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June 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, ether with methyl D-glucopyranoside 2,6-di-(9Z)-9-octadecenoate (2:1), mono-(9Z)-9-octadecenoate (INCI name: PEG-120 Methyl Glucose Trioleate)

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 Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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: Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.

Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.

TEL: +61 2 8577 8800 FAX: +61 2 8577 8888

Website: <u>www.nicnas.gov.au</u>

Director NICNAS

TABLE OF CONTENTS

UMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS	
1. APPLICANT AND NOTIFICATION DETAILS	
2. IDENTITY OF CHEMICAL	
3. COMPOSITION	
4. PHYSICAL AND CHEMICAL PROPERTIES	
5. INTRODUCTION AND USE INFORMATION	
6. HUMAN HEALTH IMPLICATIONS	
7. ENVIRONMENTAL IMPLICATIONS	
APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES	
APPENDIX B: TOXICOLOGICAL INVESTIGATIONS	
RIBLIOGRAPHY 1	

SUMMARY

The following details will be published in the NICNAS Chemical Gazette:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1562	Lubrizol International, Inc. Bronson And Jacobs Pty Ltd	Poly(oxy-1,2- ethanediyl), α-hydro-ω- hydroxy-, ether with methyl D- glucopyranoside 2,6-di- (9Z)-9-octadecenoate (2:1), mono-(9Z)-9- octadecenoate (INCI name: PEG-120 Methyl Glucose Trioleate)	ND*	≤ 20 tonnes per annum	Component of cosmetic products.

^{*}ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data 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 unreasonable risk to the health of workers.

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

Environmental risk assessment

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

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers at reformulation plants should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
 - Avoid contact with eyes and skin. 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 polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

• The notified polymer should be disposed of to landfill. Emergency procedures

• Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer 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 component in cosmetics, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 20 tonnes per annum, 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 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.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANTS Lubrizol International, Inc. (ABN 52 073 495 603) 28 River Street SILVERWATER, NSW 2128

Bronson And Jacobs Pty Ltd (ABN 81 000 063 249) 70 Marple Avenue VILLAWOOD, NSW 2163

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn ≥1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: vapour pressure, dissociation constant, flash point, flammability, explosive properties and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Yes, unspecified

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Glucamate LT

Glucamate VLT

CAS NUMBER

1338929-66-0

CHEMICAL NAME

Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy-, ether with methyl D-glucopyranoside 2,6-di-(9Z)-9-octadecenoate (2:1), mono-(9Z)-9-octadecenoate

OTHER NAME(S)

Z-118

PEG-120 Methyl Glucose Trioleate (INCI Name)

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference GPC spectra were provided.

3. COMPOSITION

Degree of Purity 99-100%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS Below classification cut-offs.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Not expected under normal conditions of use.

DEGRADATION PRODUCTS

The notified polymer is expected to biodegrade based on the presence of polyethylene glycol (PEG).

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow solid

Property	Value	Data Source/Justification		
Melting Point/Freezing Point	43 – 47°C	Measured		
Boiling Point	> 240°C at 101.3 kPa	Measured, decomposed with no		
		boiling observed		
Density	$1,180 \text{ kg/m}^3 \text{ at } 21.3 \pm 1.0 ^{\circ}\text{C}$	Measured		
Vapour Pressure	$< 1.3 \times 10^{-9} \text{ kPa}$	Estimated based on the NAMW		
		> 1,000 Da (US EPA, 2007)		
Water Solubility	Miscible with water	Measured		
Hydrolysis as a Function of pH	Not determined	Contains functionality that is expected		
		to hydrolyse slowly in the		
		environmental range (4-9) at ambient		
		temperature.		
Partition Coefficient	Not determined	Acts as an emulsifier and phases		
(n-octanol/water)		cannot be distinguished based on		
		results of the partition coefficient test.		
		results of the partition coefficient test.		

Adsorption/Desorption	Not determined	Expected to adsorb to sludge and sediment based on its surfactant properties
Dissociation Constant	Not determined	Contains no readily dissociable functionality
Particle Size	Not determined	Imported in liquid mixtures
Flash Point	Not determined	Decomposes before boiling and hence
		cannot vapourise to form a flammable mixture in the air.
Flammability	Not determined	Decomposes before boiling and hence
		cannot vapourise to form a flammable
		mixture in the air.
Autoignition Temperature	$388 \pm 5^{\circ}\mathrm{C}$	Measured
Explosive Properties	Not expected to be explosive	The structural formula contains no
		explosophores.
Oxidising Properties	Not expected to be oxidising	Estimated based on chemical structure.

DISCUSSION OF PROPERTIES

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

Reactivity

Stable under normal conditions of use.

Dangerous Goods classification

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

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured within Australia. The notified polymer may be imported as mixtures (Glucamate LT and Glucamate VLT) containing 40 - 70% of the polymer or in cosmetic products containing the polymer at a concentration of 0.35 - 3.5%.

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

Year	1	2	3	4	5
Tonnes	< 20	< 20	< 20	< 20	< 20

TRANSPORTATION AND PACKAGING

The products Glucamate LT and Glucamate VLT containing the notified polymer will be imported in 204 and 181 kg drums and 45 kg pails for reformulation into finished cosmetic products. Transportation of products containing the notified chemical throughout Australia will predominantly be by road.

USE

The notified polymer will be used as a thickener in personal care formulations. The notifier recommends that the notified polymer is used in rinse-off cosmetic products only.

OPERATION DESCRIPTION

The notified polymer will not be manufactured within Australia. The notified polymer may be imported as a mixture for reformulation or in cosmetic products containing the notified polymer at a concentration of 0.35 - 3.5%.

Reformulation

The mixtures containing the notified polymer will be weighed and pumped to the mixing tank where it will be blended with additional additives to form the finished personal care products. The mixing facilities are expected to be fully automated, well ventilated (local exhaust ventilation) and closed systems. After being reformulated, the finished products containing the notified chemical will be transferred into the retail packaging.

End use

The finished cosmetic products containing the notified polymer will be used by the public and may also be used occupationally by hairdressers and beauticians.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS

Transport and warehousing

It is expected that transport and warehouse workers handling the imported mixtures containing 40 - 70% of the notified polymer or cosmetic products containing the notified polymer at a concentration of 0.35 - 3.5% will only be exposed in the event of spills due to an accident or as a result of leaking packaging. The main route of exposure in this situation will be dermal.

Reformulation

During reformulation, dermal and ocular exposure to the notified polymer (at 40 - 70%) may occur when weighing and transferring it to the mixing tank. It is expected that negligible exposure will occur during the fully automatic and closed blending process. Workers involved in the reformulation process are expected to wear gloves, safety glasses and protective clothing to further minimise exposure. Exposure to the notified polymer at concentrations up to 3.5% during transfer of the formulated product to packaging is expected to be low due to the largely automated processes.

Inhalation exposure is expected to be negligible given the very low predicted vapour pressure of the notified polymer ($< 1.3 \times 10^{-9} \text{ kPa}$). In addition, blending and packaging facilities are expected to be well ventilated. *End use*

Hairdressers and beauticians will be exposed to cosmetic products containing the notified polymer (\leq 3.5%) during application of the products to their clients. The main route of exposure is expected to be dermal, although ocular exposure to splashes is possible. Inhalation of product mist is also possible if it is used in products applied by spray. PPE is not expected to be worn, however good hygiene practices are expected to be in place.

6.1.2. Public Exposure

Public exposure to the notified polymer at concentrations up to 3.5% is expected to be widespread and frequent through daily use of cosmetic products containing the notified polymer. Exposure to the notified polymer will vary depending on individual use patterns. The principal route of exposure will be dermal, while ocular and inhalation exposure are also possible, particularly if products are applied by spray. Accidental ingestion from the use of these types of products is also possible.

Public exposure from transport, storage, reformulation or disposal is considered to be negligible.

6.2. Human Health Effects Assessment

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

Endpoint	Result and Assessment Conclusion
Rat, acute oral toxicity*	LD50 12,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity*	LD50 12,000 mg/kg bw; low toxicity
Rabbit, skin irritation*	slightly irritating
Rabbit, eye irritation*	slightly irritating
Guinea pig, skin sensitisation – adjuvant test*	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

^{*} Test reports were not available for verification of the reported results.

Toxicokinetics, metabolism and distribution.

The notified polymer is not expected to be absorbed across biological membranes, based on the high molecular weight and low percentage of low molecular weight (< 1,000 Da) species.

Acute toxicity.

The notified polymer is considered to be of low acute toxicity via the oral and dermal routes based on tests conducted in rats and rabbits respectively.

Irritation and Sensitisation.

Based on a test conducted in rabbits the notified polymer is considered to be slightly irritating to the skin and eye. The notified polymer was not a skin sensitiser in a guinea pig maximisation test.

Mutagenicity.

The notified polymer was found to not be mutagenic using a bacterial reverse mutation test.

Health hazard classification

Based on the available data 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 data provided the notified polymer is a slight eye and skin irritant. The risk of systemic effects is expected to be low based on the high molecular weight and the absence of effects seen in the acute oral and acute dermal toxicity tests. The notified polymer was also found to not be mutagenic. Although reformulation workers will handle products containing the notified polymer at concentrations from 40 - 70%, exposure is expected to be low given the proposed use of PPE and largely enclosed, automated processes used in reformulation facilities. The risk to the occupational health and safety of reformulation workers is not considered unreasonable, due to the expected low exposure and the low hazardous nature of the notified polymer. Hairdressers and beauticians will be exposed to cosmetic products containing the notified polymer ($\leq 3.5\%$) during application of the products to their clients. Although beauticians are not expected to use PPE considering the low hazardous nature of the notified polymer and the low concentrations the risk to these workers is not considered unreasonable.

6.3.2. Public Health

The general public will be repeatedly exposed to the notified polymer via a number of different consumer products, applied to the skin.

Local effects

The notified polymer is a slight skin and eye irritant at concentrations of 40 - 70%. However, the notified polymer will be present in cosmetic products at concentrations $\leq 3.5\%$ and therefore the risk of irritancy in consumers is not expected to be unreasonable.

Systemic effects

There is no repeated dose toxicity data available for the notified polymer, however the risk of systemic effects is expected to be low based on the high molecular weight and the absence of effects seen in the acute oral and acute dermal toxicity tests and the low concentration of the notified polymer ($\leq 3.5\%$) in cosmetic products. Therefore the risk of adverse systemic effects following exposure via consumer products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

As the notified polymer will not be manufactured in Australia, environmental release will not occur during this stage of its lifecycle. The notified polymer is imported as a mixture at concentration of up to 70% for reformulation. The concentration of the notified polymer in formulated personal care products will be 0.35-3.5%. It is expected that residues in empty import containers are estimated to be < 1% and are expected to be disposed of to landfill or through a licensed waste contractor. A further 3% of notified polymer from cleaning of mixing equipment may be released to sewer or subjected to treatment in an effluent treatment plant. Accidental spills during transport or reformulation are expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer is expected to be released to sewers in domestic situations across Australia as a result of its use in personal care products such as shampoos and soaps, which are either washed off the hair and skin of consumers.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the notified polymer in empty containers are likely to share the fate of the container and be disposed of to landfill, or to be washed to sewer when containers are rinsed before recycling.

7.1.2. Environmental Fate

Environmental fate studies on the notified polymer were not provided. According to the Biological Oxygen Demand (BOD) summary on an analogous polymer, which constitutes 95% w/w of the notified polymer, it was shown to degrade by 42% over 20 days. Based on this information, the notified polymer is expected to degrade during sewage treatment. Therefore, notified polymer in sewage influent is expected to be effectively removed via degradation, in addition to its sorptive qualities. If discharged to aquatic environments the notified polymer is expected to disperse and degrade. It is expected to degrade in the environment by biotic and abiotic processes into water and oxides of carbon. The notified polymer has low potential for bioaccumulation based on its high molecular weight and its potential for biodegradation.

7.1.3. Predicted Environmental Concentration (PEC)

Since most of the polymer will be washed into the sewer, under a worst case scenario, with no removal of the notified polymer in the sewage treatment plant (STP), the resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	20,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of polymer released to sewer	20,000	kg/year
Days per year where release occurs	365	days/year
Daily polymer release:	54.79	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	Mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	12.12	μg/L
PEC - Ocean:	1.21	μg/L

The notified polymer that is not removed from waste water during STP processes may be released to the environment in STP effluent. STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be $1000~L/m^2/year$ (10~ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10~cm of soil (density $1500~kg/m^3$). Using these assumptions, irrigation with a concentration of $12.12~\mu g/L$ may potentially result in a soil concentration of approximately $80.77\mu g/kg$. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10~years may be approximately $403.9~\mu g/kg$ and $807.7~\mu g/kg$, respectively

7.2. Environmental Effects Assessment

No ecotoxicity study reports were submitted for the notified polymer. However, ecotoxicological endpoints of an analogous polymer reported in a safety data sheet provided by the notifier are tabulated below:

Endpoint	Result	Assessment Conclusion				
Acute Toxicity						
Fish	96 h LC 50 > 5000 mg/L	Not harmful to fish				
Daphnia	48 h EC50 > 1000 mg/L	Not harmful to aquatic invertebrates				
Bacterial Inhibition	IC50 > 5000 mg/L	Not harmful to microorganisms				

As there is the potential for high aquatic exposure from the use and disposal of the notified polymer, ecotoxicological endpoints of an analogue of the notified polymer are considered useful to provide a general indication of potential environmental effects for the notified polymer.

Based on the above endpoints, the notified polymer is not expected to be harmful to fish and aquatic invertebrates. In the absence of full study reports for the notified polymer endpoints, the notifier polymer is not formally classifiable under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the lower limit of the acute daphnia toxicity of the analogous polymer and an assessment factor of 1000. A more conservative assessment factor of 1000 has been applied as acute toxicity data of analogous notified polymer are available for two trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic C	ompartment
EC50 (Daphnia)	1000 mg/L
Assessment Factor	1000
PNEC:	$1000~\mu \mathrm{g/L}$

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC, the following Risk Quotient has been calculated

Risk Assessment	PEC μg/L	PNEC μg/L	Q
Q - River	12.12	1000	0.012
Q - Ocean	1.21	1000	0.001

The risk quotient for discharge of effluents containing the notified polymer to the aquatic environment, assuming a worst case with no removal during sewage treatment plant (STP) processes, indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters based on its maximum annual importation quantity. The notified polymer has a low potential for bioaccumulation and is unlikely to be persistent in the environment. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in personal care products, the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point 43 – 47°C

Method OECD TG 102 Melting Point/Melting Range.

EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.

Remarks Measured using differential scanning calorimetry

Test Facility Harlan (2012a)

Boiling Point > 240°C at 101.3 kPa

Method OECD TG 103 Boiling Point.

EC Directive 92/69/EEC A.2 Boiling Temperature.

Remarks The test substance decomposed prior to boiling.

Test Facility Harlan (2012a)

Density $1{,}180 \text{ kg/m}^3 \text{ at } 21.3 \pm 1.0 ^{\circ}\text{C}$

Method OECD TG 109 Density of Liquids and Solids.

EC Directive 92/69/EEC A.3 Relative Density.

Remarks Measured using a Quantachrome multi pycnometer

Test Facility Harlan (2012a)

Water Solubility Miscible with water at 20 °C

Method EC Directive 92/69/EEC A.6 Water Solubility.

Remarks Flask Method but miscibility with water was determined by visual observations.

Test Facility Harlan (2012a)

Partition Coefficient (n- Not determined

octanol/water)

Method EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks Notified polymer acts as an emulsifier and phases cannot be distinguished based on

results of the partition coefficient test.

Test Facility Harlan (2012a)

Adsorption/Desorption Not determined

Method Adsorption Coefficient EC 440/2008 Method C19

Remarks Notified polymer is a surface active substance and is not suitable for determination of

adsorption coefficient by HPLC.

Test Facility Harlan (2012b)

Autoignition Temperature $388 \pm 5^{\circ}\text{C}$

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and

Gases).

Remarks A yellow/blue flame and grey fumes were observed upon autoignition.

Test Facility Harlan (2011a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Genotoxicity – bacteria

TEST SUBSTANCE Glucamate LT containing 40 – 70% notified polymer.

METHOD Conducted according to Joint notification Yakusyoku 0331 No.7,

Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and

Welfare, Japan.

Pre incubation procedure

Species/Strain S. typhimurium: TA1535, TA1537, TA98, TA100

E. coli: WP2uvrA

Metabolic Activation System

Rat S9 fraction from phenobarbital/5,6-benzoflavone induced rat liver.

Concentration Range in Main Test

a) With metabolic activation: $156 - 5{,}000 \mu g/plate$ b) Without metabolic activation: $156 - 5{,}000 \mu g/plate$

Vehicle Water

Remarks - Method The dose-determination test was conducted using concentrations ranging

from $4.88 - 5{,}000 \mu g/plate$.

RESULTS

Metabolic	Test Substance Concentration (µg/plate) Resulting in:				
Activation	Cytotoxicity in	Cytotoxicity in	Precipitation	Genotoxic Effect	
	Preliminary Test	Main Test			
Absent					
Test 1	> 5,000	> 5,000	> 5,000	negative	
Present					
Test 1	> 5,000	> 5,000	> 5,000	negative	

Remarks - Results The notified chemical was tested up to the maximum recommended dose

level of 5000 μ g/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. 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 UBE (2011)

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