File No: STD/1359

April 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Tornare

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)
Hayashibara International Australia Pty Ltd (ABN 61 120 127 488)
Level 31, RBS Tower
88 Phillip Street
Sydney NSW 2000

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: molecular formula, structural formula, molecular weight, spectral data and details of use.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
UK (2006)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
MG-60 (65-75% aqueous solution)

CAS NUMBER
738602-93-2

CHEMICAL NAME
Tornare

OTHER NAME(S)
A mixture of glycosylated trehalose and hydrogenated starch hydrolysates
Maltooligosyl glucoside/hydrogenated starch hydroloyzate

MOLECULAR WEIGHT
> 500 Da for the majority (by weight) of the mixture.

ANALYTICAL DATA
Reference NMR, IR and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) Unknown

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: White solid

Property	Value	Data Source/Justification
Melting Point	66 – 124°C	Measured
Boiling Point	> 285°C at 101.3 kPa	Measured
Density	1516 kg/m^3 at 19.6°C	Measured
Vapour Pressure	1.35 × 10^{-25} kPa at 25°C	Calculated
Water Solubility	> 636 g/L at 20°C	Measured
Hydrolysis as a Function of pH	$t_{½}$ >1 year, pH 9	Measured
Partition Coefficient (n-octanol/water)	log Pow < -5.2 at 20°C	Measured
Surface Tension	69.2 mN/m at 20.9°C	Measured
Adsorption/Desorption	log K_{oc} = –0.5 at 25°C	Measured
Dissociation Constant	Not tested	The notified chemical does not contain functional groups that are expected to dissociate under environmental conditions
Particle Size	Inhalable fraction (<100 µm): 60% Respirable fraction (<10 µm): 15% MMAD = 72.2 µm	Measured
Flash Point	Not determined	Expected to have a high flash point based on the flammability and autoignition temperature results.
Flammability	Not highly flammable	Measured
Autoignition Temperature	Not auto-flammable	Measured
Explosive Properties	Not thermally sensitive, not shock sensitive and not sensitive to friction.	Measured
Oxidising Properties	Not expected to be oxidising	Estimated

* MMAD = Mass Median Aerodynamic Diameter

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

Reactivity
Stable under normal conditions of use.

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.
The notified chemical will be imported in finished cometic products (at concentrations up to 20%) and as a raw material (65-75% aqueous solution) for use in the formulation of cosmetic products.

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

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

PORT OF ENTRY
Sydney and Melbourne

TRANSPORTATION AND PACKAGING
The finished products containing the notified chemical will be imported in a variety of cosmetic containers suitable for sale. When introduced as a raw material the notified chemical will be imported in 24 kg net tin free steel cans.

USE
The notified chemical is expected to be used as a skin conditioning, emulsion stabilising or film forming agent and a humectant in cosmetic products at concentrations up to 20%.

OPERATION DESCRIPTION
The notified chemical will not be manufactured within Australia. When the notified chemical is imported in finished products they will be warehoused before distribution to customers.

Reformulation
When imported as a raw material (65-75% aqueous solution) the notified chemical will undergo quality assurance tests prior to being reformulated into cosmetic products. The notified chemical will then be weighed before being manually added to the mixing tank. The mixing facilities are expected to be fully automated, well ventilated (local exhaust ventilation) and closed systems. After being reformulated, the mixture containing the notified chemical at concentrations up to 20% will undergo further quality assurance tests before being packaged into containers.

End use
The finished cosmetic products containing the notified chemical will be used by the public and may also be used occupationally by beauticians. Depending on the nature of the product these could be applied in a number of ways such as by hand or using an applicator.

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)*
Transportation and Storage	10	4	12
Quality Control	1	3	12
Reformulation	3	8	12

EXPOSURE DETAILS
Transport and warehousing
It is expected that transport and warehouse workers handling the imported aqueous solution containing up to 65-75% notified chemical will only be exposed to the notified chemical in the event of spills due to an accident or as a result of leaking a drum. Following reformulation into cosmetic products, transport, warehouse and retail workers handling products will be exposed to concentrations of up to 20% notified chemical in the case of an accident when packaging is breached. The main route of exposure in these situations will be dermal.

Reformulation
During reformulation, dermal and ocular exposure to the notified chemical (at 65-75%) 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 impermeable gloves, goggles or face shield and protective clothing to further minimise exposure. Exposure to the notified chemical at concentrations up to 20% 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 calculated vapour pressure of the notified chemical (1.35×10^{-25} kPa at 25°C). In addition, blending and packaging facilities are expected to be well ventilated. Inhalation exposure to the notified chemical as a solid particulate is not expected as it will be imported as a 65-75% aqueous solution.

End use
Beauticians will be exposed to cosmetic products containing the notified chemical (≤ 20%) 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. PPE is not expected to be worn, however good hygiene practices are expected to be in place.

6.1.2. Public exposure

The general public will be repeatedly exposed to the notified chemical via a number of different consumer products (≤ 20%).

Exposure to the notified chemical will vary depending on individual use patterns. The greatest exposure to the notified chemical is likely to be during the use of leave on products. In a worst case scenario when used as a body lotion, exposure of up to 8 g of product containing the notified chemical at a concentration of up to 20% will be considered per day to estimate systemic exposure (SCCP, 2006). Assuming a dermal absorption of 10% and a retention factor of 1, the maximum systemic exposure to the notified chemical is expected to be 2.7 mg/kg bw/day for a 60 kg person.

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 chemical or the aqueous solution containing 65-75% notified chemical 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 > 2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2000 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
Rat, repeat dose oral toxicity – 28 days.	NOAEL > 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Chromosome Aberration Test	non genotoxic

Toxicokinetics, metabolism and distribution.

There are no toxicokinetic data on the notified chemical. The notified chemical has a molecular weight > 500 Da and a water solubility of > 636 g/L at 20ºC and partition coefficient of log Pow < -5.2 at 20ºC. The moderately high molecular weight and hydrophilicity of the notified chemical suggest that absorption across the lipid rich environment of the stratum corneum into the epidermis would be slow.

Acute toxicity.

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

Irritation and Sensitisation.

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

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

Oral administration of the test material to rats for a period of 28 consecutive days at dose levels of 50, 200 and 1000 mg/kg/day resulted in no adverse treatment related effects at any dose level. Therefore, the NOAEL was established at the highest dose level tested, which was > 1000 mg/kg bw/day in this study.

Mutagenicity.

The notified chemical was found to not be mutagenic using a bacterial reverse mutation test, and is not clastogenic to Chinese hamster lung cells *in vitro*.

Health hazard classification

Based on the data provided, the notified chemical 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 chemical is a slight eye and skin irritant. The risk of systemic effects is expected to be low based on the moderately high molecular weight and hydrophilicity of the notified chemical and the absence of effects seen in the repeat and acute oral and acute dermal toxicity tests. The notified chemical was also found to not be mutagenic or genotoxic.

Although reformulation workers will handle the neat notified chemical at concentrations from 65-75%, 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 unacceptable, due to the expected low exposure and the low hazardous nature of the notified chemical.

Beauticians will be exposed to cosmetic products containing the notified chemical (≤ 20%) during application of the products to their clients. Although beauticians are not expected to use PPE considering the low hazardous nature of the notified chemical the risk to these workers is not considered unacceptable.

6.3.2. Public health

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

Local effects

The notified chemical is a slight skin and eye irritant at concentrations of 65-75%. However, the notified chemical will be present in cosmetic products at concentrations ≤ 20% and therefore the risk of irritancy in consumers is not expected.

Systemic effects

Based on the NOAEL of > 1000 mg/kg bw/day and a worst case systemic exposure of up to 2.7 mg/kg bw/day estimated when using body lotions the MOE is expected to be > 370. An MOE greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences. Therefore the risk of adverse systemic effects following exposure via consumer products is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as a component of finished cosmetic products and will also be imported as a raw material in aqueous solution for blending. The notified chemical is expected to be released to landfill as residue remaining in containers (estimated to be up to 1% of the annual import volume) and released to sewer from the cleaning of blending equipment (3%).

Accidental spills during transport or reformulation are expected to involve minimal amounts of notified chemical and will be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical is expected to be washed to sewer as a result of its use pattern (skin care cosmetics and other cosmetic products).

RELEASE OF CHEMICAL FROM DISPOSAL

Residue of the notified chemical in empty containers (1%) will share the fate of the container and will either be disposed of to landfill, or washed to sewer when containers are rinsed before recycling.

7.1.2 Environmental fate

The notified chemical is readily biodegradable and is expected to be largely degraded by sewage treatment processes. A small proportion may be discharged to receiving waters in treated effluent as the notified chemical is water soluble with a low adsorption coefficient, yet the notified chemical is expected to disperse and degrade. Bioaccumulation is not likely as the notified chemical is water soluble and readily biodegradable. For the details of the environmental fate studies refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC can be estimated as outlined below based on the hypothetical worst case assumptions of complete discharge to receiving waters via sewage treatment works nationwide.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	6.47	µg/L
PEC - Ocean:	0.65	µg/L

The notified chemical is predicted to be readily biodegradable, hence its removal from effluent by sewage treatment plant (STP) processes is expected. However, in this worst case model, the majority of the notified chemical is assumed to be released in 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 chemical 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 6.474 µg/L may potentially result in a soil concentration of approximately 43.16 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 215.8 µg/kg and 431.6 µg/kg, respectively.

7.2. Environmental effects assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 >100 mg/L	Not harmful to fish
Daphnia Toxicity	EC50 >100 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	E_rC50 >100 mg/L	Not harmful to algae
Inhibition of Bacterial Respiration	IC50 >1000 mg/L	Not harmful to microbial respiration

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified chemical is classified as not harmful to fish, aquatic invertebrates, algae and microbial respiration.

7.2.1 Predicted No-Effect Concentration

The PNEC can be determined as outlined below by application of a hundredfold assessment factor, as data are available for three trophic levels, to the endpoint for fish, daphnia and algal toxicity.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Fish, daphnia, algae).	>100	mg/L
Assessment Factor	100	
PNEC:	>1,000	µg/L

7.3. Environmental risk assessment

The risk quotients (Q = PEC/PNEC) are tabulated below.

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	6.47	> 1000	< 0.006
Q - Ocean:	0.65	> 1000	< 0.001

The notified chemical is not expected to pose a risk to the environment as the calculated risk quotients are much less than one.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided, the notified chemical 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 chemical is not considered to pose an unacceptable risk to the health of workers.

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not expected to pose a 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.
- 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 physical containment, collection and subsequent safe removal.

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 chemical is introduced in a powdered form.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a cosmetic ingredient at concentrations up to 20%, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 10 tonnes, or is likely to increase, significantly;
  - the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet
The MSDS of the 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 66 – 124ºC

Method	OECD TG 102 Melting Point/Melting Range.
Remarks	Determined using the capillary method and using DSC. Several endothermic heat events were observed in the DSC. No significant protocol deviations.
Test Facility	RCC (2005b)

Boiling Point > 285ºC at 101.3 kPa

Method	OECD TG 103 Boiling Point.
Remarks	The notified chemical decomposed at 285ºC prior to boiling. No significant protocol deviations.
Test Facility	RCC (2005b)

Density 1516 kg/m^3 at 19.6ºC

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Pycnometer method. No significant protocol deviations.
Test Facility	RCC (2005c)

Vapour Pressure 1.35×10^{-25} kPa at 25ºC

Method	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Calculated No significant protocol deviations.
Test Facility	RCC (2005d)

Water Solubility > 636 g/L at 20ºC

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Simplified Flask Method. The result of the preliminary test indicated that the notified chemical is miscible with water, and that the main test using the shake flask method was not possible as a saturated solution could not be prepared. The notified chemical (5.2g) was dissolved in water (5mL) and the concentration of the notified chemical was confirmed by calibrated HPLC to be >636 g/L.
Test Facility	RCC (2005e)

Hydrolysis as a Function of pH

Method	OECD TG 111 Hydrolysis as a Function of pH. EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	$t_{½}$
9	25	> 1 year

Remarks	Due to peak interference from buffer salts, no hydrolysis experiments were conducted at

pH 4 and pH 7. However, the notified chemical was assessed as hydrolytically stable at environmental pH upon examination of its chemical structure. There was no significant degradation of the notified chemical at pH 9 (50°C), and there was <10% degradation after 5 days. It was estimated that the half life was >1 year under representative environmental conditions (25°C), and that the notified chemical was hydrolytically stable at pH 9.

Test Facility RCC (2006)

Partition Coefficient (n-octanol/water) log Pow < -5.2 at 20ºC

Method In-house method.

Remarks The OECD HPLC Method (TG 117) and Flask Method (TG 107) were reportedly unsuitable for the determination of the partition co-efficient. Instead, the partition coefficient (log Pow < -5.2) was calculated from the individual solubilities of the notified chemical in n-octanol (< 0.004 g/L) and in water (> 636 g/L), both values determined by HPLC.

Test Facility RCC (2005e)

Surface Tension 69.2 mN/m at 20.9ºC

Method OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.

Remarks Concentration: 0.1%

Test Facility RCC (2005f)

Adsorption/Desorption – screening test log K_{oc} = –0.5 at 25°C

Method OECD TG 121 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).

Remarks HPLC using evaporative light scattering detection (ESLD, time adjusted) and UV detection. The retention time of the notified chemical was compared to the retention times of six standards (log K_{oc} range 1.25–5.63). The notified chemical eluted fastest, hence the log Koc is <1.25. Extrapolation of the regression curve calculated the log K_{oc} of the notified chemical to be – 0.5, and a K_{oc} value of 0.3.

Test Facility RCC (2005g)

Particle Size MMAD = 72.2 µm

Method OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (µm)	*Mass (%)*
< 5	9.1
< 10	14.9
< 50	42.1
< 100	59.7
< 150	73.2
< 200	81.5
< 250	86.6
< 500	99.4

Remarks The particle size was determined using a combined method of laser diffraction and sieving.
No significant protocol deviations.

Test Facility RCC (2005h)

Flammability Not highly flammable

Method	EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks	No significant protocol deviations.
Test Facility	RCC (2005i)

Autoignition Temperature Not auto-flammable

Method	EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks	No significant protocol deviations.
Test Facility	RCC (2005j)

Explosive Properties Not thermally sensitive, not shock sensitive and not sensitive to friction.

Method	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	No significant protocol deviations.
Test Facility	Institute of Safety & Security (2005)

Oxidizing Properties Not expected to be oxidising

Method	Based on the UN recommendations for the transport of dangerous goods(orange book, 3rd edition 1999).
Remarks	No significant protocol deviations.
Test Facility	RCC (2005k)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (65-75% aqueous solution)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/HanBrl: Wist (SPF)
Vehicle	Test substance administered as supplied
Remarks - Method	The test substance was administered by gavage at a rate of 2759 mg/kg bw, which correlates to a dose rate of 2000 mg/kg bw for the notified chemical. GLP compliant. No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	6 Female	2759	0/6

LD50	> 2759 mg/kg bw for the test substance > 2000 mg/kg bw for the notified chemical
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 chemical is of low toxicity via the oral route.
TEST FACILITY	RCC (2004a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical (95% purity)
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/HanBrl: Wist (SPF)
Vehicle	Water
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. GLP compliant.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	There were no test substance-related dermal reactions.
Signs of Toxicity - Systemic	There were no deaths or test-substance related clinical signs. There were no signs of systemic toxicity.
Effects in Organs	No abnormalities were noted at necroscopy
Remarks - Results	Body weight gains were as expected.

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY RCC (2004b)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical (65-75% aqueous solution)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (1 male, 2 female)
Vehicle	Test substance administered as supplied
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. GLP compliant.

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	0.33	0.67	0.33	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 3 rabbits produced very slight erythema at the 24 hour observation. Slight erythema was still present on 1 rabbit at 48 hour observation. All treated skin sites appeared normal at the 72-hour observation.
No corrosive effects were noted.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY RCC (2004c)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical (65-75% aqueous solution)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (1 male, 2 female)
Observation Period	72 Hours
Remarks - Method	Conjunctival discharge was not measured. GLP compliant.

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	0.67	0	0.33	1	< 72 hours	0
Conjunctiva: chemosis	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 mild conjunctival irritation. One treated eye appeared normal at the 24 hour observation, a second at the 48 hour observation with the remaining eye appearing normal at the 72 hour observation.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	RCC (2004d)

B.5. Skin sensitisation

TEST SUBSTANCE	Notified chemical (65-75% aqueous solution)
METHOD	OECD TG 406 Skin Sensitisation - Guinea Pig Maximisation Test EC Directive 96/54/EC B.6 Skin Sensitisation - Guinea Pig Maximisation Test
Species/Strain	Guinea pig/Himalayan spotted Ibm: GOHI; SPF
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 75% topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 75% topical: 100
Signs of Irritation	Signs of irritation were seen in all of the test group animals during the induction phase.
CHALLENGE PHASE	
1st challenge	topical: 25%
Remarks - Method	No significant protocol deviations. GLP compliant.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	25%	1/10	0/10
Control Group	25%	0/5	0/5

Remarks - Results	There were no deaths or substance-related signs of toxicity during the study. After challenge 1/10 (10%) animal showed a score of 1 at the 24 hour observation. This was below the 30% cut-off for evidence of positive responses to meet the classification criteria. The positive control confirmed the sensitivity of the test system.
CONCLUSION	The test substance was not a skin sensitiser under the conditions of the test.
TEST FACILITY	RCC (2004e)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical (95% purity)
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/HanBrl:WIST (SPF)

Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 Dose regimen: 7 days per week
Vehicle	Water
Remarks - Method	No significant protocol deviations. GLP compliant.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5 per sex	0	0/10
low dose	5 per sex	50	0/10
mid dose	5 per sex	200	0/10
high dose	5 per sex	1000	0/10

Mortality and Time to Death

There were no unscheduled deaths during the study.

Clinical Observations

There were no treatment related clinical signs noted during the study apart from increased locomotor activity in male animals in the treated groups. No effects were seen in female animals and hence the increased locomotor activity is considered to be of no toxicological significance. There were no significant differences in the bodyweight gain and food consumption between the control and treated groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology – Male rats in the high and low dose groups had significant increases in neutrophil concentrations that were within the range for the historical control data. Statistically significant high mean corpuscular haemoglobin (MCH) and mean corpuscular volume (MCV) levels were present in female animals in the mid dose group. MCH values were slightly above the range of the historical control data while MCV values were within the range of the historical control data. As the effects seen were within historical values or not dose dependent they are considered to be of no toxicological significance.

Clinical Chemistry – A significant dose dependent decrease was seen in the total bilirubin concentrations for male animals in all three treatment groups but as the effect was within the range of the historical control data and only present in male animals it is considered to be of no toxicological significance. A significant increase in triglyceride concentration in low dose male animals but was within the range of the historical control data and not dose dependent and hence considered to be of no toxicological significance.

Effects in Organs

There was a significant reduction in spleen to body and spleen to brain weights in mid dose males. These findings were not seen in the other dose groups and hence are considered incidental.

A range of macro- and microscopic findings were noted in individual animals including in the control group, however there was no dose response relationship seen and the findings were considered to be part of the normal background pathology of rats of this age and strain.

Remarks – Results

No adverse treatment related effects were seen at any dose level and hence the NOAEL can be regarded as the highest dose level tested.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as > 1000 mg/kg bw/day in this study, based on the absence of any adverse effects at any of the dose rates tested.

TEST FACILITY RCC (2005l)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical (95% purity)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure and Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2uvrA.
Metabolic Activation System	Rat S9 fraction from phenobarbitone/β-napthoflavone induced rat liver.
Concentration Range in Main Test	*Plate incorporation procedure* a) With metabolic activation: 3 – 5000 µg/plate b) Without metabolic activation: 3 – 5000 µg/plate *Pre incubation procedure* a) With metabolic activation: 33 – 5000 µg/plate b) Without metabolic activation: 33 – 5000 µg/plate
Vehicle	Water
Remarks - Method	Two main tests were conducted the first using the plate incorporation procedure and the second using the pre incubation procedure. No significant protocol deviations. GLP compliant.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1 (plate)	> 5000	> 5000	> 5000	negative
Test 2 (pre)		> 5000	> 5000	negative
Present				
Test 1 (plate)	> 5000	> 5000	> 5000	negative
Test 2 (pre)		> 5000	≥ 333	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. 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 chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	RCC (2005m)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical (65-75% aqueous solution)
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	Chinese Hamster Lung
Metabolic Activation System	Rat S9 fraction from Phenobarbital/5,6-benzoflavone induced rat liver.
Vehicle	Water
Remarks - Method	No significant protocol deviations. GLP compliant.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 1250*, 2500*, 5000*	6 hours	24 hours
Test 2	0*, 1250*, 2500*, 5000*	24 hours	24 hours
Present			
Test 1	0*, 1250*, 2500*, 5000*	6 hours	24 hours
Test 2	-	-	-

*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	-	-	-	-

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	The notified chemical was not clastogenic to Chinese Hamster Lung cells treated in vitro under the conditions of the test.
TEST FACILITY	Shin Nippon (2004)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 A Ready Biodegradability: DOC Die-Away Test.
Inoculum	Aerobic activated sludge from a domestic wastewater treatment plant
Exposure Period	14 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved organic carbon (DOC) using a Shimadzu TOC-5000A analyser
Remarks - Method	The ready biodegradability was tested according to guidelines above at a test concentration of 75 mg/L. The test was terminated ahead of schedule 14 days after exposure because the biodegradation curves of the test and reference substances had reached a plateau for three determinations. A reference (sodium benzoate, 50 mg/L) control and toxicity control (notified chemical, 75 mg/L, and reference substance, 50mg/L) were run in parallel. Test conditions: 23°C, pH 7.1-7.3.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
3	94	3	99
7	99	7	99
10	100	10	100
14	100	14	100

Remarks - Results	The test substance was degraded 100% within the first 14 days of exposure and was degraded >70% in a ten day window. The reference substance was completely degraded over the first three days, thus validating the test. Biodegradation amounted to 97% with 14 days of exposure in the toxicity control, thus the notified chemical is not considered toxic to microbial respiration.
CONCLUSION	The notified chemical is readily biodegradable
TEST FACILITY	RCC (2005n)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	Zebra fish (*Brachydanio rerio*)
Exposure Period	96 hour
Auxiliary Solvent	None
Water Hardness	216 mg $CaCO_3$/L
Analytical Monitoring	HPLC was used to determine the concentration of the notified chemical
Remarks – Method	After a range finding test, a limit test was performed in accordance with the guidelines at a test concentration of 100 mg/L. Test conditions: pH 8.0–8.6, 21–22°C, ≥8.3 mg O_2/L.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	7	0	0	0	0	0
100	99–109	7	0	0	0	0	0

LC50	>100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	There was no mortality observed in the fish exposed to the test substance at a concentration of 100 mg/L. There was no mortality in the control, thus validating the test.

CONCLUSION The notified chemical is not harmful to fish

TEST FACILITY RCC (2005o)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC was used to determine the concentration of the notified chemical
Remarks - Method	After a range finding test, a limit test was conducted in accordance with the guidelines at a test concentration of 100 mg/L. Test conditions: 20°C, 16 h–8 h light dark cycle, pH 7.9, ≥8.7 mg O_2/L.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	20	0	0
100	99–100	20	0	0

EC50	>100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	There was no immobilisation observed in the daphnids exposed to the test substance at a concentration of 100 mg/L. There was no mortality in the control, thus validating the test.

CONCLUSION The notified chemical is not harmful to aquatic invertebrates

TEST FACILITY RCC (2005p)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Desmodesmus subspicatus* (formerly known as *Scenedesmus subspicatus*)
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L Actual: 28–103 mg/L

Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	HPLC was used to determine the concentration of the notified chemical
Remarks - Method	After a range finding test, a limit test was conducted in accordance with the guidelines at a test concentration of 100 mg/L. Test conditions: 24 h illumination, 23°C, pH 7.9–8.7.

RESULTS

Biomass		*Growth*	
E_bC_{50} mg/L at 72 h	*NOEC mg/L*	*E_rC_{50} mg/L at 72 h*	*NOEC mg/L*
>100	100	>100	100

Remarks - Results	The measured concentrations of the notified chemical in solution ranged from 103 mg/L at the start of the test, to 28 mg/L at the end of the test. As the notified chemical was determined to be hydrolytically stable the decline in concentration was reported to be caused by photolytic degradation from the strong light irradiation during the test. There was no inhibitory effect observed on the growth of the algae exposed to the test substance at a nominal concentration of 100 mg/L (mean measured 53 mg/L). Microscopic examination of the algal cells indicated that there were no observable differences between the algae exposed to the test substance and the control algae. The biomass of the control increased 104–fold, thus validating the test.
CONCLUSION	The notified chemical is not harmful to algae
TEST FACILITY	RCC (2005q)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Aerobic activated sludge from a domestic wastewater treatment plant
Exposure Period	3 hours
Concentration Range	Nominal: 1000 mg/L Actual: Not tested
Remarks – Method	After a range finding test, a limit test was conducted in accordance with the guidelines at a test concentration of 1000 mg/L. Test conditions: 20°C, ≥2.5 mg O_2/L.
RESULTS	
IC50	>1000 mg/L
NOEC	1000 mg/L
Remarks – Results	The test material had no inhibitory effect on the respiration rate on the activated sludge after the incubation period of 3 h at a concentration of 1000 mg/L. Variation in the respiration rates of the control after 3 h contact time was ±2.4%, and the IC50 of the reference material (3,5–dichlorophenol) was 13 mg/L (95% CI: 7.6–22 mg/L), thus validating the test.
CONCLUSION	The notified chemical is not harmful to microbial respiration
TEST FACILITY	RCC (2005r)

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