 96 hours
- Auxiliary Solvent: None

Water Hardness	Not reported
Analytical Monitoring	Gas chromatography (GC) for test concentration determinations
Remarks – Method	The study was conducted by exposing fish (10 for each test group) to the notified polymer at different nominal concentrations ranging 1.0 – 10 000 mg/L. Test solutions were prepared by firstly stirring the mixture of the notified polymer and water for 1 day, then after a resting period of 2 hours, the clear aqueous phase (Water Accommodated Fraction or WAF) was separated from the floating organic phase by filtration through a glass fibre for use in the tests. A slight to medium turbidity was observed for the 1000 mg/L test concentration. Test conditions included: pH 8.0 – 8.6, temperature ranged 19.4 - 22.5˚C and the lowest oxygen saturation level of 66%.

RESULTS

*Concentration mg/L Nominal**	*Number of Fish*	*Mortality*				
		2-4 h	*24 h*	*48 h*	*72 h*	*96 h*
0	10	0	0	0	0	0
1.0	10	0	0	0	0	0
100	10	0	0	0	0	0
1000	10	0	0	0	0	0
3000	10	0	0	0	0	0
10000	10	0	0	0	0	0

*Analysis of the test preparations showed concentrations < 0.1mg/L.

LL50	> 10 000 mg/L at 96 hours (WAF)
NOEL	10 000 mg/L at 96 hours (WAF)
Remarks – Results	During the duration of the test the fish showed no signs of abnormal behaviour. Considering no effects to the tested fish were observed, the slight variations of test conditions from the recommended ranges are not considered to have any effect to the test results.

CONCLUSION	The notified polymer is not considered to be harmful to fish up to the limit of solubility in water
TEST FACILITY	Henkel (1998a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Analysis of the test concentrations were determined by gas chromatography (GC)
Remarks - Method	The test was conducted in duplicate at a nominal concentration of 100 mg/L at 20.0 – 20.2˚C. Test solutions were prepared by stirring the mixture of the notified polymer and water for 1 day, and after a resting period of 2 hours, the clear aqueous phase (Water Accommodated Fraction or WAF) was separated from the floating organic phase by filtration through a glass fibre for use in the tests. A blank control (duplicate) and reference control using potassium dichromate were used.

RESULTS

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

*Analysis of the test preparations showed concentrations < 0.1mg/L

EL50	> 100 mg/L at 48 hours (WAF)
NOEL	100 mg/L at 48 hours (WAF)
Remarks - Results	The 24 h EC50 of the reference substance was between 0.9 – 1.9 mg/L (in this case 1.4 mg/L) and therefore met the validity criterion of the test. Throughout the duration of the tests the daphnia showed no abnormal behaviour. There were no immobilized organisms observed during the 48 hour test period.
CONCLUSION	The notified polymer is not considered to be harmful to daphnids up to the limit of solubility in water
TEST FACILITY	Henkel (1998b)

C.2.3. Inhibition of microbial activity

TEST SUBSTANCE	Notified polymer
METHOD	Oxygen Depletion Inhibition Test with *Pseudomonas putida*. DIN draft 38412 Part 27, November 1992.
Species	*Pseudomonas putida* (representative of bacteria sludge in surface waters)
Exposure Period	30 minute
Concentration Range	Nominal: 10 000 mg/L
Remarks – Method	The acute toxicity of the notified polymer to *Pseudomonas putida* was determined in the oxygen depletion inhibition test after 30 minutes with simultaneous aeration. The test was conducted in duplicate at a nominal concentration of 10 000 mg/L at 20.8 – 21.2˚C.
RESULTS	
IC50	> 10 000 mg/L
NOEC	10 000 mg/L
Remarks – Results	A mean inhibition of 2% was detected at the tested concentration. The IC10 > 10 000 mg/L.
CONCLUSION	The notified polymer is not harmful to the sludge bacteria.
TEST FACILITY	Henkel (1998c)

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