File No: LTD/1841

August 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in KERAVIS PE NT-LQ-(WD)/KERAVIS PE-(WD)/KERAVIS-(WD) (INCI Name: Hydrolyzed Vegetable Protein PG-Propyl Silanetriol)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

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:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1841	Croda Singapore Pte Ltd	Polymer in KERAVIS PE NT-LQ-(WD) / KERAVIS PE-(WD) / KERAVIS-(WD) (INCI Name: Hydrolyzed Vegetable Protein PG-Propyl Silanetriol)	ND*	≤ 1 tonne per annum	Component of rinse-off cosmetic products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 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 use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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 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 importation volume exceeds one tonne per annum notified chemical;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of rinse-off cosmetic products, or is likely to change significantly;
- the amount of polymer being introduced has increased, 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 (M)SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Croda Singapore Pte Ltd (ABN: 34 088 345 457)
Suite 102, Level 1, 447 Victoria Street
WETHERILL PARK NSW 2164

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1,000 Da (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and site of reformulation.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Japan (2010)

2. IDENTITY OF CHEMICAL

MARKETING NAMES
KERAVIS
KERAVIS PE
KERAVIS PE NT

OTHER NAMES
Hydrolyzed Vegetable Protein PG-Propyl Silanetriol (INCI Name)

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference GPC and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear yellow liquid (aqueous solution containing the notified polymer)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified polymer will be imported in an aqueous solution.
Boiling Point	Not determined	The notified polymer is expected to decompose before reaching boiling point.
Density	Not determined	The notified polymer will be imported in an aqueous solution.
Vapour Pressure	Not determined	The notified polymer will be imported in an aqueous solution.

Water Solubility	Miscible	The notified polymer is supplied as an aqueous solution.
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable groups and is expected to hydrolyse in the environmental range of pH 4-9.
Partition Coefficient (n-octanol/water)	Not determined	Proteins are able to rearrange tertiary structure to become amphipathic.
Adsorption/Desorption	Not determined	Proteins are able to rearrange tertiary structure to become amphipathic.
Dissociation Constant	Not determined	No dissociable functionalities.
Flash Point	Not determined	The notified polymer is expected to decompose before reaching boiling point.
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Not expected to oxidize under normal conditions of use

DISCUSSION OF PROPERTIES
The notified polymer is manufactured in an aqueous solution and will typically contain 79-86% water. The notified polymer is not anticipated to be isolated at any stage during manufacture, reformulation and use.

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

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. The notified polymer will be imported in to Australia as a blended bulk raw material at 10-25% concentration to be formulated into end-use cosmetic products.

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

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

PORT OF ENTRY
Brisbane, Melbourne, Perth and Sydney

TRANSPORTATION AND PACKAGING
The notified polymer will be imported by sea or air in container sizes ranging from 500 mL to 200 L and transported by rail/road to the site of reformulation. After reformulation, the end-use products will be packaged into small containers and transported by rail/road to the warehouse for later distribution to retailers.

USE
The notified polymer will be used as an ingredient in rinse-off cosmetic products at < 1% concentration.

OPERATION DESCRIPTION
The notified polymer will not be manufactured within Australia. The notified polymer will be imported as a blended bulk raw material at 10-25% concentration to be formulated into rinse-off cosmetics.

Reformulation
The notified polymer will be formulated into rinse-off cosmetic products at ≤ 1% final concentration. The procedure for incorporating the notified polymer into end-use products will likely vary depending on the nature

of the reformulated products and blending facilities and may involve both automated and manual transfer steps. In general, it is expected that for the reformulation process, the notified polymer will be weighed and added to mixing tank where it will be blended with additional additives to form the finished cosmetic products. It is expected that the blending operations will be highly automated and occur in a fully enclosed environment. This will be followed by automated filling of the reformulated products into retail packaging of various sizes. During the reformulation process, samples may be taken for quality control testing.

End-use
The finished cosmetic products will contain the notified polymer at < 1% concentration. The products will be used by consumers and professionals such as beauticians. The products are expected to be directly applied by hand and rinsed off shortly after application.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Dockside worker	< 1	1-5
Transport worker	1-8	5-10
Blending operator	< 1	1-200
Quality control personnel	< 1	1-200
Salon workers	Unspecified	365

EXPOSURE DETAILS
Dockside and transport workers may come into contact with the notified polymer at ≤ 25% concentration in the unlikely event of accidental spill or rupture of containers.

During reformation, dermal and ocular exposure of blending operators and quality control personnel to the notified polymer at up to 25% concentration may occur during weighing and transfer stages, blending, sampling for quality control, packaging and cleaning and maintenance of equipment. The notifier has stated that exposure to the notified polymer is expected to be minimised through the use of local and general ventilation and enclosed systems and the use of personal protective equipment (PPE) such as coveralls, impervious gloves and safety goggles and good industrial hygiene measures.
Exposure to the notified polymer in end-use products (at < 1% concentration) may occur in professions where the services provided involve the application of cosmetic products to clients (e.g. salon workers and hair dressers). Such professionals may use some PPE to minimise repeated exposure. If PPE is used and good hygiene practices are in place, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using the products containing the notified polymer.

6.1.2. Public Exposure
Public exposure to the notified polymer is expected to be widespread and frequent through daily use of cosmetic products containing it at < 1% concentration. The principal route of exposure will be dermal.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix A.

Endpoint	*Result and Assessment Conclusion*
Skin irritation (in vitro)	slightly irritating
Human, skin sensitisation – RIPT	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	mutagenic
Genotoxicity – in vitro L5178Y TK +/- Mouse lymphoma Assay	non genotoxic

Toxicokinetics, metabolism and distribution.
No toxicokinetics, metabolism and distribution studies were submitted for the notified polymer. For dermal absorption, molecular weights below 100 Da are favourable for absorption and molecular weights above 500 Da

do not favour absorption (ECHA, 2014). Given the relatively high expected molecular weight of the notified polymer (NAMW > 500 Da) dermal absorption is expected to be low. However, the notified polymer can be degraded by skin enzymes and the resulting metabolites may be absorbed more readily.

Irritation and sensitisation.
The notified polymer was reported to be slightly irritating to skin when tested using an *in vitro* MatTek EpiDerm skin model test.

The notified polymer was not irritating or sensitising to the skin when applied undiluted in a human repeat insult patch test (HRIPT) with 99 test subjects.

Systemic toxicity.
No information on the acute or repeated dose toxicity of the notified polymer was provided. The notified polymer is unlikely to readily cross biological membranes, and contains no functional groups that would imply a risk of systemic toxicity.

Mutagenicity/Genotoxicity.
Two *in vitro* mutagenicity tests were conducted. The notified polymer was reported to be mutagenic in a bacterial reverse mutation Ames test and was reported non-genotoxic in Mouse Lymphoma assay using L5178Y TK +/- cell lines. The notified polymer is protein hydrolysate which can be enzymatically acted upon releasing free amino acids. Amino acids and proteins are known to interfere in Ames test and may give false positive results (Nylund and Einistő, 1993 and Aeschbacher *et al*., 1983). Based on this, the result of Ames test was not considered for assessment of the hazard characteristics of the notified polymer.

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Transport and Reformulation
Workers may experience dermal and accidental ocular exposure to the notified polymer (at up to 25% concentration) during transport and formulation processes. The notifier has stated that processes will include use of enclosed, automated processes with adequate ventilation, along with the use of PPE (impervious gloves, safety glasses and coveralls) should further minimise the potential for exposure.

Therefore, under the expected scenarios for transport and reformulation, the risk to workers from use of the notified polymer is not considered to be unreasonable.

End-use
Workers involved in professions where the services provided involve the application of cosmetic products to clients (e.g. hairdressers or beauty salon workers), may be exposed to the notified polymer during their application of products to salon clients. Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. Based on the information available, the risk to workers associated with use of the notified polymer at ≤ 1% concentration in cosmetic products is not considered to be unreasonable.

6.3.2. Public Health
Members of the public may be repeatedly exposed to the notified polymer during the use of rinse-off cosmetic products at up to 1% concentration. Based on available information on the notified polymer, skin irritation and sensitisation effects from use of the notified polymer at the proposed concentrations of ≤ 1% in rinse-off cosmetic products are not expected.

The repeated dose toxicity effects of the notified polymer have not been determined. However, systemic exposure is expected to be limited by the predicted low dermal absorption, the low concentration (< 1%) and it use in only rinse off products. In addition, the notified polymer contains no functional groups that would imply a risk of systemic toxicity.

Therefore, based on the information available, the risk to the public associated with the use of the notified polymer at ≤ 1% concentration in rinse-off cosmetic 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

The notified polymer is not expected to be released from storage except in the unlikely event of an accidental spill. If spillage occurs, the notified polymer is expected to be contained and absorbed using an absorbent material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The end use products containing the notified polymer are designed to be applied to hair. Due to the high water solubility of the notified polymer, it is expected to be washed off and enter the sewer. Environmental exposure can therefore be expected to be widespread but diffuse. The majority of the notified polymer is expected to be released to the sewer. The notified polymer is expected to be largely removed by adsorption to sludge at the sewerage treatment plants before treated effluent is released to surface water.

RELEASE OF CHEMICAL FROM DISPOSAL

The residual notified polymer remaining in the import containers 1% (10 kg) will be immobilised in landfill by adsorption to soil and organic matter. Waste water containing notified polymer produced at the site of formulation will be disposed of to trade waste systems and then biological processing treatment plants. From here the wastewater will then be appropriately disposed of to sewers. The end use containers which will contain small amounts of residual notified polymer will be disposed to landfill as domestic waste.

7.1.2. Environmental Fate

Following its use in Australia, the majority of the notified polymer is expected to enter the sewer system before potential release to surface waters on a nationwide basis. It is expected to be degraded during the wastewater treatment process. Based on its amphipathic properties partitioning to sludge is expected. The notified polymer has low potential to bioaccumulate based on its high water solubility. In surface waters, the notified polymer is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. Based on the reported use in cosmetics products, it is assumed that 100% of the total import volume of the notified polymer is expected to be released to the sewer. The release is assumed to be nationwide over 365 days per year. It is conservatively assumed that 0% of the notified chemical will be removed during sewage treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.61	µg/L
PEC - Ocean:	0.06	µg/L

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 0.61 µg/L may potentially result in a soil concentration of approximately 4.0 µg/kg from each year of irrigation. 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 20.2 µg/kg and 40.4 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted.

7.2.1. Predicted No-Effect Concentration

A PNEC cannot be calculated as no ecotoxicity data were submitted.

7.3. Environmental Risk Assessment

A risk quotient cannot be calculated as the ecotoxicity data required to determine the PNEC are not available. Based on its amphipathic properties the notified polymer is expected to partition to sludge during waste treatment process. The notified polymer has low potential to bioaccumulate based on its high water solubility. On the basis of the likely biodegradability and the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Irritation – skin (in vitro)

TEST SUBSTANCE: Notified polymer

METHOD: MatTek Corporation EpiDerm™ Skin Model *in vitro* Toxicity Test – Similar to OECD TG 439 In vitro Skin Irritation: Reconstructed Human *Epidermis* Test Method

Vehicle: None

Remarks - Method: MatTek EpiDerm tissue samples were treated with the test substance (100 µL) and negative control for 1, 4 and 24 h exposure times. The identity of the negative control was not given. Following treatment, the viability of the tissues was determined after a 3-hour exposure to MTT (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyl-tetrazolium bromide) and conversion to formazan derivative, and the absorbance of each sample was measured at 570 nm. With the absorbance of the negative control defined as 100%, the percent absorbance of the test substance was determined. The percent viability was used to calculate the ET_{50} (the time at which the EpiDerm tissue viability was reduced 50% compared to control tissues).

RESULTS

Test material concentration	*test material incubation time (hours)*	*Percent viability*	*Percent inhibition*
100%	1	111	-11
100%	4.5	68	32
100%	20	27	73

Remarks - Results: The test substance elicited an ET_{50} of 8.7 hours. According to MatTek Corporation, as a general guideline a test substance having an ET_{50} between 4 and 12 hours is classified as moderate to mild irritant.

CONCLUSION: The notified polymer was slightly irritating to the skin under the conditions of the test.

TEST FACILITY: CPT (2003)

A.2. Skin sensitisation – human volunteers

TEST SUBSTANCE: Notified polymer

METHOD: Repeated insult patch test with challenge

Study Design: Induction Procedure: 200 µL of the undiluted test substance was applied to the infrascapular area of the back, either to the right or left of the midline. This procedure was performed Mondays, Wednesdays and Fridays for three consecutive weeks until 9 applications of the test article had been made. Subjects removed the patches 24 hours after each application.

Rest Period: approximately 14 days

Challenge Procedure: challenge patch applied on virgin sites. The patches were removed after 24 h, and sites were scored at patch removal and 72 h after patch removal.

The study was conducted in 2 panels with 52 participants in panel 1 and 47 participants in panel 2.

Study Group: 67 F, 32 M; age range 16 to 79 years

Vehicle: None

Remarks - Method: Semi-occluded. The test substance was spread on a 2.5 cm × 2.5 cm patch.

RESULTS

Remarks - Results	99/109 enrolled subjects successfully completed the test procedure. The 10 test subjects who discontinued participation, did it for various reasons not related to application of test substance. There was no skin reactivity observed at any time during the course of the study.
CONCLUSION	The test substance was non-irritating and non-sensitising under the conditions of the test.
TEST FACILITY	CPT (2002)

A.3. Genotoxicity – in vitro

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
Cell Type/Cell Line	L5178Y TK +/- 3.7.2c mouse lymphoma cell line
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
Vehicle	RPMI 1640 cell culture media
Remarks - Method	No significant deviations from the OECD guidelines. Due to significant increase in osmolality at 5,000 µg/mL, the maximum concentration of test substance used in the test was limited to 3,750 µg/mL.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	156.25*, 312.5*, 625*, 1250*, 2500* & 3750*	4 & 24 hours	48 hours	10 – 14 days
Test 2	156.25*, 312.5*, 625*, 1250*, 2500* & 3750*	4 & 24 hours	48 hours	10 – 14 days
Present				
Test 1	156.25*, 312.5*, 625*, 1250*, 2500* & 3750*	4 hours	48 hours	10 – 14 days
Test 2	156.25*, 312.5*, 625*, 1250*, 2500* & 3750*	4 hours	48 hours	10 – 14 days

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Dose-range Finding Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	> 3,750	> 3,750	Negative
Test 2		> 3,750	Negative
Present			
Test 1	> 3,750	> 3,750	Negative
Test 2		> 3,750	Negative

Remarks - Results	The maximum dose level used in the mutagenicity tests were limited by a test substance-related increase in osmolality. the positive control gave a satisfactory response and the negative controls were comparable with historical data, confirming the validity of the test system.
CONCLUSION	The notified polymer was not clastogenic to L5178Y TK +/- 3.7.2c mouse lymphoma cell line treated in vitro under the conditions of the test.
TEST FACILITY	Harlan (2011)

BIBLIOGRAPHY

Aeschbacher, H.U. (1983) Interactions of Histidine-Containing Test Substances and Extraction Methods with the Ames Mutagenicity Test. Mutation Res., 113 p103-116. (Published research article).

CPT (2002) Repeated Insult Patch Test Protocol No.: 1.01. (Study No. C02-0886.02, November, 2002). NJ, USA, Consumer Product Testing Co. (Unpublished report submitted by the notifier).

CPT (2003) The MatTek Corporation EpiDerm™ Skin Model *In Vitro* Toxicity Testing System (Study No. V03-0057-1, October, 2003). NJ, USA, Consumer Product Testing Co. (Unpublished report submitted by the notifier).

ECHA (2014) Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7c: Endpoint specific guidance, November 2014, version 2.0. European Chemicals Agency, http://echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf.

Harlan (2011) Keravis: L5178Y TK +/- Mouse Lymphoma Assay (Study No. 41004160, May, 2011). Shardlow, UK, Harlan Laboratories Ltd. (Unpublished report submitted by the notifier).

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

Nylund, L and Eistinő, P (1993) Mutagenicity Testing of Protein-Containing and Biological Samples Using the Ames/Salmonella Plate Incorporation Test and The Fluctuation Test. Mutation Res., 272 p205-214. (Published research article).

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.