File No: LTD/1276

July 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Sorbityl Laurate

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 Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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

Sorbityl Laurate

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Croda Singapore Pty Ltd (trading as Croda Australia, ABN 34 088 345 457)
44-46 Mandarin Street
Villawood NSW 2163

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: import volume, details of use, spectral data, methods of detection and determination and impurities.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Particle size distribution

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
D-glucitol, monododecanoate

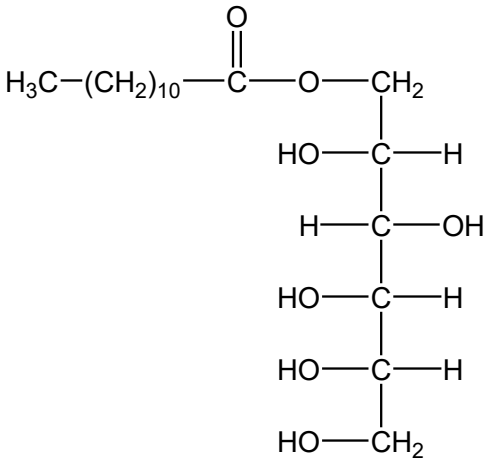
OTHER NAME(S)
Glucitol, monolaurate
Lauric acid sorbitol ester
Lauric acid, monoester with D-glucitol
Sorbitol monolaurate
Sorbitol laurate
Sorbityl laurate
SCS 7056

MARKETING NAME(S)
Sorbityl Laurate (notified chemical)
Arlatone LC (product containing 5-25% of the notified chemical)

CAS NUMBER
26657-97-6

MOLECULAR FORMULA
$C_{18}H_{36}O_7$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
364.468

METHODS OF DETECTION AND DETERMINATION

METHOD	HPLC
Remarks	A reference spectrum was provided.
TEST FACILITY	Safepharm Laboratories Ltd (2006a)

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia as a component of the product Arlatone LC (powder, 5-25% notified chemical) or as a component of personal care products (up to 1.3%).

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

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

USE
The notified chemical is used in personal care products, such as skin creams, in levels up to 1.3%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
At present no port of entry is known for this product.

IDENTITY OF MANUFACTURER/RECIPIENTS

The notified chemical is being registered in Australia as part of a global marketing campaign. No customers have been identified for Australia.

TRANSPORTATION AND PACKAGING

The notified chemical will be imported either in personal care products, in plastic or glass containers, or in the product Arlatone LC, in 200 L steel drums and/or 20 L pails. It will be transported by road or rail.

5.2. Operation description

Formulation of a product containing the chemical is not anticipated however there is the potential that formulation may occur in the future. A possible scenario of reformulation would involve the manual weighing and addition of the notified chemical to mixers into which other cosmetic chemicals would be added. These mixers could be open and closed, depending on the formulation being prepared. The notified chemical could exist in personal care preparations at concentrations up to 1.3%. The formulation would then be packaged into plastic and glass containers and distributed for sale.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Delivery to wharf	10	4 hours/day	40 days/year
Distribution (Storage & Transport)	100	6 hours/day	240 days/year
Formulation Preparation	200	6 hours/day	240 days/year
End use	1000	6 hours/day	240 days/year

Exposure Details

Transport and storage

Delivery and distribution workers are not expected to be exposed to the chemical unless an accidental spill occurs.

Reformulation

Dermal, ocular and inhalation exposure to the notified chemical from drips, spills and splashes may occur during transfer, blending and filling operations, although the potential for exposure is usually greatest during initial transfer of the imported powder (5-25% notified chemical) from drums and/or pails to the mixing vessel. After blending workers could be exposed to the notified chemical as a solution at a concentration of up to 1.3%. During the reformulation processes it is expected that exposure would be limited by engineering controls such as adequate ventilation and by the use of personal protective equipment such as safety glasses, impervious gloves and protective clothing. The notifier indicates that the workers handling the imported powder will be trained in dust handling procedures.

Beauty Industry

Intermittent, wide-dispersive use with direct handling is expected to occur among cosmeticians and beauticians.

Retail

Dermal exposure could occur during the use and demonstration of products containing the notified chemical (concentrations up to 1.3%). Due to the nature of the products (i.e. skin creams) no protective equipment is expected to be worn.

5.4. Release

RELEASE OF CHEMICAL AT SITE

During reformulation, losses of the notified chemical will be attributed to spills, equipment washing and imported container residue. It is estimated that the worst case scenario of waste of the notified substance generated during reformulation is:

Spills: 1% of import volume (up to 10 kg), this is likely to be disposed of to landfill.

Import container residues: 1% of import volume (up to 10 kg), this is likely to be disposed of to landfill.
Equipment wash water: 1.5% of import volume (up to 15 kg), this is likely to be disposed of to sewer.

RELEASE OF CHEMICAL FROM USE
The product is expected to be applied in small quantities to the skin.

It is estimated that 1% (maximum 10 kg) of finished product containing the notified substance will remain in the "empty" end-use container. This is expected to be disposed of as domestic waste.

Assuming no retention by skin, then the entire applied product (approximately 99% (maximum 990 kg) of the total import amount) will ultimately enter the sewer through washing. This will be in a diffuse and widespread manner.

5.5. Disposal

The chemical should be disposed of to landfill from occupational spills. However public use of the product will result in disposal of the product to sewers. Any chemical remaining in the container will be disposed of to landfill.

5.6. Public exposure

Since the notified polymer will be in products sold to the general public, widespread public exposure is expected. Exposure to the notified chemical will vary depending on the type of cosmetic product and individual use patterns.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Pale grey waxy solid

Melting Point/Freezing Point 36 to 81°C

METHOD OECD TG 102 Melting Point/Melting Range.
Remarks Determined using differential scanning calorimetry. A wide endotherm was observed; therefore a melting range is given. This can also be referred to as the softening temperature/range.
TEST FACILITY SafePharm Laboratories Ltd (2006a)

Boiling Point 512°C at 101.3 kPa (calculated)

METHOD OECD TG 103 Boiling Point.
Remarks Initial determination by differential scanning calorimetry. The notified chemical gradually decomposed with boiling from approximately 122°C. Therefore, since no true value for boiling temperature could be determined a calculated value, using an adaptation of the Stein and Brown method, is given.
TEST FACILITY SafePharm Laboratories Ltd (2006a)

Density 1110 kg/m^3 at 20°C

METHOD OECD TG 109 Density of Liquids and Solids.
Remarks Determined using a gas comparison pycnometer.
TEST FACILITY SafePharm Laboratories Ltd (2006a)

Vapour Pressure < 1.5 kPa at 25°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Determined using a vapour pressure balance. The balance readings were too low

and variable for a line of best fit to have any meaning. The value was therefore extrapolated from a single point which would give the highest estimated value.

TEST FACILITY SafePharm Laboratories Ltd (2006b)

Water Solubility < 1 mg/L at 20 ± 0.5°C

METHOD OECD TG 105 Water Solubility

Remarks The water solubility was observed by visual estimation. The chemical is likely to be surface active and during preliminary tests the notified chemical was observed to form an emulsion. The test material may not have reached equilibrium and hence the value of < 1 m g/L is likely to be too low. The molecular structure of the notified chemical likewise suggests that this value is likely to be too low. Modelling data suggest values of 53.76 and 3.2603×10^5 mg/L but this may be inaccurate due to the difficulty in modelling multiple oxygen atoms capable of engaging in hydrogen bonding.

TEST FACILITY SafePharm Laboratories Ltd (2006a)

Hydrolysis as a Function of pH

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

pH	*T (°C)*	*$t_{½}$ < days>*
4	25	>365
7	25	>365
9	25	4.85

Remarks Degradation rate of the notified chemical was performed at pH 9 at 50, 60 and 70 °C and extrapolated to 25°C. No degradation of the notified substance was observed at 50°C at pH 4 and 7. 1% co-solvent of methanol was used to aid solubility.

TEST FACILITY SafePharm Laboratories Ltd (2006a)

Partition Coefficient (n-octanol/water) Not determined

Remarks The notified chemical is likely to be surface active. The shake flask method is not a valid test on surface active materials. As water solubility could not be accurately calculated log Pow could not be estimated from solubilities in water and n-octanol.

Adsorption/Desorption Not determined

Remarks The notified chemical is likely to be surface active. A log Pow and water solubility could not be accurately determined. HPLC methods and estimations from log Pow values are likely to be prone to serious error. Prediction models such as Quantitative Structure Activity Relationships (QSARs) are also likely to be prone to serious error due to modelling difficulties with multiple oxygen atoms capable of engaging in hydrogen bonding. Furthermore the models do not take into account the potential formation of colloidal aggregates.

Dissociation Constant Dissociation constant range 13.01-15.66

Remarks The dissociation constants of the individual functional groups were calculated (using ACD/I-lab Web Service) to be between 13.01 and 15.66. These values are outside the range and scope of the OECD Method 112 and therefore no experimental testing was possible. The notified chemical is likely to remain in its non ionic form throughout the environmental pH range of 4 – 9.

Particle Size Not determined

Remarks	The notifier has indicated that given that the chemical is isolated as a waxy solid the particle size range is likely to include only a small proportion of particles in the respirable range (< 10 μm), with most of the particles in the inhalable range (< 100 μm).

Flash Point > 225°C

METHOD	EC Directive 92/69/EEC A.9 Flash Point.
Remarks	Determined using the closed-cup method. The experiment was conducted over two temperature ranges: ambient to 110°C, and 115°C to 225°C. No flash point below the boiling temperature.
TEST FACILITY	SafePharm Laboratories Ltd (2006b)

Flammability Limits Not determined

Remarks	Due to low vapour pressure, the notified chemical is expected to have limited flammability. The chemical does not evolve gases on contact with water.

Autoignition Temperature 378ºC

METHOD	92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY	SafePharm Laboratories Ltd (2006b)

Explosive Properties Not predicted to be explosive.

METHOD	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	The result for the explosive properties was predicted to be negative based on the chemical structure and the oxygen balance of the notified chemical.
TEST FACILITY	SafePharm Laboratories Ltd (2006b)

Oxidizing Properties Not predicted to have oxidising properties.

METHOD	EC Directive 92/69/EEC Draft A.21 Oxidizing Properties (Solids).
Remarks	Based on the chemical structure the result for the oxidizing properties has been predicted as negative.
TEST FACILITY	SafePharm Laboratories Ltd (2006b)

Reactivity

Remarks	Under standard conditions the notified chemical is stable.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Genotoxicity – bacterial reverse mutation	non mutagenic

7.1. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA
Metabolic Activation System	Phenobarbitone, β-napthoflavone induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 5000 µg/plate. b) Without metabolic activation: 5000 µg/plate.
Vehicle	Dimethyl sulphoxide
Remarks - Method	No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	1500 (TA100),	1500	5000	negative
Test 2	> 5000 (*E. Coli*)	5000	5000	
Present				
Test 1	1500 (TA100),	5000	5000	negative
Test 2	> 5000 (*E. Coli*)	5000	5000	

Remarks - Results	The test material caused a reduction in background in Salmonella strains at 1500 µg/plate or 5000 µg/plate. No toxicity was noted to *E. coli*: WP2 uvrA. A waxy precipitate was observed at 5000 µg/plate. No significant increase in revertant colonies was recorded. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm Laboratories Ltd (2006c)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted. The notified chemical contains alcohol functional groups, which are likely to rapidly biodegrade, and according to Biowin v4.02 modelling the chemical is likely to be readily biodegradable. The notified chemical is surprisingly insoluble (according to the shake flask method) and is accordingly likely to adsorb to sediments. In spite of being surprisingly insoluble it is unlikely to bioaccumulate as the chemical is likely to be readily biodegradable.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is used in skin care products and is likely to be released to sewer throughout Australia. Assuming the scenario where all of the notified substance (1 tonne) is imported as a formulation and assuming no retention by skin, it is presumed that 99% (990 kg) of the total (all of the applied product) will ultimately enter the sewer through washing. The resultant Predicted Environmental Concentration (PEC) of this worst case scenario would be 0.66 µg/L at sewage outfall. (990 kg ÷ (20.5 million persons × 200 L per person × 365 days)).
Due to the indeterminacy of the water solubility it is difficult to predict what portion of the notified chemical is expected to adsorb to the sewage sludge and what portion will remain dissolved. However, any of the chemical released to waterways is expected to biodegrade to oxides of carbon and water vapour. The notified chemical in the sewage sludge will either be disposed of to landfill or incinerated to form oxides of carbon and water vapour.

Residues in empty packaging amounting to a maximum of 10 kg are likely to undergo biodegradation in landfill.

9.1.2. Environment – effects assessment

No ecotoxicity data were provided and accordingly no Predicted No Effect Concentration (PNEC) could be calculated. The chemical is however likely to biodegrade rapidly and is unlikely to have any long lasting environmental effects.

9.1.3. Environment – risk characterisation

The Risk Quotient (RQ) cannot be calculated from comparing the PEC with the PNEC. However, the release of the chemical is expected to be widespread and disperse; and the notified chemical is likely to biodegrade rapidly. There is likely to be an adequate safety margin, and therefore it is unlikely that the notified chemical will pose an unacceptable risk to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Reformulation

Dermal, inhalation, and possibly ocular, exposure to the notified chemical is expected to be greatest during manual weighing and transfer processes of the imported powder, although this exposure will be limited due to the use of engineering controls and personal protective equipment. The particle size of the imported powder is unknown.

Beauty industry

According to EASE (1997) modelling of this work environment in which beauticians apply

products containing the notified chemical with their hands (assuming wide dispersive use, with intermittent, direct handling) dermal exposure in the range of 1-5 mg/cm^2/day of products containing up to 1.3% of the notified polymer could result. Assuming a surface area of 840 cm^2 (area of both hands) and a bodyweight of 60 kg (female workers) this equates to a dermal exposure of 0.18-0.91 mg/kg bw/day.

9.2.2. Public health – exposure assessment

Based on exposure estimates for skin lotions and facial moisturisers in Europe (SDA, 2005), public exposure (dermal) to the notified polymer in Australia has been estimated using the following assumptions:

- Bodyweight of 60 kg
- Worst case concentration of notified polymer in products = 1.3%
- 100% retention factor
- 100% dermal absorption
- Product usage is similar in Australia to Europe.

Product(s) used	*Worst case exposure (mg/kg bw/day)*
Skin lotions	1.2
Facial moisturiser	0.35

The combined worst case exposure from the use of both types of products would be 1.55 mg/kg bw/day. The expected public exposure to the notified chemical is therefore low.

Since products containing the notified chemical 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

The notified chemical was found to be non-mutagenic to bacteria in the Bacterial Reverse Mutation test. No other toxicological data was submitted. Based on the limited available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

The molecular weight of the notified chemical is less than 500 Daltons. This indicates that absorption across biological membranes, and therefore systemic exposure, is possible. Structurally related sorbitan esters are known to hydrolyse to the fatty acid and sorbitan (sorbitol anhydride) when ingested (Elder, 1985). Therefore, based on the chemical structure it is likely that any absorbed notified chemical will be hydrolysed to give sorbitol and lauric acid. Both of these chemicals have been found to have low orders of toxicity and are approved for use as food additives (JEFCA, 1973; JEFCA, 1998).

The local toxicity effects of the notified chemical, such as irritation and sensitisation, are unknown. The structurally related chemical sorbitan laurate has been found to be: irritating to rabbit skin when applied daily (irritating at 10-100% after 3 days, and irritating at 1-100% after 10 days); and non-irritating at 30% and 100% concentration in a Schwartz Prophetic Patch Test on human skin (Elder, 1985). This chemical was also found to be non-irritating to the rabbit eye. The Cosmetic Ingredient Review (CIR) Expert Panel in the US considered this chemical safe for use in cosmetics up to a concentration of 10% (Elder, 1985).

Therefore, although only limited toxicological data was submitted it is likely that the notified chemical will have low systemic toxicity. Based on data available for a structurally related chemical sorbitan laurate, the notified chemical may be irritating to the skin.

9.2.4. Occupational health and safety – risk characterisation

Although the notified chemical may be irritating to the skin the risk of irritancy effects in reformulation workers would be reduced due to the limited exposure through use of engineering controls and personal protective equipment, and the concentration of notified chemical in the imported product (5-25%).

The risk of systemic effects in workers during manual reformulation processes is also expected to be low due to the limited exposure through use of engineering controls and personal protective equipment, and the expected low systemic hazard of the notified chemical.

As the particle size of the imported powder and the local toxicity effects after inhalation are unknown inhalation of dust should be controlled by adequate ventilation. The NOHSC exposure standard for nuisance dust of 10 mg/m^3 should be observed.

Although workers in the beauty industry may be dermally exposed to the notified chemical, the risk is expected to be low due to the low concentration of notified chemical in the products (up to 1.3%) and the expected low hazard of the chemical at this concentration.

9.2.5. Public health – risk characterisation

Based on the low concentration of the notified chemical in the consumer products, and therefore the low public exposure, as well as the expected low hazard of the chemical, the risk to the public is expected to be low.

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

10.1. Hazard classification

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

10.2. Environmental risk assessment

The chemical 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 the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product Arlatone LC provided by the notifier was reviewed by NICNAS and 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 product Arlatone LC 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 implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in powdered form:
  - Local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in powdered form:
  - Avoid inhalation of dust
  - Avoid skin contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the product Arlatone LC:
  - Chemical-resistant gloves
  - Protective clothing

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the 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.

Disposal

- The notified chemical should be disposed of by authorised landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical collection by sweeping or shovelling into suitable containers for disposal. Wash spillage area with detergent and water.

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
  - the importation volume exceeds one tonne per annum notified chemical;

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

EASE (1997) EASE (Estimation and Assessment of Substance Exposure) for Windows version 2.0; Health and Safety Executive, UK and AIAI, Edinburgh.

Elder, R.L., ed. (1985) Final report on the safety assessment of sorbitan stearate, sorbitan laurate, sorbitan sesquioleate, sorbitan oleate, sorbitan tristearate, sorbitan palmitate, and sorbitan trioleate. J. Am. Coll. Toxicol. **4**:65-121.

JEFCA (1973) Sorbitol. In: WHO Food Additive Series No. 5 – Toxicological Evaluation of Some Food Additives including Anticaking agents, Antimicrobials, Antioxidants, Emulsifiers and Thickening Agents. Joint FAO/WHO Expert Committee on Food Additives, World Health Organisation, Geneva.

JEFCA (1998) Saturated Aliphatic Acyclic Linear Primary Alcohols, Aldehydes, and Acids. In: WHO Food Additive Series No. 40 – Safety Evaluation of Certain Food Additives and Contaminants. Joint FAO/WHO Expert Committee on Food Additives, World Health Organisation, Geneva.

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

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.

SafePharm Laboratories Ltd (2006a) SCS 7056: Determination of General Physico-chemical Properties (Study No. 1743/0049, 1 February 2006). Derbyshire, UK, SafePharm Laboratories Ltd. (Unpublished report submitted by notifier).

SafePharm Laboratories Ltd (2006b) SCS 7056: Determination of Hazardous Physico-chemical Properties (Study No. 1743/0050, 27 January 2006). Derbyshire, UK, SafePharm Laboratories Ltd. (Unpublished report submitted by notifier).

SafePharm Laboratories Ltd (2006c) SCS 7056: Reverse Mutation Assay "Ames Test" Using *Salmonella Typhimurium* and *Escherichia Coli* (Study No. 1743/0051, 25 January 2006). Derbyshire, UK, SafePharm Laboratories Ltd. (Unpublished report submitted by notifier).

SDA (2005) Exposure and Risk Screening Methods for Consumer Products Ingredients. Washington, The Soap and Detergent Association

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.