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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

BiOH 5000

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

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
 IDENTITY OF CHEMICAL 	
3. COMPOSITION	
4. PHYSICAL AND CHEMICAL PROPERTIES	
5. INTRODUCTION AND USE INFORMATION	
 HUMAN HEALTH IMPLICATIONS. 	
6.1 Exposure assessment	
6.2. Human health effects assessment	
6.3. Human health risk characterisation	
7. ENVIRONMENTAL IMPLICATIONS	
7.1. Environmental Exposure & Fate Assessment	
7.2. Environmental effects assessment	
7.3. Environmental risk assessment	
8. CONCLUSIONS AND REGULATORY OBLIGATIONS	
Hazard classification	9
Human health risk assessment	
Environmental risk assessment	
Recommendations	
Regulatory Obligations	10
APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES	11
APPENDIX B: TOXICOLOGICAL INVESTIGATIONS	
B.1. Acute toxicity – oral	
B.2. Irritation – skin	
B.3. Genotoxicity – bacteria	12
BIBLIOGRAPHY	14

FULL PUBLIC REPORT

BiOH 5000

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S) International Sales & Marketing Pty Ltd (ABN 36 467 259 314) 262 Highett Road, Highett VIC 3190

NOTIFICATION CATEGORY Limited: Synthetic polymer with $Mn \ge 1000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT) Data items and details claimed exempt from publication: Chemical name, molecular formula, structural formula, composition of polymer, spectral data, methods of detection and determination, degree of purity, hazardous impurities/residual monomers, imported volume, use details, identity of recipients and sites.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT) Variation to the schedule of data requirements is claimed as follows: Hydrolysis and adsorption/desorption

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S) Nil

NOTIFICATION IN OTHER COUNTRIES None known

2. IDENTITY OF CHEMICAL

MARKETING NAME(S) BiOH 5000, BIOH 9000

CAS NUMBER Not assigned

OTHER NAME(S) Biobased Polyol, Modified Oligomeric Vegetable Oil

MOLECULAR WEIGHT >1000 Da

ANALYTICAL DATA Reference IR, GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >70%

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

ADDITIVES/ADJUVANTS None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES Nil

DEGRADATION PRODUCTS

When heated, the polymer slowly polymerizes, as evidenced by an increase in viscosity.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Viscous liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Between -21°C and 5°C	Measured
Boiling Point	$145 - 150^{\circ}C$	Measured
Density	1,000 kg/m ³ at 25°C	Measured
Vapour Pressure	1.4 x 10 ⁻¹ kPa at 20°C	Measured
Water Solubility	< 0.002 g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not measured	See below
Partition Coefficient	$\log P_{ow} = 1.29-3.68 \pmod{2.13}$ at	Measured (HPLC method)
(n-octanol/water)	24°C	
Adsorption/Desorption	Not measured	See below
Dissociation Constant	Not applicable	No dissociable groups
Particle Size	Not applicable	Notified chemical is a liquid
Flash Point	130°C	Measured
Flammability Limits	-	Not determined
Autoignition Temperature	402°C	Measured
Explosive Properties	Not expected to be explosive	Estimated (based on structural
		indication of explosive properties)

DISCUSSION OF PROPERTIES

While the notified polymer contains groups that are susceptible to hydrolysis, any hydrolysis is likely to be slow under environmental conditions because of the low water solubility. High soil mobility can be predicted for some components, based on their relatively low partition coefficients, but mobility in soils is expected to be retarded by the surface activity of the notified polymer.

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

Reactivity

The polymer is expected to be stable under normal conditions and does not have any structural indications of oxidising properties or other unusual activity.

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 BIOH 5000 containing >99% of the notified polymer.

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

Year	1	2	3	4	5
Tonnes	100-300	300-1000	300-1000	1000-3000	1000-3000

PORT OF ENTRY Melbourne, Sydney, Brisbane and Perth.

IDENTITY OF MANUFACTURER/RECIPIENTS

Polyurethane manufacturing sites are located in Melbourne, Sydney, Brisbane and Perth.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 16 to 20 tonne flexibags inside a shipping container and transported directly to customers by road.

USE

The notified polymer is used in the manufacture of flexible polyurethane foam.

OPERATION DESCRIPTION

The notified polymer will be imported into Australia in a product (BIOH 5000) containing >99% of the notified polymer. At the polyurethane manufacturing sites, it will be pumped directly from the delivery container via dedicated hard piping into dedicated bulk steel tanks of 25 to 30 tonne capacity for storage.

The notified polymer is dispensed continuously from the bulk storage tank to the foam machine mixer via a pump and closed loop pipework that prevents any exposure or spillage of the notified polymer. All other chemicals used in the foam formulation are also dispensed continuously from their storage tanks via a pump and pipework to the mixing head as well as a return pipe to allow for recirculation prior to the foam pour. This creates a closed loop system which eliminates any waste of individual ingredients and also reduces exposure to foam manufacture workers during foam production.

As the notified polymer is mixed with the other chemicals in the foam machine mixer, the reacting foam mixture is deposited continuously onto a conveyor. The chemicals react with each other and expand to create a polyurethane foam. The conveyor is fully enclosed and extracted to remove any vapours. The fresh foam is cut into buns before being cured overnight in a ventilated building. Once cured, the buns are moved to the storage building. The foam will be used to manufacture bedding and furniture articles.

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)
Storage and transport	2	0.2 hrs per day	4 days per year
Foam manufacturing workers	4	0.2 hrs per day	12 days per year
QC Laboratory staff	4	0.1 hrs per day	100 days per year
R&D Laboratory staff	2	0.3 hrs per day	20 days per year
Maintenance Operators	8	0.5 hrs per day	4 days per year

EXPOSURE DETAILS

Worker exposure to the notified polymer in neat form during importation and transportation is not expected, except in the unlikely event of an accident where the packaging may be breached.

At foam manufacturing sites, there is a potential for dermal, ocular and inhalation exposure to the notified polymer during unloading, as the flexibag will be connected to the unloading hose using a camlock fitting. A small amount of notified polymer may drip or splash out of the hose after each unloading, resulting in exposure of liquid and vapours to skin (hands), eyes and inhalation of the manufacturing operator. However, exposure will be low as workers will wear protective clothing (overalls), safety boots, nitrile gloves and safety goggles during unloading. Furthermore, exposure by inhalation would be minimal as the unloading area is outside under cover.

After unloading, the notified polymer is dispensed continuously from the bulk storage tank to the foam machine mixer via a pump and closed loop pipework that prevents any exposure or spillage of the notified polymer. Therefore, exposure is expected to be low during this process. The reacting foam mixture is deposited continuously onto a conveyor to create a polyurethane foam. The conveyor is fully enclosed and extracted to remove any vapours. By this time, the notified polymer will be consumed during the polymerisation process to form part of the polyurethane foam matrix and will not be bioavailable. Therefore, dermal and inhalation exposure to workers involved in handling the foam buns during storage or cutting is also expected to be low.

The quality control and R&D staff will be involved in taking samples from the bulk tank to perform laboratory tests prior to production and during product development. This is achieved by opening the sample valve on the bulk tank and pouring the notified polymer. This procedure may result in exposure to liquid and vapours from drips, splashes and spills to skin (hands), eyes and inhalation. However, exposure is expected to be low as

small samples (1-10L) will be handled and protective clothing (laboratory coat), safety glasses and latex gloves will also be worn during sampling and testing to reduce exposure to the notified polymer.

Workers may be exposed to the notified polymer during cleaning of filters and maintaining pumps. However, exposure is expected to be low as workers involved in maintenance will wear protective clothing (overalls), safety glasses, safety boots and nitrile gloves.

6.1.2. Public exposure

The notified polymer is intended for industrial use only and therefore, general public will not be exposed to the notified polymer as such. However, polyurethane foam, which is produced after mixing the notified polymer with other chemicals, will be made available to the public in the form of articles such as bedding and furniture. Considering that the notified polymer is unlikely to be bioavailable in the polyurethane foam and that polyurethane foam articles will most likely to be covered by a single layer of clothing, exposure to the general public from the use of polyurethane foam is expected to be low.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer and a structurally related analogue are summarised in the table below. The details of the toxicological investigations conducted on the notified polymer can be found in Appendix B.

Endpoint	Test Substance	Result and Assessment Conclusion
Rat, acute oral toxicity	Notified polymer	oral LD50 >5000 mg/kg bw
		low toxicity
Rat, acute dermal toxicity	Analogue 1	LD50 >20 mL/kg bw
		low toxicity
Rabbit, skin irritation	Notified polymer	non-irritating
Rabbit, eye irritation	Analogue 1	non-irritating
Guinea pig, skin sensitisation – adjuvant test	Analogue 1	inadequate evidence of
		sensitisation
Mutagenicity – bacterial reverse mutation	Notified polymer	non mutagenic
Genotoxicity – in vitro gene mutation –	Analogue 1	non genotoxic
mouse lymphoma cells (TK +/- locus of L5178Y)		
Genotoxicity – in vitro gene mutation –	Analogue 1	non genotoxic
hamster CHO cells		
Genotoxicity – in vitro chromosome aberration –	Analogue 1	non genotoxic
human lymphocytes		
Developmental and reproductive effects-Rat	Analogue 1	Negative
Carcinogenicity	Analogue 1	Negative

Toxicokinetics, metabolism and distribution.

No data was available to assess toxicokinetics, metabolism and distribution of the notified polymer. Based on a significant amount of low molecular weight species with MW <1000 and n-octanol (log P_{ow} 1.29-3.68), the notified polymer has some potential to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure. Inhalation may lead to direct absorption across the epithelium of the respiratory tract.

Acute toxicity.

The notified polymer was of low acute oral toxicity in rats. Acute dermal and inhalation toxicity data were not available on the notified polymer. However, based on the analogue data, the notified polymer is likely to have low acute dermal toxicity.

Irritation and Sensitisation.

The notified polymer was not irritating to the skin of rabbits. Eye irritation and skin sensitisation data on the notified polymer were not available. Analogue data indicated that the notified polymer is unlikely to be an eye irritant.

Although skin sensitisation tests with the analogue data indicated that the analogue chemical was not a skin sensitiser, it was also clearly stated that the skin sensitisation tests did not constitute a particularly robust investigation and the analogue chemical was tested at a very dilute concentration (0.1%). Furthermore, it is also noted that the notified polymer has a structural alert for skin sensitisation and a significant amount of low

molecular weight species with molecular weight <1000. Therefore, considering the above, skin sensitisation potential of the notified polymer cannot be ruled out.

Repeated Dose Toxicity (sub acute, sub chronic, chronic).

No data was available on notified polymer to assess the potential for repeat dose toxicity.

Mutagenicity.

The notified polymer was found to be non-mutagenic in a bacterial reverse mutation test. No data was available on notified polymer for chromosomal aberration tests. However, analogue data on chromosomal aberration tests was negative. Therefore, the notified polymer is unlikely to be a genotoxic.

Carcinogenicity.

No data was available on notified polymer to assess the potential for carcinogenicity. However, based on chronic studies on the analogue, the notified polymer is not expected to have carcinogenic potential.

Toxicity for reproduction.

No data was available on notified polymer to assess the potential for toxicity for reproduction. However, based on the analogue data, the notified polymer is not expected to have reproductive effects.

Health hazard classification

Based on the available data the notified polymer is not 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

Based on available studies/analogue data, the notified polymer was of low acute oral toxicity in rats and is likely to be of low acute dermal toxicity. The notified polymer was not irritating to the skin of rabbits. Analogue data indicated that the notified polymer is unlikely to be an eye irritant and that skin sensitisation potential of the notified polymer cannot be ruled out.

Therefore, the primary risk to workers from repeated dermal exposure to the notified polymer is the possibility of developing skin sensitisation. There is a potential for dermal exposure during various processes involving the notified polymer such as transport, storage, unloading, foam manufacturing, quality control, R&D, cleaning, and maintenance. Based on its structure, the potential of the notified polymer to cause skin sensitisation cannot be ruled out. Inhalation exposure could occur during the polyurethane formation when heat is generated. However, considering the use of PPE and engineering controls, the level of risks to workers presented by the use of notified polymer is expected to be low and is not considered to be unacceptable.

Furthermore, during foam manufacturing process, the notified polymer will be consumed during the polymerisation process to form part of the polyurethane foam matrix and will not be bioavailable. Therefore, risks to workers involved in handling the foam buns during storage or cutting is also expected to be low and not considered to be unacceptable.

6.3.2. Public health

The primary exposure to general public will result from repeated dermal exposure to articles made of polyurethane foam, which is produced after mixing the notified polymer with other chemicals. Considering that the notified polymer is consumed in the polyurethane reactions and is unlikely to be bioavailable in the polyurethane foam, exposure to the general public from the use of polyurethane foam articles is expected to be low. Therefore, the risk to general public from the use of polyurethane foam is low and not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The release of the notified polymer at the manufacturing site will be minimal. Release will only occur from connecting and disconnecting hoses during unloading. This is estimated to be up to 1 kg per delivery, with up to 50 deliveries per year across all foam manufacturing sites. This equates to up to 50 kg per annum. All spills are contained with absorbent material which is collected and disposed of through licensed waste disposal contractors.

The notified polymer is not released to air, soil or water as all unloading bays are bunded and have concrete floors. Any spilled polymer is collected in absorbent material.

RELEASE OF CHEMICAL FROM USE

As the notified polymer is consumed during the chemical reaction to produce polyurethane foam, there is no release from use to air, water, soil or landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

After delivery of the notified polymer, the empty flexibag (polyethylene bag) may be able to be recycled. It is estimated that up to 20 kg remains inside the bag. This equates to 1,000 kg per year (for 50 deliveries). Residues are likely to be landfilled with the bag, but may be washed to sewer during recycling.

Any notified polymer disposed of by licensed waste contractors is disposed of via thermal decomposition.

7.1.2 Environmental fate

Residues disposed of to landfill can be expected to slowly degrade *in situ*, based on the structure of the notified polymer. Residues washed to sewer are expected to undergo partial removal with sludge. Any residues discharged to surface waters are expected to slowly degrade.

7.1.3 Predicted Environmental Concentration (PEC)

It is neither necessary nor meaningful to determine a PEC as aquatic exposure is expected to be minimal.

7.2. Environmental effects assessment

No ecotoxicity data were submitted.

7.2.1 Predicted No-Effect Concentration

The PNEC cannot be determined as there are no aquatic toxicity data.

7.3. Environmental risk assessment

The notified polymer is not considered to pose a risk to the environment as it will be consumed during foam manufacture with minimal aquatic exposure expected.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced and as diluted for use:
 - Exhaust ventilation if inhalation exposure may occur.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in the products BiOH 5000:
 - Avoid contact with the skin
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in the products BiOH 5000:
 - Gloves, 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.

Disposal

• The notified chemical should be disposed of to landfill.

Emergency procedures

• Spills or accidental release of the notified chemical 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(2) of the Act; if
 - the function or use of the chemical has changed from manufacturing of polyurethane foam, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 3000 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet

The MSDS of a 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

Physico-chemical properties were conducted on a product containing >70% notified polymer.

Melting Point/Fr	eezing Point	Between -21°C and 5°C (complete melt)
Method Test Facility	DSC-Perkin Elmer I Cargill Scientific Re	
Boiling Point		145 – 150°C (degradation temperature)
Method Remarks Test Facility		nposes before it boils. aboratory, Inc. (2005)
Density		1,000 kg/m ³ at 25°C
Method Test Facility	ASTM D1217, modi Phoenix Chemical L	ified aboratory, Inc. (2005)
Vapour Pressure		1.4 x 10 ⁻¹ kPa at 20°C
Method Remarks Test Facility	ASTM D2879 (Isote A report was not pro Phoenix Chemical L	
Water Solubility		< 0.002 g/L at 20°C
Method Remarks Test Facility		er Solubility. bility was determined at pH 4 by a gravimetric method, following raction of saturated aqueous solutions
Partition Coeffici octanol/water)	ient (n-	$\log P_{ow} = 1.29-3.68 \text{ (mean 2.13) at } 24^{\circ}\text{C}$
Method Remarks Test Facility	OECD TG 117 Parti HPLC Method ISI (2005)	tion Coefficient (n-octanol/water).
Flash Point		130°C
Method Remarks Test Facility	ASTM D93-02A, St Summary only was p Cargill R&D laborat	
Autoignition Ten	operature	402°C at 100.7 kPa
Method		EEC A.15 Auto-Ignition Temperature (Liquids and Gases).

Test Facility Chilworth Technology Ltd (2008)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

Toxicological investigations were conducted on a product containing >70% notified polymer.

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.
Species/Strain	Rat/Outbred Albino
Vehicle	None
Remarks - Method	No significant protocol deviations.

RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	5 (F)	5000	0
LD50 Signs of Toxicity		t show any signs of toxic	city for the duration of the
Effects in Organs Remarks - Results	study (14 days). No unusual findings were found during necropsy in all the dosed animals. All animals gained weight by the end of the study (Day 14).		
Conclusion	The notified chemic	al is of low toxicity via the	e oral route.
TEST FACILITY	Toxikon Corporation	n (2008a)	
B.2. Irritation – skin			
TEST SUBSTANCE	Notified polymer		
METHOD Species/Strain Number of Animals Vehicle Observation Period Type of Dressing Remarks - Method	Rabbit/New Zealand 3 (2 M, 1F) None 72 hours Semi-occlusive.		sion. 0.4 mL was applied to each
RESULTS			
Remarks - Results	toxicity were evider	nt in any of the animals du	the study. No overt signs of uring the course of the study ed in any of the three animals
CONCLUSION	The notified chemic	al is non-irritating to the sl	kin.
TEST FACILITY	Toxikon Corporation	n (2008b)	
B.3. Genotoxicity – bacteria			
TEST SUBSTANCE	Notified polymer		
Method	OECD TG 471 Bacterial Reverse Mutation Test.		

	Plate incorporation method for main test, pre-incubation method for confirmation
Species/Strain	S. typhimurium: TA1535, TA1537, TA98, TA100
	E. coli: WP2uvrA
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Concentration Range in	a) With metabolic activation: 0.21, 0.062, 0.185, 0.56, 1.67, 5.0 µL/plate
Main Test	b) Without metabolic activation: 0.21, 0.062, 0.185, 0.56, 1.67, 5.0
	μL/plate
Vehicle	Saline solution
Remarks - Method	No significant protocol deviations. Concentrations were chosen on the
	basis of a range finding study. All controls and test groups were plated in
	triplicate.

RESULTS

Metabolic	Test Substance Concentration (μL /plate) Resulting in:			
Activation	Cytotoxicity in	Cytotoxicity in	Precipitation	Genotoxic Effect
	Preliminary Test	Main Test	-	
Absent				
Test 1	>5.0	>5.0	>5.0	Negative
Test 2	>5.0	>5.0	>5.0	Negative
Present				
Test 1	Not performed	>5.0	>5.0	Negative
Test 2	Not performed	>5.0	>5.0	Negative

Remarks - Results

In the two main tests, neither an increase in the number of revertant colonies or a dose-related response was observed with or without metabolic activation.

No inhibition in the growth of the test strains was observed with or without metabolic activation. No precipitate was observed on any of the concentration levels, with or without metabolic activation.

The revertant colonies of the positive controls showed an increase of more than twice that of the negative controls, indicating that the study performed properly.

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

TEST FACILITY	Toxikon Corporation (2008c)
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