File No: STD/1217

14 November 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

PPG-3 Benzyl ether myristate

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 and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

This Full Public Report is 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:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, 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

FULL PUBLIC REPORT

PPG-3 Benzyl ether myristate

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Croda Singapore Pte Ltd (Trading as Croda Australia) (ABN: 34 088 345 457)
Suite A1, Ground Floor, 44-46 Mandarin Street, Villawood, NSW 2163

NOTIFICATION CATEGORY
Standard: Polymer with NAMW < 1000 (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

- Import volumes
- Chemical name
- CAS number
- Molecular and structural formulae
- Molecular weight
- Spectral data
- Percentage of notified chemical in final products

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: [*List]*
Physical and Chemical Properties:
Vapour pressure
Partition coefficient
Adsorption/desorption
Dissociation constant
Flammability limits
Explosive properties.

Schedule attachment Part C1
Acute toxicity – oral, dermal, inhalation
Irritation – skin and eye
Skin sensitization
Repeat dose toxicity
Genotoxicity in vitro
Genotoxicity in vivo

Schedule attachment Part C2
Environmental fate – Ready biodegradability and bioaccumulation
Inhibition of microbial activity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LTD(EIP)/1236

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

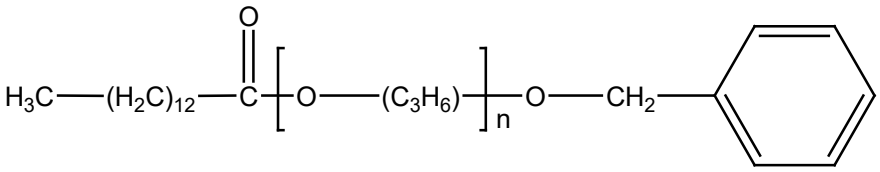
CHEMICAL NAME
Poly[oxy(methyl-1,2-ethanediyl)], α-(1-oxotetradecyl)-ω- (phenylmethoxy)-

OTHER NAME(S)
PPG-3 Benzyl ether myristate

CAS NUMBER
642443-86-5

MOLECULAR FORMULA
$(C_3H_6O)_n$ $C_{21}H_{34}O_2$

STRUCTURAL FORMULA



where n = 1-7 (approximately 50% with n= 2 or 3)

MOLECULAR WEIGHT
493 where n = 3 or 434 where n=2. The molecular weight would vary with the degree of propoxylation.
A GPC analysis was performed. However the low molecular weight was outside the calibration range of the polystyrene standard, and results were not consistent with the structure of the polymer.

MARKETING NAME(S)
Crodamol STS

SPECTRAL DATA

METHOD	GC/Mass Spectrometry
Remarks	Individual peaks were identified, representing the notified polymer with different numbers of propylene oxide molecules. Impurities (residual reactants) were also identified. The polymer can also be analysed via HPLC, as was done in identifying peaks for dermal penetration testing (section .7.18)
TEST FACILITY	Not identified

3. COMPOSITION

DEGREE OF PURITY
> 90 %

4. 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 at a neat concentration in 175 kg closed plastic lined steel drums and will be reformulated in Australia.

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

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

USE
Crodamol STS will be used in the manufacture of rinse off hair products such as shampoos. The

notified polymer will be present at < 1% concentration in the product. Fifty percent of the manufactured shampoo will be exported overseas, with the remainder used in Australia.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Formulators of hair care products.

TRANSPORTATION AND PACKAGING
The notified polymer will be shipped into Sydney, Australia at a neat concentration in 175 kg closed plastic lined steel drums. The notified polymer will be transported from the dockside to the formulation site in NSW, where it will be stored and formulated into hair care products. The finished hair care products will be typically packaged into small sealed consumer sized 300 mL plastic bottles. These plastic bottles are then sealed with plastic closures and packed in cardboard cartons before being transported by truck or van to end-users (hair salons, retail outlets).

5.2. Operation description

Importation, Transport and Storage
The notified polymer will be imported in Australia at 100% concentration as Crodamol STS. It will be transported by road in 175 kg closed plastic lined steel drums to the formulation site at in NSW, where it will be stored and formulated into hair care products.

Formulation
During manufacture of hair care products, an operator will open the drums, connect pumping equipment to the drums and dose the required amount of the notified polymer into a mixing vessel. The drum of raw material is heated to (~80ºC) prior to pumping. Other ingredients will also be added and the mixture is blended in either a closed mixing vessel. Mixing operation is automated. Prior to packaging, sampling and quality testing of the hair products are carried out in the laboratory. The formulated products will then be transferred by pump into a storage tank connected to a multiple head filler machine and automatically poured into push on caps 300 mL plastic bottles. The concentration of the notified polymer in the hair care products will be a maximum of 1%.

The bottled products will be sealed with plastic closures and packed in cardboard cartons and will be transported to distribution warehouses for retail outlets or hair salons. Retail workers will handle the finished products in their retail packaging.

End-use
The small containers of product will be packed in cardboard cartons and will be distributed by road to retail outlets for consumer use or distributed to hair salons for application to customers.

5.3. Occupational Exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transporting and warehousing	5-10	2-3 hours/day	50 days/year
Operators	20-50	8 hours/day	150 days/year
Laboratory technicians	2	2-3 hours/day	150 days/year
Maintenance	3	2-3 hours/day	10 days/year
Hairdressers	> 1000	1 hour per day	200-240 days/ year
Retail workers	> 1000	1 hour per day	10 days/year

Exposure Details
Importation, Transport and Storage

Exposure to workers involved in the importation, storage and transport of the notified polymer are not expected. Exposure is only expected in the unlikely event of an accidental spill. No controls are required. Gloves, coveralls and goggles are available if required.

Formulation of Preparation
Dermal and ocular exposure to the notified polymer (100%) may occur during: opening and closing of containers; weighing and transferring of the notified polymer from the containers to the smaller containers and then to mixing vessel; and connecting and disconnecting transfer and filling lines. Following reformulation any exposure will be to products containing up to 1% of the notified polymer. Exposure to the finished product is most likely during packaging and unitising of finished consumer products.

The mixing vessels are enclosed and the filling machines are automated and fitted with local exhaust ventilation to capture any volatile or aerosol materials at the source. To prevent exposure workers wear overalls, safety glasses and/or safety shoes and impervious gloves.

Quality Control/Maintenance
Limited dermal exposure to small quantities may occur during sampling and testing or during machine maintenance. To minimise exposure workers will wear laboratory coats, safety glasses and rubber gloves.

End-Use
Intermittent dermal exposure to hairdressers is likely to occur when applying hair care products such as shampoos to the hair of customers in salons, as gloves will probably not be used for this process. Based on similar products, the quantity used per application will be approximately 8 grams. Repeated exposure may occur through use of the product on different customers. Some accidental ocular exposure may occur. Inhalation exposure is not expected. The low concentration of the notified polymer in the hair care products (< 1%) will reduce the exposure of hairdressers.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified polymer will be transported from the dockside to the formulation site in NSW, where it will be stored and formulated into hair care products. Release volumes from the formulation process will be low.

During the formulation of hair care products the estimated annual losses of notified polymer are:

Spills		less than 1%	< 50 kg
	Landfill		
Equipment cleaning	1% max		50 kg
	Sewer		
Import container residuals	less than 1%	< 50 kg	Landfill
Total Annual Loss			< 150 kg

RELEASE OF CHEMICAL FROM USE
The notifier has indicated that at least 50% of the manufactured shampoo will be exported overseas. Less than 50% of the notified polymer will remain in the Australian market.

Following application of hair care products, almost all of the notified polymer will be washed from hair and released to sewer. The end use containers are expected to be disposed of with normal household garbage to landfill. The residues of notified polymer remaining in these bottles are expected to be 2% or up to 50 kg/annum of the domestic use.

5.5. Disposal

During formulation, spills and import containers and any residues present will be disposed of to landfill. The end use containers are expected to be disposed of with normal household garbage to landfill. All the reformulation waste will be treated in an on-site treatment plant.

The majority of the notified polymer used in hair care products domestically will ultimately be

disposed of to sewer.

5.6. Public exposure

Public exposure during transport, storage and retail distribution is unlikely unless the packaging is breached.

The notified polymer will be used in the manufacture of hair care products such as shampoos, which will be available to the public through hair salon and retail outlets. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified polymer at up to 1%. In most cases exposure is expected to be limited to 8 grams (< 0.08 grams of notified polymer) per application. The product will only remain in contact with hair and scalp for 1-3 minutes before it is washed off.

Since haircare products are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Clear viscous liquid

Boiling Point >300°C at 101.3 kPa

METHOD OECD TG 103 Boiling Point.
Remarks The study was performed in duplicate. No distinct boiling plateau was seen up to the maximum temperature of 311°C. The change in colour from a clear liquid to an orange-yellow liquid during both studies suggests that thermal degradation of Crodamol STS may have occurred during heating.
TEST FACILITY Vizon SciTec (2005).

Density 949.6 kg/m^3 at 21°C

METHOD OECD TG 109 Density of Liquids and Solids.
Remarks
TEST FACILITY Vizon SciTec (2005)

Vapour Pressure Not determined

Remarks Test not conducted. On the basis of the moderately high molecular weight and boiling point of the notified polymer the vapour pressure is expected to be relatively low.

Water Solubility 7.86 mg/L at 20°C

METHOD 1.1 g of Crodamol STS were dispersed in distilled water in a 2000 mL volumetric flask. This solution had a uniform haze.
2) 10 mL of this solution was pipetted to a 100 mL graduated cylinder containing 10 mL of distilled water. The cylinder was capped, shaken, and allowed to settle. The resulting solution was hazy.
3) Step 2) was repeated with 10 mL aliquots of distilled water until the solution was no longer hazy. This occurred after the addition of 60 mL of distilled water to the original 10 mL of hazy solution. (ie. The final volume of the cylinder was 70 mL).

The calculated water solubility of Crodamol STS is 7.86 mg/L.
Remarks No further details provided.
TEST FACILITY Not identified

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	$t_{½}$
4	25	> 365 days
7	25	> 365 days
9	25	> 365 days

Remarks The notified polymer consists of a mixture of at least 3 homologs for which it was not possible to conduct a test according to the test guideline. However, as the notified polymer is amenable to GC and HPLC techniques, a similar to the test OECD Guideline 111 screening test was conducted. These tests were carried out at three different pH levels at 50°C. Chromatography of the solutions after 5 days indicated that less than 10% hydrolysis was observed in all pH levels. Therefore, the notified polymer is considered hydrolytically stable.

TEST FACILITY Vizon SciTec (2005)

Partition Coefficient (n-octanol/water) Not determined

Remarks Test not conducted. The notified polymer has emollient properties. As such, it is not possible to measure the partition co-efficient and get meaningful results.

Adsorption/Desorption Not determined

Remarks Test not conducted. The notified polymer is expected to bind readily to, or be associated with, soil or sediments.

Dissociation Constant Not determined

Remarks The notified polymer does not contain dissociable groups.

Particle Size Not applicable.

Remarks The notified polymer is a liquid at room temperature.

Flash Point 210ºC at 101.3 kPa

METHOD In house method based on OJEC Method A.9 and ASTM D 93. Method analogous to EC Directive 92/69/EEC A.9 Flash Point, using Pensky-Martens closed cup apparatus.

Remarks The study was carried out in duplicate. The notified polymer is a C2 combustible liquid.

TEST FACILITY Vizon SciTec (2005)

Flammability Limits Not determined, as the notified polymer is not classed as flammable.

Autoignition Temperature 345ºC at 102.5 kPa

METHOD In-house method analogous to 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases)

1. Crodamol STS (100 – 500 µL) was placed in a 0.5 L flask heated to 240ºC and the flask was observed in the dark.
2. The procedure was repeated at varying temperatures and the lowest temperature that Crodamol STS was observed to ignite was the auto-ignition termperature.

Remarks The quantity of sample = 500 µL, Time lag to auto-ignition = < 1 sec., Reaction Threshold Temperature = 240 ºC

TEST FACILITY Chilworth Technology (2005)

Explosive Properties Not determined

Remarks Based on the functional groups, the notified polymer is not expected to have explosive properties.

Reactivity

Remarks Under normal conditions of storage the polymer is not expected to undergo degradation. It may react with strong oxidising agents. Hazardous polymerisation of the polymer will not occur.

7. TOXICOLOGICAL INVESTIGATIONS

A. The summary table and individual studies below relate to testing of the notified polymer.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	not performed
Rat, acute dermal LD50	not performed
Rat, acute inhalation LC50	not performed
Skin irritation – in vitro MatTek EpidDerm skin model	non-irritating
Eye irritation - HET-CAM study	practically non-irritating up to 30%
Eye irritation – Bovine corneal opacity and permeability study	slightly irritating
Skin sensitisation – Human repeat insult patch test.	no evidence of sensitisation
Rat, repeat dose toxicity	not performed
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration	non genotoxic
Genotoxicity – in vivo	not performed
Pharmacokinetic study – in vitro skin permeability	permeable to some components
Phototoxicity – human study	no evidence of phototoxicity

7.1. Acute toxicity – oral

Not performed.

7.2. Acute toxicity – dermal

Not performed

7.3. Acute toxicity – inhalation

Not performed

7.4. Irritation – skin – Irritancy Potential by In vitro MatTek EpiDerm skin model

TEST SUBSTANCE Notified polymer, Lot number: 141-247

METHOD The MatTek Corporation EpiDerm™ Skin Model *In vitro* Toxicity Testing System.

Remarks – Method Normal human epidermal keratinocytes cultured to form a multilayered, highly differentiated model of the human epidermis. Cell viability is determined by the activity of mitochondrial succinate dehydrogenase, which reduces a yellow, water soluble, tetrazolium salt to a purple, insoluble formazan derivative. The amount of reduction is determined by spectrophotometry.

The cell layer is incubated with the test substance and controls in microplates, extracted and the absorbance read at 570 nm.

RESULTS

Test substance concentration & Exposure time	*Percent Viability*	*Percent Inhibition*

(100% - 1 hr)	107	-7
(100% - 4.5 hr)	88	12
(100% - 20 hr)	98	2

Remarks – Results

The ET-50 is a measure of 50% cell viability. The ET-50 was estimated by interpolation to be >24 hours. The irritation guidelines were according to the MatTek Corporation.

CONCLUSION

Under the conditions of this test, the notified polymer at 100% has an expected *in vivo* dermal irritancy potential in the non-irritating range.

TEST FACILITY

Consumer Product Testing (2002)

7.51. Irritation – eye

The Hen's Egg Test – Utilizing the Chorioallantoic Membrane (HET-CAM)

TEST SUBSTANCE

Notified polymer Lot No. P-2829 at 1 %, 7.5 %, 15 % in aqueous solution

METHOD

Hen's Egg Test (HET) - Chorioallantoic Membrane (CAM) Test. Modification of that described by Kemper and Luepke (1986).

Species: White Leghorn chicken eggs

Number of eggs: 4 for each test concentration and control

Observation period: Readings taken at 0.5, 2 and 5 minutes

Treatment: After a 10-day incubation at 37.2°C, the shell over the air section of each egg was removed and following hydration, the inner membrane was removed to reveal the CAM. A 0.3 mL test solution was added to each CAM for a period of twenty seconds and effects of hyperemia, haemorrhage (including minimal haemorrhage) and coagulation were observed over a period of 5 minutes.

The reactions of the CAM, blood vessels, including the capillaries, and the albumin were examined and scored for irritant effects such as:

Effect	*Scores at time (min):*		
	0.5	2	5
Hyperemia	5	3	1
Minimal Hemorrhage ("Feathering")	7	5	3
Hemorrhage (Obvious leakage)	9	7	5
Coagulation and/or Thrombosis	11	9	7

The numerical, time dependent scores were totalled for each CAM. Each reaction type can be recorded only once for each CAM, therefore the maximum score per CAM is 32. The mean score was determined for all CAM's similarly tested.

Remarks - Method

No details of test substance preparation was included. Corn oil was the only control substance included in the study.

RESULTS

Test Solution	*Average Irritation score*
Negative control – Corn oil (100 %)	1.25
Notified polymer (1 %)	0.50
Notified polymer (7.5 %)	3.50
Notified polymer (15 %)	3.50

Remarks - Results

Previous studies were stated by the study authors to have shown that the CAM of the hen's egg is more sensitive to liquid irritants than is the rabbit eye.

Therefore, the CAM results for the test article at a specific concentration equate to the Draize results for the test article at two times that concentration.

CONCLUSION Under the conditions of this test, the notified polymer is predicted to be practically non-irritating to the eye at a concentration of up to 30 %.

TEST FACILITY Consumer Product Testing Co. (2003)

7.52. Irritation – eye – Bovine Corneal Opacity and Permeability Assay

TEST SUBSTANCE Notified polymer, Lot # P-2961

METHOD In-house method based on method of Gautheron et al (1992) and scoring method of Sina et al (1995).

Remarks – Method The bovine corneal opacity and permeability assay (BCOP) was used to assess the potential ocular irritancy of the test article to isolated bovine corneas. Bovine corneas, obtained as a by-product from freshly slaughtered animals, were mounted in special holders and exposed to the test article. An *in vitro* score was determined for the test article and the positive control, ethanol, based on the induction of opacity and on permeability (to fluorescein) in the isolated bovine corneas. Five corneas were tested with the test article. Based on changes in corneal opacity and permeability (relative to the control corneas), an *in vitro* score was determined. Scores of the test article and the positive control were corrected on the basis of results of the negative control, sterile deionized water.

RESULTS

Test substance	*Conc.*	*Exposure time*	*Mean opacity value*	*Mean OD_{490} Value*	In vitro *score*	*pH*
Crodamol STS	Neat	10 minutes	1.0	0.002	1.0	NCC
Ethanol (positive control)	Not stated	10 minutes	33.3	1.461	55.2	Not stated

NCC – No colour change, the pH value could not be determined because the test article did not cause a colour change on the pH paper.

Remarks – Results *In Vitro* Score:
From 0-25 = mild irritant
From 25.1 to 55 = moderate irritant
From 55.1 and above= severe irritant

The test article could not be completely rinsed from the treated corneas because of its oily nature and residual test article was observed in the BCOP chamber treated with test article. The residual test article prolonged the test article exposure to the treated corneas, which may have increased the level of damage.
The results of the assay showed that article did not cause any significant damage to the treated corneas.

CONCLUSION Under the test conditions, the notified polymer can be considered a mild irritant.

TEST FACILITY Institute for In Vitro Sciences, Inc (2004)

7.6. Skin sensitisation – human volunteers Human Repeat Insult test

TEST SUBSTANCE	Notified polymer Lot number P-2775
METHOD	Tests conducted in accordance with ICH Guideline E6 for Good Clinical Practice and requirements provided for in 21 CFR parts 50 & 56.
Study Design	Induction Procedure: Nine repeat, 24-hour applications of approximately 0.2 ml of the test substance under semi occluded patch at three applications per week for 3 weeks conditions, to the same skin area between the scapulae. Inspection of the site for irritation was performed prior to re-application. Rest Period: 14 days. Challenge Procedure: A single application following the induction procedure was applied to a new test site adjacent to the original Induction test site. The site was inspected for irritation twenty-four and seventy-two hours post-application.
Study Group	99 qualified males and females, ranging in age from 16 to 79 years completed the study.
Vehicle	Test substance administered as supplied.
Remarks - Method	10 subjects discontinued during the study for reasons unrelated to administration of the test substance.
RESULTS	
Remarks - Results	No adverse skin reactions indicative of irritation or sensitisation were observed throughout the study.
CONCLUSION	The notified polymer was non-irritating and non-sensitising under the conditions of the test.
TEST FACILITY	Consumer Product Testing (2002a)

7.7. Repeat dose toxicity

Not performed

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer Lot P-2775
METHOD	Method analogous to OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from Aroclor 1254-induced rat liver.
Concentration Range in Main Test	a) With metabolic activation:0 - 5000 µg/plate b) Without metabolic activation:0 – 5000 µg/plate
Vehicle	100 % Ethanol, test substance added as solution
Remarks - Method	Due to a technical error, no data were collected with tester strain TA1535 in the presence of S9 activation in the preliminary study. As toxicity was not observed in the other *Salmonella* test conditions, the test was not repeated. A confirmatory assay was not performed, based on clear negative results in the main test.

RESULTS

Metabolic	*Test Substance Concentration (µg/plate) Resulting in:*

Activation	*Cytotoxicity in Preliminary Test*	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 5000	> 5000	≥100	Negative
Test 2				
Present				
Test 1	> 5000	> 5000	≥1500	Negative
Test 2				

Remarks - Results: No toxicity was observed. Precipitate was observed in the preliminary test but did not affect scoring. The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of microsomal enzymes prepared from Aroclor 1254 induced rat liver (S9). Positive controls confirmed the sensitivity of the test system.

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

TEST FACILITY: BioReliance (2002)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE: Notified polymer Lot # P-2961

METHOD: OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Species / Cell Type: Chinese hamster ovary (CHO) cells
Metabolic Activation System: Liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Vehicle: Ethanol
Remarks – Method: No significant deviations from the protocol or assay method SOPs occurred during the conduct of this study.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	39, 313, 625, 1250*, 2500*, 5000*	4 hours	20 hours
Test 2	39*, 313*, 625, 1250*, 2500, 5000	20 hours	20 hours
Present			
Test 1	39, 313, 625, 1250*, 2500*, 5000*	4 hours	20 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	*Cytotoxicity in Preliminary Test**	*Cytotoxicity in Main Test**	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 1500	≥ 1250	≥ 313	negative
Test 2	≥ 1500	≥ 1250	≥ 313	negative
Present				
Test 1	≥ 1500	>5000	≥ 313	negative

* based on > 50% decrease in cell growth index

Remarks - Results: The percentage of cells with structural or numerical aberrations in the test article-treated groups was not significantly increased above that of the solvent control at any dose level (p>0.05, Fisher's exact test), either in the

presence or absence of metabolic activation. Positive controls confirmed the sensitivity of the test system.

CONCLUSION The notified chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test.

TEST FACILITY BioReliance (2004)

Remarks – Results The percentage of cells with structural or numerical aberrations in the test article-treated groups was not significantly increased above that of the solvent control at any dose level ($p>0.05$, Fisher's exact test). The results are summarised below:

CONCLUSION The notified polymer was not clastogenic to CHO cells treated in vitro under the conditions of the test.

TEST FACILITY BioReliance, 2004 (summary only provided) reference not finalised

7.10. Genotoxicity – in vivo

Not performed

7.11. Pharmacokinetic/toxicokinetic – *In-vitro* Human Skin Penetration

TEST SUBSTANCE Notified polymer

METHOD *In vitro* human skin penetration using human epidermal membrane. The notified polymer was applied topically as a neat solution using 3 different female epidermal membranes, obtained during abdomnoplasty and frozen until use.

Remarks – Method An isocratic HPLC assay was used to identify five distinct peak components of Crodamol STS and to estimate their solubility in receptor phase solutions to ensure adequate skin condition provision prior to the performance of human epidermal penetration studies.

The chemical identity of the 5 peaks used for the study was not confirmed. However the notifier has advised that the peaks would elute in the same order from both GC and HPLC analysis. Based on this information, Peak 1 is assumed to be PPG-1 benzyl myristate, Peak 2 PPG-2 benzyl myristate and Peak 3-5 to be PPG-3, PPG-4 and PPG-5 benzyl myristate respectively.

The proportion of Crodamols STS represented by the 5 peaks, and the relative proportions of the 5 peaks is not known.

Absorption across human female epidermal membranes (from three different donors, n=8 per donor) was determined over a 24 hr period using classical static horizontal Franz-type diffusion cells (surface area approximately 1.3 cm^2). The membranes were prepared from full thickness tissue using the heat-separation technique that involves immersion in water at 60^oC for 1 minute and peeling of the epidermis from the underlying dermis. Membrane integrity was ensured before commencement of the study using electrical resistance. Crodamol STS was applied to the epidermal membranes at a dose level of 10 mg/cm^2 and receptor phase samples were taken at 2, 4, 8, 12 and 24 hrs and assayed for Crodamol STS constituent peaks.

No mass balance calculations were carried out to enable recovery to be estimated.

RESULTS

Skin Donor	*Mean Diffusion*	*Amount of test substance penetrating (Fraction of calculated applied amount) at time:*				
		2 hr	*4 hr*	*8 hr*	*12 hr*	*24 hr*
1	***Peak 1***	0	0	0.0253	0.0284	0.0816
	Peak 2	0	0	0.0503	0.0545	0.0705
	Peak 3	Nothing detected in any of the samples				
	Peak 4	Nothing detected in any of the samples				
	Peak 5	Nothing detected in any of the samples				
2	***Peak 1***	0	0	0.0013	0.0050	0.0195
	Peak 2	0	0.0104	0.0417	0.0439	0.0655
	Peak 3	Nothing detected in any of the samples				
	Peak 4	Nothing detected in any of the samples				
	Peak 5	Nothing detected in any of the samples				
3	*Peak 1*	0	0	0	0	0.0030
	Peak 2	0	0.0329	0.0414	0.0499	0.0646
	Peak 3	Nothing detected in any of the samples				
	Peak 4	Nothing detected in any of the samples				
	Peak 5	Nothing detected in any of the samples				

Remarks – Results

Penetration of peaks 1 and 2 into the receptor phase of the three different skin donors was observed to varying extents. Limited permeability of peak 1 was observed in skins 2 (approximately 2% of applied amount at 24 h) and 3 (approx. 0.3% of applied amount at 24 h) compared to the significantly more permeable skin 1 (approx. 8% of applied amount at 24 hrs). This observation could possibly be attributed to the older age of the skin 1 donor (70 years).

There was no significant difference in the absorption of peak 2 between the three skin donors at time points later than 8 hrs after application. Penetration of peak 2 at 24 hrs following application was approximately 6.5-7% of the applied amount.

No traces of peaks 3-5 were observed in the HPLC chromatograms of the receptor phase analysis at any of the time points examined.

The epidermis was not analysed for retained material.

CONCLUSION

There was varying permeability of human skin in vitro to different components of Crodamol STS. The notified polymer with n=1 and n=2 (lowest degree of propoxylation) was observed to be absorbed. Penetration of these components to the receptor cell was determined to be < 10% of the amount applied.

TEST FACILITY

University of Queensland (2005)

7.12 – Phototoxicity

TEST SUBSTANCE

Notified polymer Lot. P-2829

METHOD

Skin phototoxicity study in human volunteers (in-house method, Protocol 7.04).

Remarks – Method

Ten subjects were selected for participation. The low back, between the

scapulae and the beltline, lateral to the midline, served as the treatment area. The area was free of sunburn, suntan, scars, active dermal lesions, and uneven skin tones. A Xenon Arc Solar Simulator was used as the source of ultraviolet light.

The Minimal Erythemal Dose (MED) of the unprotected skin of each subject was determined by a progressive sequence of timed UV light exposures, graduated incrementally by 25% over that of the previous exposure.

Test Method: Three test sites were outlined on the back with a kin marker. Two sites were treated with the test product, one to be irradiated and one not to be irradiated. The third site remained untreated but was irradiated.

An amount sufficient to cover the contact surface (or ~ 0.2 ml) was applied to the ¾" x ¾" gauze portion of an adhesive dressing. This was then applied to the appropriate treatment site to form an occluded patch.

Twenty-four hours later, the patches were removed and the appropriate sites (one treated site and one untreated site) were irradiated with 0.5 MED of UVB irradiation followed by 20 joules of UVA irradiation.

All test and control sites were examined at 24 and 48 hours following irradiation.

The criteria for a positive (phototoxic) reaction is based upon interpretation of erythemal responses as follows – If the degree of erythema/tanning noted on the treated, irradiated site is significantly greater than that observed on the non-treated, irradiated control site, the test material may be judged phototoxic.

RESULTS

Remarks – Results	Observations remained negative throughout the study (i.e. no visible skin reaction was noted).
CONCLUSION	Under the conditions of this study the notified polymer did not induce a response indicative of a phototoxic reaction.
TEST FACILITY	Consumer Product Testing (2003a)

B. Toxicology data from analogues and related chemicals

Toxicological data on close analogues of the notified polymer were not available, however studies are available on some related chemicals (mentioned below), and are included in section 9.2.3 where appropriate.

Considerable data on the esters of fatty acid esters of propylene glycol, eg propylene glycol stearate, has been analysed in Cosmetic Ingredient Reviews (CIR 1983, CIR 1999).

Limited data are available on the non-propoxylated ester analogue benzyl laurate (BIBRA, 2005).

Benzyl alcohol is a potential metabolite of the notified polymer and has been included in the OECD SIDS programme (OECD, 2001).

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted. Based on its low molecular weight the polymer has the potential to cross biological membranes and bioaccumulate. However, as the levels at which the notified polymer will potentially be released to the environment are very low and will be dispersed across Australia the potential for bioaccumulation is low.

8.2. Ecotoxicological investigations

In addition to the results presented below, the notifier also provided data on surrogates. As these were not accepted as appropriate surrogates these have not been included below.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE

METHOD	ESA Standard Operating Procedure 117, which is based on methods described by USEPA (1994), ISO 7346-1, and OECD Method 203. Test type – Static, non-renewal
Species	Rainbowfish *Melanotaenia splendida*
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	Not Provided
Analytical Monitoring	Conductivity, pH and dissolved oxygen
Remarks – Method	The test substance was noted to be insoluble in the dilute mineral water used as the diluent, forming globules on mixing. Hence, water accommodated fractions (WAFs) were prepared. The test concentrations were prepared from dilutions of a 1:9 stock solution. The stock solution was stirred for 24 h and allowed to stand for 24 h to separate the aqueous and non-aqueous phases. However, during stirring a fine emulsion formed which failed to separate fully on standing. Traces of the test material were noted in the 1100, 3300 and 10000 mg/L test levels. A diluent water control was also prepared. 4 replicates for each test concentration and control were prepared; containing 5 randomly selected larval fish each. This is an Imbalance Test (not defined) only and the NOEC and LOEC values were calculated, after appropriate transformation of data, using the Dunnetts or non-parametric test. The EC50 value was determined using the trimmed Spearmen-Karber Method. These calculations were performed using TOXCALC v5.0.

RESULTS

Concentration mg/L		*Number of Fish*	*% Imbalance*
Nominal (WAF)	*Actual*		*96 h*
0 (control)		20	0
11		20	0
33		20	0
110		20	0
330		20	90
1100		20	100
3300		20	Not Seeded
10000		20	Not Seeded

EC50	540 mg/L WAF (95 CI 460-627 mg/L) at 96 hours.
NOEC	330 mg/L WAF at 96 hours (based on mortality)
LOEC	1100 mg/L WAF at 96 hours (based on mortality)

Remarks – Results	It was noted that within minutes of seeding of the test vessels with test concentrations of 1100 mg/L (WAF) imbalance was observed. Hence, fish were not exposed to higher test concentrations. The above data would appear to show a dose response curve. However, the levels of treatment are well above the measured water solubility, it is therefore unclear as to whether the toxicity is resulting from a physical effect or the toxicity of the polymer.
CONCLUSION	The notified polymer showed some toxicity to rainbowfish. However, the origin and level of the toxicity is uncertain.
TEST FACILITY	ECOTOX (2006)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	In Accordance with NATA endorsed ESA Standard Operating Procedure 101. This procedure is based on methods described by the USEPA (1993) and adapted for use with the locally collected *C. dubia.*
Species	*Ceriodaphnia dubia*
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	
Remarks - Method	Test concentrations WAFs were prepared in an analogous manner to that described in the fish study above. The 1250-10000 mg/L test levels were observed to be opaque with emulsion and exhibited a high viscosity which the report indicates was likely unsuitable for *C. dubia* survival. The dilute mineral water (DMW) used was prepared by mixing 20% Perrier mineral water with deionised water, with vitamin B12 and selenium supplements. The EC50 estimates (with 95% confidence limits) were determined using the trimmed Spearman-Karber method. The NOEC and LOEC were determined by performing a Steels Many-one Rank Test for non-parametric data. These calculations were performed using TOXCALC v5.0.

RESULTS

Concentration (ppm)	*Number of Ceriodaphnia*	*% Survival at 24 h (Mean ± SD)*	*% Survival at 48 h (Mean ± SD)*
0 (control)	20	100 ± 0.0	100 ± 0.0
39	20	100 ± 0.0	100 ± 0.0
78	20	100 ± 0.0	100 ± 0.0
156	20	100 ± 0.0	100 ± 0.0
313	20	30 ± 11.6*	0.0 ± 0.0
625	20	0.0 ± 0.0	0.0 ± 0.0
1250	20	0.0 ± 0.0	0.0 ± 0.0
2500	20	0.0 ± 0.0	0.0 ± 0.0
5000	20	0.0 ± 0.0	0.0 ± 0.0
10000	20	0.0 ± 0.0	0.0 ± 0.0

*Significantly reduced survival compared with the control treatment (Steel's Many-One Rank Test, P=0.05, 1-tailed).

EC50	221.0 mg/L (WAF) at 48 hours
NOEC	156 mg/L (WAF) at 48 hours

LOEC	313 mg/L (WAF) at 48 hours
Remarks - Results	No significant mortalities were observed at or below the 313 mg/L treatment at 48-h, and consequently the NOEC and LOEC estimates were 156 and 313 mg/L respectively. The above data would appear to show a dose response curve. However, the concentration of the test substance was not determined in the test media, the levels of treatment are well above the measured water solubility, it is therefore unclear as to whether the observed effects are resulting from a physical effect or the toxicity of the polymer. Effects at 1250 mg/L WAF and above appear to have been physical (highly viscous emulsions).
CONCLUSION	The notified polymer showed some toxicity to *C. dubia*. However, the origin and level of the toxicity is uncertain.
TEST FACILITY	ECOTOX (2005)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	72 h
Concentration Range	Nominal: 10000, 5000, 2500, 1250, 625, 313, 156, 78 and 39 mg/L
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	
Remarks - Method	Test concentrations were prepared in an analogous manner to that described in the fish study above. The 1250-10000 mg/L test levels were observed to be opaque with emulsion and exhibited a high viscosity which the report indicates was likely unsuitable for *S. capricornutum* growth. The dilute mineral water (DMW) used was prepared by mixing 20% Perrier mineral water with deionised water, with vitamin B12 and selenium supplements. The EC50 estimates (with 95% confidence limits) were determined using the trimmed Spearman-Karber method. The NOEC and LOEC were determined by performing a Steels Many-one Rank Test for non-parametric data. These calculations were performed using TOXCALC v5.0.
RESULTS	
Remarks - Results	IC50 = 179.8 mg/L at 72 h NOEC = 78 mg/L at 72 h LOEC = 156 mg/L at 72 h The 72-h (with 95% confidence limits) of the notified polymer to *S. capricornutum* was estimated to be 179.8 (130-214) mg/L. No significant reduction in cell density was observed at or below the 156 mg/L treatment compared with the control treatment, and consequently the NOEC and LOEC estimates were 78 and 156 mg/L, respectively.
CONCLUSION	The above results indicate that the notified polymer is practically non-toxic (Mensink *et al*, 1995) to *S. capricornutum* and is not classified according to GHS (United Nations, 2003).

TEST FACILITY	ECOTOX (2005)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Formulation
The reformulation site has a wastewater treatment system comprising a 100 000 L averaging tank, a solids separator, a grease remover, automatic pH adjustment and a dissolved air flotation (DAF) tank. It is estimated that 40 000 L/day will be treated. Based on 150 batches per year and a total of 50 kg of notified polymer, the average daily release would be 0.137 kg. It is estimated that the sewer concentration would be 3.42×10^{-5} ppm, assuming that no polymer is removed by the treatment plant.

In a worst case based on maximum annual imports of 5 tonne per annum, 50% (50% of products exported) of which is released to sewer and assuming that none is removed during sewage treatment processes, the following Predicted Environmental Concentration (PEC) has been calculated:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	50.000%	
Annual quantity of chemical released to sewer	2,500.000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	6.85	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.67	µg/L
PEC - Ocean:	0.17	µg/L

The plastic import drums containing residual notified polymer (up to 10 kg per annum) will be disposed of to landfill. The bottles in which the hair product will be sold to consumers and the residues they contain (up to 5 kg per annum) will be disposed of either in domestic landfill or recycled.

The majority of the notified polymer will be incorporated into hair products and as such will almost completely be released to the environment.

9.1.2. Environment – effects assessment

The results of the ecotoxicity studies indicate that the notified polymer is practically non-toxic to rainbowfish (EC50 540 mg/L), ceriodaphnia (EC50 271 mg/L) and algae (IC50 180 mg/L). However, there is some doubt about the level and origin of the observed toxicity for rainbowfish and ceriodaphnia. On this basis a PNEC of 0.18 mg/L has been determined from the endpoint for the most sensitive organism and applying an assessment factor of 1000.

9.1.3. Environment – risk characterisation

The Risk Quotient (Q) has been calculated as follows by dividing the PEC by PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	1.67	180	0.009
Q - Ocean:	0.17	180	0.001

The values of the worst case risk quotients for the aquatic environment are less than 1, for both marine and fresh water organisms, indicating an acceptable risk to the aquatic compartment. While in a sewage system some adsorption could occur, this could be offset by the doubt that the toxicity results may be underestimated. Over time in landfill, the notified polymer it is expected to adsorb to soil and sediments and degrade slowly through biotic and abiotic processes to give water and oxides of carbon.

Therefore, the environmental exposure and overall environmental risk from the notified polymer is expected to be acceptable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport & Storage

Occupational exposure to the notified chemical during its transport and storage, or of finished products containing < 1% notified chemical, is only likely in the event of accidental container spillage involving breach of packaging. Exposure in these circumstances is expected to be infrequent and limited by use of appropriate personal protective equipment (PPE) during clean-up operations.

Reformulation and packaging

Worker exposure to the notified chemical during reformulation into hair care products may occur when weighing the notified chemical and adding it to the mixing vessel, and also during sampling for QA testing. Any exposure is expected to be primarily dermal. Ocular exposure is less likely but could occur. Inhalation exposure is not expected to occur in these processes. Exposure would be limited by the expected use of PPE.

Exposure to products containing < 1% of the notified chemical during mixing and filling operations is expected to be low, as the concentration is low, and exposure is limited by engineering and PPE controls.

End-use in salons

Repeated dermal exposure and possible ocular exposure to salon workers can occur when products containing < 1% of the notified chemical are dispensed and applied to customers' hair. Exposure would be limited by use of gloves and safe work practices. However gloves may not be worn routinely in these settings.

9.2.2. Public health – exposure assessment

Widespread public exposure is expected to hair care products such as shampoos containing < 1% of the notified polymer. The main potential route of exposure would be dermal, through scalp and hands. Some accidental ocular exposure is also possible. Exposure would be reduced because the polymer will be used in "wash-off" products. However some residual polymer may be deposited on the skin due to its oily nature (noted in the bovine corneal opacity and permeability test).

Since haircare products are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

9.2.3. Human health – effects assessment

Toxicokinetics, metabolism and distribution.

A skin permeability study using human skin in vitro indicated that some (unquantified) components of the notified polymer can penetrate skin. Because the polymer contains constituents of different molecular weight, the permeability of 5 major constituents was tested separately. Those with the lowest degree of propoxylation (and likely to be the most lipophilic) showed the greatest permeability. There was considerably variation between the test skins from different donors. The highest penetration was 8% after 24 h, with no penetration in any skin after

2 h. No skin penetration occurred with polymer constituents with 3 or more propylene oxide units.
No further information on metabolism was provided. If de-esterification occurred, it would release myristic acid and propoxylated benzyl alcohol, and eventually benzyl alcohol.

Acute toxicity.
No studies on the notified polymer were carried out. However the non-propoxylated analogue benzyl laurate has low acute oral and dermal toxicity in laboratory animals (BIBRA, 2005). A range of related chemicals which are fatty alcohol adducts of propylene glycol also showed low acute toxicity (CIR, 1983, 1999). The low molecular weight benzyl alcohol, a possible metabolite of the notified polymer, has moderate acute toxicity with an LD50 in rats of 1610 mg/kg (OECD, 2001).

Irritation and Sensitisation.
In vitro studies of potential of the notified polymer to cause skin irritation (MatTek EpiDerm) or eye irritation [HET-CAM and bovine corneal opacity and permeabiltity (BCOP) assays] indicated that the material has low or very low irritancy potential. The HET-CAM assay predicted low irritancy up to 30%. A human repeat insult patch test (RIPT) was negative for both irritation and sensitisation. No animal studies were provided for these endpoints. Benzyl laurate was a moderate irritant on rabbit skin but produced no sensitisation reactions in a small number of volunteers (BIBRA, 2005). Propylene glycol stearate at 100% showed mild skin irritation, which was greatly reduced at concentrations of 55% and below, and low eye irritation potential (CIR, 1983). There is no direct correlation between the in vitro irritation studies and the criteria for classification under the NOHSC guidelines (NOHSC, 2004). However, based on the available information it is likely that the notified polymer would not be classified for skin or eye irritation. Similarly, based on the results of the RIPT only, a classification for sensitisation would not be applied.

Repeated Dose Toxicity
No information was supplied on the notified polymer itself for this endpoint. Propylene glycol stearate was of low toxicity in a 13-week feeding study, and in a 13-week dermal toxicity study of a product formulation containing 2.2% of the chemical (CIR, 1983). The possible metabolite benzyl alcohol was considered to have low repeated dose toxicity in long-term studies, with a NOAEL ≥ 400 mg/kg/bw/day for rats and ≥ 200 mg/kg/bw/day for mice. At higher doses in rats in a 13-week study, toxic effects such as lesions in the brain, thymus, skeletal muscle and kidney were seen (OECD SIDS, 2001).

Genotoxicity.
The notified polymer was negative in a bacterial reverse mutation study and in an in vitro chromosome aberration test. No in vivo genotoxicity data was provided.

Other endpoints
The notified polymer was not phototoxic to the skin in a study with human volunteers.

Observations on Human Exposure.
The notifier has advised that no adverse effects from use of the notified polymer in other countries has been observed.

Hazard classification for health effects.

Based on the available data, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Only limited data are available on the health effects of the notified polymer, and on the health effects of related chemicals. The data suggest that the chemical is of low acute toxicity, and is not a sensitiser or genotoxic. It may cause slight skin and eye irritation, however these effects would be greatly mitigated by the low concentration of the notified chemical in formulated hair

products.

Based on an in vitro skin penetration study, a proportion of the notified polymer would be absorbed from the skin. Therefore the possibility of systemic effects cannot be excluded. No repeat dose study was submitted, therefore a margin of exposure could not be calculated.

Skin and eye irritation could result from worker exposure to the notified chemical. It is expected that the risk would be controlled by appropriate engineering measures, PPE and safe work practices at the reformulation sites, and for cleanup of any accidental spillage in transport or storage.

Similarly, use of PPE for those workers in contact with products containing the notified chemical at < 1% in salons or at the reformulation sites would reduce any risk from dermal or ocular exposure to low levels. It is noted that PPE may not be used in salons, however the concentration of use is relatively low.

Overall the risk to workers is considered low, based on the known toxicity and potential for exposure. However it should be noted that a full toxicological profile of the chemical is not available, and that animal studies for sensitisation were not performed.

9.2.5. Public health – risk characterisation

Only limited data are available on the health effects of the notified polymer, and on the health effects of related chemicals. The data suggest that the chemical is of low acute toxicity, and is not a sensitiser or genotoxic. It may cause slight skin and eye irritation, however these effects would be greatly mitigated by the low concentration of the notified chemical in formulated hair products and the fact that the products will be washed off after use.

Based on an in vitro skin penetration study, a proportion of the notified polymer would be absorbed from the skin. Therefore the possibility of systemic effects cannot be excluded.

The risk of lethal effects as a result of accidental ingestion is considered to be low, given the expected low acute toxicity and the low concentration of the notified polymer in the formulated products.

Based on its intended use and the low concentration of the notified chemical, it is considered that the notified chemical will not present a risk to public health. However it is noted that a full toxicological profile of the chemical is not available, and that animal studies for sensitisation were not performed.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the classification of notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.
The notified polymer is not classified under the GHS for human health effects or for the environment..

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the polymer is not considered to pose a risk to the

environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used in wash-off hair products up to 1%.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Overalls (or similar protective apparel)
  - Safety glasses
  - Safety footwear
  - Impervious gloves

- No specific engineering controls or work practices are required for the safe use of the notified chemical 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 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
  - Do not allow material or contaminated packaging resulting from spills to enter drains, sewers or water courses.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Gross spills/release of the notified chemical should be contained by sand or inert powder and earth. Collect and seal in properly labelled drums for disposal in landfill.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- If any reports of adverse effects of the notified chemical on workers or the public are received; or
- If the notified polymer is used in "wash-off" personal care products at >5%; or
- If the notified polymer is used in "leave-on" personal care products.

or

(2) Under Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

13. BIBLIOGRAPHY

BIBRA (2005) Benzyl laurate (3pp) BIBRA working group /BIBRA Information Services. Abstract accessed at Toxnet Toxicology Data Network http://toxnet.nim.nih.gov/cgi-bin/sis/search/f?./temp/~JSDHg0:1:BODY 15/10/06.

Bioreliance (2002) Bacterial Reverse Mutation Assay: Crodamol STS. Study Number AA65FC.502.BTL for Croda Inc., Edison NJ. BioReliance, Rockville MD. Study completion date 4/11/02. (Unpublished report provided by notifier).

Bioreliance (2004) In vitro mammalian chromosome aberration test. Crodamol STS, Lot # P-2961. Study number AA88YV.331.BTL for Croda, Inc., Edison NJ. Study completed 7/6/04. BioReliance, Rockville, Maryland. (Unpublished report provided by notifier)

Chilworth Technology (2005) Auto-Ignition Temperature Test on a Sample of Crodamol STS. Final report 26/7/05 No. GLP13941R1V1/05 for Vizon SciTec Inc. Chilworth Technology, Southhampton UK (unpublished report provided by notifier).

CIR (1983) Cosmetic Ingredient Review: Final Report on the Safety Assessment of Propylene Glycol Stearate and Propylene Glycol Stearate Self-Emulsifying. Journal of the American College of Toxicology. Vol 2 Number 5, 1983. pp 101-122.

CIR (1999) Cosmetic Ingredient Review: Final Report on the Safety Assessment of Propylene Glycol (PG) Dicaprylate, PG Dicaprylate/Dicaprate, PG Dicoate, PG Dipelargonate, PG Isostearate, PG Laurate, PG Myristate, PG Oleate, PG Oleate SE, PG Dioleate, PG Dicaprate, PG Diisostearate, and PG Dilaurate. International Journal of Toxicology, Vol 18(Suppl. 2), pp 35-52.

Consumer Product Testing (2002) The MatTek Corporation EpiDerm Skin Model In vitro Toxicity Testing System. Test Article: Crodamol STS, Lot number: 141:247. Experiment reference No. V02-0126-2. Consumer Product Testing (Summary only supplied).

Consumer Product Testing (2002a) Repeated Insult Patch Test, Protocol 1.01: Crodamol STS. Experiment reference number C02-0886.01. Report for Croda Inc., Edison, New Jersey. Consumer Product Testing Co., Fairfield, New Jersey. (Unpublished report provided by notifier).

Consumer Product Testing (2003) The Hen's Egg Test – Utilizing the Chorioallantoic Membrane (HET-CAM): Crodamol STS. Experiment reference number V05-0154. Final report 2/10/03 for Croda Inc., Edison, New Jersey. Consumer Product Testing Co., Fairfield, New Jersey. (Unpublished report provided by notifier).

Consumer Product Testing (2003a) Phototoxicity, Protocol No. 7.04: Crodamol STS. Experiment reference number S03-0868.01. Final report for Croda Inc., Edison, New Jersey. Consumer Product Testing Co., Fairfield, New Jersey. (Unpublished report provided by notifier).

ECOTOX (2006) Toxicity Assessment of Crodamol STS to Larval Rainbow fish. ECOTOX Services Australasia Pty Ltd. Unit 27/2 Chaplin Drive, Lane Cove NSW 2066, Australia.

ECOTOX (2005) Toxicity Assessment of Crodamol STS. ECOTOX Services Australasia Pty Ltd. Unit 27/2 Chaplin Drive, Lane Cove NSW 2066, Australia.

Gautheron P, Dukie M, Alix D and Sina J.F. (1992) Bovine Corneal Opacity and Permeability Test: An in Vitro Assay of Ocular Irritancy. Fundamental and Applied Toxicology 18:442-449. (Paper not sighted).

Institute for In Vitro Sciences (2004) Bovine Corneal Opacity and Permeability Assay: Crodamol STS. Study number 04AE93.350000, Project number 3781. Final report 23/8/04. Institute for In Vitro Sciences, Inc., Gaithersburg, MD (Unpublished report provided by notifier).

Kemper F H & Luepke N P (1986) The HET-CAM Test: An Alternative to the Draize Test. FD Chem. Toxic. 24:pp 495-496 (Paper not sighted)

Mensink BJWG, Montforts M, Wijkhuizen-Maslankiewicz L, Tibosch H and Linders JBHJ (1995) Manual for summarising and evaluating the environmental aspects of pesticides. National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands. Report No. 679101022.

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

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

OECD (2001) SIDS Initial Assessment Profile: Benzoates Category. SIAM 13, 6-9 November 2001. Accessed at http://www.inchem.org/documents/sids/sids/BENZOATES.pdf

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.

University of Queensland (2005) In-Vitro Human Skin Penetration of Crodamol –STS. A report to John Issa 30/9/05 from Dr Sheree Cross and Professor Michael Roberts. Therapeutics Research Unit, Department of Medicine, University of Queensland, Princess Alexandra Hospital, Brisbane. (Unpublished study provided by notifier).

Sina J.F., Galer D.M. Sussman R. G, Gautheron P.D, Sargent E V, Leong B, Shah P V, Curren R D, and Miller K. (1995) A collaborative evaluation of seven alternatives to the Draize eye irritation test using pharmaceutical intermediates. Fundamental and Applied Toxicology 26:20-31. (Study not sighted)

Vizon SciTec (2005) Physical/Chemical Properties of Crodamol STS, CAS [notified polymer] Study number 4-06-06-0124B for Croda Inc., Edison NJ USA. Report August 11, 2005. Vizon SciTec Inc., Vancouver BC, Canada. (unpublished report provided by notifier).