File No: NA/809

23 April 2020

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

1,4-cyclohexanedicarboxylic acid, di-2-propenyl ester, polymer with 1,2-propanediol

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, National Occupational Health and Safety Commission, 92-94 Parramatta Road, Camperdown NSW 2050, between the following hours:

Monday - Wednesday	8.30 am - 5.00 pm
Thursday	8.30 am - 8.00 pm
Friday	8.30 am - 5.00 pm

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

For enquiries please contact the Administration Coordinator at:

Street Address: 92 -94 Parramatta Rd CAMPERDOWN NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA
Telephone: (61) (02) 9577 9514 FAX (61) (02) 9577 9465

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

1,4-cyclohexanedicarboxylic acid, di-2-propenyl ester, polymer with 1,2-propanediol

1. APPLICANT

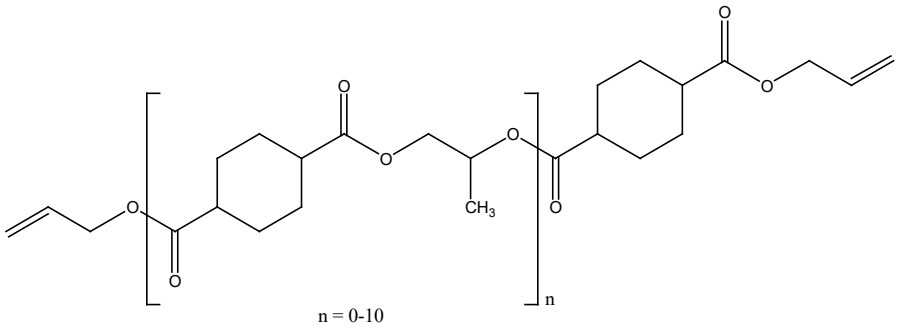
Sola International Holdings Ltd. (Research Centre) of 19 COOROORA CRESCENT, LONSDALE SA 5160 has submitted a limited notification statement in support of their application for an assessment certificate for 1,4-cyclohexanedicarboxylic acid, di-2-propenyl ester, polymer with 1,2-propanediol.

2. IDENTITY OF THE CHEMICAL

Details of exact import volume and amount used in formulation have been exempted from publication in the Full Public Report and the Summary Report.

Chemical Name:	1,4-cyclohexanedicarboxylic acid, di-2-propenyl ester, polymer with 1,2-propanediol
Chemical Abstracts Service (CAS) Registry No.:	153048-38-5
Other Names:	Diallyl-1,4-cyclohexanedicarboxylic acid, polymer with propylene glycol; Allyl ester resin; Allyl ester oligomer
Marketing Name:	DA-101
Molecular Formula:	$C_{14}H_{20}O_4 + (C_{11}H_{16}O_4)n$ (where n= 0-10)

Structural Formula:



Number-Average Molecular Weight (NAMW): 1190

Weight-Average Molecular Weight (WAMW): 2665

Low Molecular Weight Species
Molecular Weight < 500: ≃ 10%
Molecular Weight < 1 000: ≃ 35%

Polydispersity: 2.24

Weight Percentage of Ingredients:

Chemical Name	*CAS No.*	*Weight %*	*Toxic Properties**	*Exposure Standards*[#]
Allyl alcohol	107-18-6	27.7	T; R23/24/25; R36/37/38	2 ppm TWA; 4 ppm STEL
1,4-Cyclohexane dicarboxylic acid	1076-97-7	60.2		
Propylene glycol	57-55-6	12.1	-	-

- **List of Designated Hazardous Substances* (NOHSC, 1999);
- [#]*Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment* (NOHSC, 1995)

Method of Detection and Determination: Ultraviolet/Visible spectrum, Infra Red spectrum, NMR spectrum, Mass spectrum

Spectral Data: supplied

The notified chemical is a colourless to pale yellow viscous liquid with a slight odour and is made up of a random copolymer. The notified chemical is made from the polymerisation reaction of 1,4-cyclohexane dicarboxylic acid with allyl alcohol and propylene glycol, which is catalysed by dibutyltinoxide. The notified chemical's constituents are depicted.

IR (Infrared), UV/visible and ^{1}H and ^{13}C NMR chromatographs were also submitted for the identification of the notified substance.
A Gel Permeation Chromatography trace and its associated printout were supplied to determine the NAMW and percentage of low molecular species.

3. PHYSICAL AND CHEMICAL PROPERTIES

All physical and chemical properties were determined for the notified chemical.

Appearance at 20°C & 101.3 kPa: Colourless or pale yellow, viscous liquid

Melting Point: -5°C

Boiling Point: 292.5°C at 1025 hPa

Specific Gravity:	1.14 at 20°C
Particle Size:	Not applicable (liquid)
Vapour Pressure:	7.5 x 10^{-7} kPa at 25°C
Water Solubility:	22.3 mg/L at 20°C at pH 7.6-7.7 (by TOC) 17.8 mg/L at 20°C at pH 7.5 (for H-DATP, by HPLC) (see comments below)
Partition Co-efficient (n-octanol/water):	Three components detected (see comments below): log P_{ow} = 2.84 at 20°C; log P_{ow} = 4.19 at 20°C; log P_{ow} = 5.59 at 20°C; Remaining components were not detected but were considered to be log P_{ow} > 6.2
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0 = 165 days (see comments below) $T_{1/2}$ at pH 7.0 = 332 days $T_{1/2}$ at pH 9.0 = 7.8 days

Adsorption/Desorption:	Eight components were detected, four with the following values (see comments below):
	log K_{oc} = 2.87;
	log K_{oc} = 3.77;
	log K_{oc} = 4.49;
	log K_{oc} = 5.13;
	Remaining components log K_{oc} > 5.38

Dissociation Constant:	Not determined (see comments below)
Flash Point:	175°C (Closed Cup)
Flammability Limits:	Not highly flammable
Autoignition Temperature:	400°C
Explosive Properties:	Not explosive
Reactivity/Stability:	Not expected to be reactive

Comments on Physico-Chemical Properties

The boiling point of the notified chemical was determined by the Siwoloboff method (OECD TG 103) to be 292.5°C (Jolly, 1999a).

The vapour pressure of the notified chemical was determined by a vapour pressure balance method (OECD TG 104) to be 7.5 x 10^{-4} Pa at 25°C (Jolly, 1999). The notified chemical can be classified as very slightly volatile (Mensink et al., 1995).

The water solubility of the notified chemical was determined by the flask shaking method (OECD TG 105) and was measured by total dissolved organic carbon (TOC) to be 14.9

mgC/L at 20°C, which is equivalent to 22.3 mg/L of test substance (Jolly, 1999a). HPLC analysis indicated that the solubility of the notified chemical was primarily due to the dissolution of what is thought but not confirmed by the notifier to be its smallest component, diallyl 1,4-cyclohexane dicarboxylate (H-DATP), depicted as n = 0. The analysis determined that 17.8 mg/L of this component was present in the saturated solutions of the test material. The notifier considers that the result obtained by TOC analysis is higher due to dissolution of more soluble impurities and the presence of only small amounts of other components of the polymeric mixture which were not detected by the HPLC analysis. The notifier indicates that H-DATP is known to comprise approximately 15% of the notified chemical DA-101 and that the calibration solutions for the HPLC analysis were corrected to account for this level of purity. However, the GPC data for the notified chemical DA-101 indicates that there is only 7% of low molecular weight material below a MW of 500.

Hydrolysis of the notified chemical was determined by EC Directive 92/69/EEC, method C10 (Jolly, 1999b). The water solubility test indicated that only a single component, H-DATP depicted as n = 0, of the notified chemical mixture was significantly soluble in water. The notifier presumed this component to be representative of the remaining components as they form part of a homologous series. At pH 4 and 7 the hydrolysis rate constant and half-life for the smallest component were measured at elevated temperatures, from which the values of rate constants at 25ºC were extrapolated using the Arrhenius relationship. At pH 9 the hydrolysis rate constant and half-life for the smallest component were measured directly at 25ºC. The half-lives of the smallest component were determined at pH 4, 7 and 9 to be 165, 332 and 7.8 days, respectively. The notifier expects that the remaining components of the notified chemical DA-101 will degrade in a similar manner, albeit at slightly different rates which would possibly be limited by their rates of dissolution. The notified substance contains ester linkages and, under the conditions of the test, the notified chemical may be considered as slightly to moderately hydrolysing (Mensink et al., 1995).

The partition coefficient log P_{OW} of the notified chemical between n-octanol and water was determined to be 2.84 to 5.59 at 30°C using reverse phase HPLC by a method similar to OECD TG 117. The wide range represents values for three components of the polymeric mixture. The retention times by reverse phase HPLC were compared to the retention times of six standard reference materials with known log P_{OW} under the test conditions of 2.1, 3.0, 3.6, 4.7, 5.7 and 6.2, respectively. The first component with log P_{OW} of 2.84 was considered by the notifier to be the smallest component of the polymeric mixture H-DATP, depicted as n = 0. The remaining components of the notified chemical that were not detected by the HPLC method were considered by the notifier to elute after the DDT standard and have log P_{OW} of greater than 6.2. All components of the notified chemical, except for the smallest component where n = 0, would be considered as very hydrophobic (Lyman et al., 1982).

The adsorption/desorption coefficient of the notified chemical was determined to be 2.87 to 5.13 at 30ºC by a HPLC method (OECD draft TGP/94 75). The wide range represents values for four of eight components of the polymeric mixture detected. The retention times by reverse phase HPLC were compared to the retention times of six standard reference materials with known log K_{OC} under the test conditions of 1.43, 2.18, 3.04, 3.40, 4.41 and 5.38, respectively. The first component with log K_{OC} of 1.43 was considered by the notifier to be the smallest component H-DATP of the polymeric mixture depicted as n = 0. The remaining four components of the notified chemical that were detected by the HPLC method were observed by the notifier to elute after the DDT standard and have log K_{OC} of greater than 5.38. The smallest component H-DATP of the notified chemical where n = 0, would be

considered as having low mobility (McCall et al., 1980). The next component with a log K_{OC} of 3.77 would be considered as slightly mobile while all the other components would be considered immobile.

The dissociation constant of the notified chemical was not determined. The notified chemical has no dissociable groups and apart from the smallest component, where n = 0, the notified chemical is poorly water-soluble.

4. PURITY OF THE CHEMICAL

Degree of Purity: 99.9% typical; 99.7% < purity < 100%

Hazardous Impurities:

Chemical name:	Allyl alcohol
Synonyms:	2-propen-1-ol
CAS No.:	107-18-6
Weight percentage:	0.03% (range 0 - 0.05)
Toxic properties:*	T; R23/24/25; R36/37/38
Chemical name:	Acrolein
Synonyms:	Acrylaldehyde, 2-propenal
CAS No.:	107-02-8
Weight percentage:	0.0004% (range 0 – 0.05)
Toxic properties:*	T+; R26; R25; R34;
Chemical name:	Dibutyl tin oxide
CAS No.:	818-08-6
Weight percentage:	0.07% (range 0 – 0.2)
Health effects:	Central nervous system; immunotoxicity; irritation
Exposure standards[#]:	TWA- 0.1 mg/m^3; STEL- 0.2 mg/m^3; Absorption through the skin may be a significant source of exposure

- ** List of Designated Hazardous Substances* (NOHSC, 1999)*;*
- *[#]TWA- Time weighted average, STEL- Short term exposure limit; Exposure Standards for Atmospheric Contaminants in the Occupational Environment* (NOHSC, 1995)

Non-hazardous Impurities (> 1% by weight): None

Maximum Content of Residual Monomers/Reactants:

Chemical Name	*CAS No.*	*Weight %*
Allyl alcohol	107-18-6	< 500 ppm
Dibutyl tin oxide (catalyst)	818-08-6	< 0.2%

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia, but will be imported in 200 L steel drums by sea and transported to the notifier's warehouses by road. Less than 100 tonnes/year will be imported over the next five years. The imported solution contains a high percentage of the notified chemical.

The notified chemical will be used as a raw material component in the manufacture of ophthalmic and sun-wear lenses, whereby it will be formulated with other additives at a final concentration less than 80%. From 1997, the notified chemical has been in use in Australia under a commercial evaluation permit granted under section 21G of the Act.

6. OCCUPATIONAL EXPOSURE

Transport and storage:
The notified chemical will be imported in 200 kg steel drums by sea and will be transported from the dockside by road to the notifer's warehouse for storage and use. Waterside, transport and storage workers would only be exposed to the notified chemical in the event of a spill. Cargo unloaders will use a fork-lift to unload the containers. Fork-lifts will also be used at the notifier's warehouse site to unload trucks and transfer steel drums to storage. The nature of the packaging used for transport minimises the likelihood of release or loss of the chemical in incidents.

The notifier stated that any spills would be dyked and prevented from entering water systems. Absorbent material would be used to absorb spills, which would be stored in suitably labelled containers for disposal. Spillage areas would be wiped with acetone moistened rags, which are to be incinerated. Workers involved in clean up tasks would be required to wear appropriate personal protective equipment to avoid eye and/or skin contamination.

Process workers:
Exposure to the notified chemical may occur during the various stages of ophthalmic lens manufacturing process. Process description and exposure is detailed below.

Test substance preparation and waste disposal- 1 hour/day, 30.3 days/year
Drums of the notified chemical are transferred from the storage area into the manufacturing area. The notified chemical is manually added to the mixing vessel (maximum capacity of 1 000 kg). Accordingly, operators may be exposed to the neat notified chemical as they empty the steel drums into the blender and from spills and waste generated during the process. Dermal and/or ocular exposure are expected to be the main routes, though inhalation exposure is also possible as this is an open system. However, the latter is expected to be low,

given the chemical's low vapour pressure and the use of general exhaust ventilation. Mixing occurs mechanically in a closed system and thus exposure is limited. Seven operators will be involved in formulation and disposal of waste.

Filling operations- 7.6 hours/day, 230 days/year
After mixing, the formulation is vacuum transferred to a storage vessel from which it is pumped into dispensing vessels through a tap in the lid, when required for filling. The material containing the notified chemical is then discharged into the curing containers/mould assemblies from a pressure pot via a needle. This process consists of an open system and may be either automated or manual. Operators may be exposed to the notified chemical (< 80% in liquid resin) during filling and loading/unloading of mould assemblies from the filling machine (because waste liquid resin is generated at this stage), and when loading mould assemblies into ovens for curing. Exposure would mainly occur via the skin and/or eyes, with less potential for inhalation given the physico-chemical properties of the notified chemical and the use of general exhaust systems. Exposure to odours and vapours generated during the curing operation and at high temperatures is expected to be low, given that curing ovens are located in a remote area of the workplace with exhaust ventilation.

Exposure from handling and disassembling the cured assemblies and plastic lenses is also expected. Approximately 3.5% of the chemical remains in the uncured form with another 2.5% of unreacted monomers in the cured optical lenses, presenting a source of dermal contact for the operators. Given the small concentrations of the chemical, exposure is expected to be low. The notifier stated that 25 workers would be involved in the filling process.

Workers involved in the manufacturing operations are required to wear chemical safety glasses/goggles with side shields, latex gloves, natural fibre laboratory coats and enclosed footwear when handling the chemical.

Maintenance- 1 hour/day, 10.1 days/year
Workers will be exposed to the notified chemical during regular maintenance of the blender, mould assemblies and curing oven, and all equipment used with the test substance. Exposure to residual liquid chemical or the polymerised solid form would be via skin and eye contact or skin, respectively.

Exposure to the notified chemical may also occur during cleaning and at disposal of waste liquid resin and acetone washings. The notifier stated that acetone is used to clean the equipment, spills and areas where the chemical is formulated. These areas and production curing ovens are cleaned regularly. Nine workers would be involved in maintenance operations.

Laboratory staff (R&D)
Research and development at Sola International Holdings comprises the small scale production of lenses involving mixing, filling and curing and disposal of waste. Exposure to the notified chemical may occur via inhalation of aerosols, or by skin and/or eye contact, but is expected to be low given the engineering control measures and the use of personal protective equipment when handling the notified chemical.

Disposal of Drums:
Empty drums are collected by a contract container reconditioning company. Truck drivers

(one driver) manually load and unload the drums onto the trucks and transport to the reconditioner's site. Exposure during loading/unloading is possible, but is expected to be low since chemical residues are very low. Drum reconditioning entails draining of any residual monomer, rinsing with water at ambient temperature, then caustic at 90ºC, then water and drying. Skin and eye contact are the main routes of exposure, which is expected to be for 1 hour/day on 6.6 days/year. The residues are collected and mixed with general caustic washings and removed by a wastewater disposal company for treatment. Exposure is expected to be low because of the small volume of residues and the use of appropriate personal protective equipment. Three workers will be involved in drum reconditioning.

Drums not destined for reconditioning are rinsed with water, crushed and sent to landfill. Exposure to the chemical is expected to be low because residues of the chemical are estimated below 100 g.

7. PUBLIC EXPOSURE

Public exposure is only likely by contact with lenses in which the substance is in a cured state. Exposure to consumers will be through leaching of unreacted monomers from the polymerised lenses. This leaching is anticipated to be minimal.

8. ENVIRONMENTAL EXPOSURE

Release

After importation by sea the notified chemical will be transported *via* road without repackaging in closed 200 L steel drums; potential release would only be through accidental spills. The Material Safety Data Sheet (MSDS) details procedures to protect the environment in these cases. Once received by Sola International Holdings, the drums are stored separately from the workplace until required.

The notifier indicates that some release of the notified chemical may occur during formulation, however, they are expected to be minimal and would be contained within a dyked area and collected by absorbent material.

The notified chemical will be formulated at the production site at < 80% into an 80 kg batch which will be discharged as 25 kg batches into containers prior to transfer to moulds and the curing oven. The notifier estimates that up to 4.2 kg of waste formulation containing < 4 kg of the notified chemical will be produced for each 80 kg formulation batch. Similarly, the notifier also indicates that 0.4 kg of formulation waste containing < 0.4 kg of the notified chemical would be produced at the R&D site per batch. It is presumed that the R&D batch size is approximately a tenth of the size of the production batch and that the majority of manufacture occurs at the production site. At import of < 100 tonnes per year, then < 5 tonnes of notified chemical may be lost per year contained in formulation waste.

Waste notified chemical will also be produced from the cleaning of equipment. The notifier indicates that production would occur on 260 days of the year and that the maximum daily quantity of acetone washings are 200 mL containing 0.02 kg of the notified chemical and 800 mL containing 0.08 kg of the notified chemical at the R&D and production sites, respectively. If the entire notified chemical is used for production, approximately 21 kg of waste notified chemical will be produced per year from the cleaning of equipment in acetone

washings.
Some waste residue will remain in the 'empty' drums after use. The notifier estimates that a maximum of 100 g of the notified chemical residue will remain in each empty drum. Approximately 150 drums of chemical will be imported each year and contain, once emptied, < 50 kg of notified chemical residue. Drums of the notified chemical are expected to be disposed of by registered waste drum disposal companies by either recycling or landfill.

The notified chemical will not be directly marketed to the public, but formulated and polymerised into ophthalmic lenses at the Sola International Holdings site or Sola Optical Australia.

Fate

All released notified chemical waste from process production will be contained on-site and treated prior to disposal *via* landfill. During the cleaning stage of the manufacturing process there is no release to the cleaning water as the notified chemical DA-101 is completely contained within the final finished product lenses as part of a cross-linked matrix. The notifier indicates that the final product contains less than 3.5% of free notified chemical. All waste water at the site is treated to remove sedimentation and adjusted to pH 5-10 before release to the sewage system.

Residues from equipment and containers cleaned with acetone will be incinerated. The notifier supplies no information concerning the fate of the notified chemical once incinerated. However, it should share the same fate as acetone and be burnt to oxides of carbon and hydrogen.

Drum residues are expected to be disposed of by registered waste drum disposal companies by either drum recycling, incineration or landfill. If the empty drums are not rinsed and recycled, the notified chemical residues will end up in landfill and tend either to adsorb to or be associated with soils and be immobile.

The ultimate fate of the bulk of the notified chemical will be associated with the lenses. These will be disposed to landfill in a very diffuse manner and in locations countrywide. In landfill, the chemical will be immobile as it is in a solid, high molecular weight polymeric form that is expected to be very insoluble in water.

The majority of the notified chemical is not expected to cross biological membranes due to its high molecular weight and large size, and should not bioaccumulate (Connell, 1989). However, the GPC data for the notified chemical DA-101 indicates that there is approximately 35% of low molecular weight material below a MW of 1000. The majority of this material is expected to be soluble and should not bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of 1,4-cyclohexanedicarboxylic acid, di-2-propenyl ester, polymer with 1,2-propanediol, also known as DA-101

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 1 000 mg/kg	(Sato, 1994)
skin irritation	rabbit	Very slightly irritating	(Parcell, 1998a)
eye irritation	rabbit	Slightly irritating	(Parcell, 1998b)
skin sensitisation	guinea pig	Non-sensitising	(Coleman, 1998)

9.1.1 Oral Toxicity (Sato, 1994)

Species/strain:	Rat/SD
Number/sex of animals:	12 males
Observation period:	7 days
Method of administration:	Oral (gavage); single dose of 0, 100, 300 or 1 000 mg/kg bw of test substance suspended in PEG#400; Control group animals received 10 mg/kg bw of PEG#400 alone
Test method:	Similar to OECD TG 401
Mortality:	None
Clinical observations:	Diarrhea was observed in test substance treated animals and in control group animals at 3 and 6 hours and 6 hours following administration, respectively.
Morphological findings:	None
Comment:	Diarrhea was attributed to the solvent PEG#400 as it was also observed in the control group animals treated only with the solvent. Necropsied animals revealed no changes attributable to the test material.
LD_{50}:	> 1 000 mg/kg bw
Result:	the notified chemical was of low acute oral toxicity in rats

9.1.4 Skin Irritation (Parcell, 1998a)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	72 hours
Method of administration:	0.5 mL of the test substance was applied to shorn intact skin (one site/animal) under semi-occlusive dressing for 4 hours. Following exposure, the treatment sites were washed with warm water.
Test method:	OECD TG 404
Comment:	All Draize scores were zero for each rabbit at 1, 2, and 3 days after patch removal. No signs of toxicity or ill health were observed in any of the rabbits. One animal revealed transient very slight erythema one hour after patch removal, which resolved completely after 24 hours. No signs of skin reactions were observed in other animals during throughout the study.
Result:	the notified chemical was transiently very slightly irritating to the skin of rabbits

9.1.5 Eye Irritation (Parcell, 1998b)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	72 hours
Method of administration:	0.1 mL of the test substance was instilled into one eye, with the other eye serving as an untreated control.
Test method:	OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation											
Animal	***1 hour***			***1 day***			***2 days***			***3 days***		
Cornea	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***
1	0[1]		0	0		0	0		0	0		0
2	0		0	0		0	0		0	0		0
3	0		0	0		0	0		0	0		0
Iris												
1	0			0			0			0		
2	0			0			0			0		
3	0			0			0			0		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	0	-	1	0	-	0	0	-	0	0	-
2	1	1	-	1	0	-	1	0	-	0	0	-
3	1	1	-	1	1	-	1	0	-	0	0	-

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge
- = not measured

Comment: Animals showed no signs of toxicity or ill health following administration of the test substance.

Neither corneal damage nor iridial inflammation were observed following administration of the test substance.

Conjunctival inflammation was observed in all animals one hour after instillation of the test substance, which appeared to persist for two days.

Result: the notified chemical was slightly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation (Coleman, 1998)- Magnusson & Kligman Maximisation Test (Magnusson and Kligman, 1970)

Species/strain: Guinea pig/Dunkin-Hartley albino

Number of animals: Control: 5 males;
Test: 10 males

Induction procedure:

test group:

day 0	three pairs of *i.d.* injections (0.1 mL) into the skin of the scapular area: i) FCA 50:50 in distilled water; ii) the test substance, diluted to 10% v/v in Alembicol D; iii) the test substance diluted to 10% v/v in a 50:50 mixture of Alembicol D and FCA;
day 7	The same area was shaved free of hair and pretreated by gentle rubbing with 0.5 mL of 10% w/w sodium lauryl sulphate in petrolatum. After 24 hours, filter paper saturated with 0.4 mL of the undiluted test substance was applied to the treated area and held under occlusive dressing for 48 hours.

Challenge procedure:

day 21	filter paper saturated with 0.2 mL of undiluted test substance and a 50% v/v in Alembicol D were applied to shorn sites on the anterior and posterior of the left flank, respectively and held under occlusive dressing for 24 hours.
control group:	treated similarly to test animals omitting the test substance from the intradermal injections and topical applications.

Test method: OECD TG 406

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours****	***48 hours****
50%	0**/10	0/10	0/10	0/10
100%	0/10	0/10	0/10	0/10

* time after patch removal

** number of animals exhibiting positive response (Draize score $\geq$ 1)

Comment: Slight irritation was observed in test animals at sites injected (*i.d.*) with the test substance and test substance with the vehicle Alembicol D. Slight irritation was also observed in control animals at the sites treated with the vehicle alone.

Topical application of the undiluted test substance resulted in slight erythema in both test and control animals.

Treatment with the test substance had no toxic or ill effects on the animals.

Result: the notified chemical was not sensitising to the skin of guinea pigs

9.2 Overall Assessment of Toxicological Data

The notified chemical was of low acute oral toxicity with LD_{50} > 1 000 mg/kg bw in rats. It was very slightly irritating to the skin of rabbits and slightly irritating to the eyes of rabbits. The notified chemical was not sensitising to the skin of guinea pigs.

The notified chemical cannot be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* based on the findings of the skin and eye irritation and sensitisation studies.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicology data were submitted.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The intended use pattern of the notified chemical DA-101 is not expected to result in a significant release to the environment, as waste will be either landfilled or incinerated. Landfilled notified chemical waste will be expected to absorb to soils and sediments and be immobile. Incinerated notified chemical waste will release oxides of carbon and hydrogen. In the event of spills and minor releases during transfer operations, the MSDS of the chemical contains information on procedures to reduce release to the environment.

There is no direct data to support the claim of complete combustion of the notified chemical to oxides of carbon and hydrogen when incinerated. However, it is evident that the notified chemical, composed of hydrocarbon, will not survive the temperatures at which the acetone washings will be burnt.

The bulk of the notified chemical will be found as part of a cross-linked polymer matrix that goes into making the lenses. The notified chemical will be immobile as it is in a solid, high molecular weight polymeric form that is expected to be very insoluble in water.

Given the above, environmental exposure and the overall environmental hazard is expected to be low.

Conclusions
The notified chemical is not likely to present a hazard to the environment when it is stored, transported and used in the described manner.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical was of low acute oral toxicity in rats. It was very slightly irritating the skin of rabbits and slightly irritating to the eyes of rabbits. The notified chemical was not sensitising to the skin of guinea pigs.

The notified chemical cannot be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* based on the findings of the skin

and eye irritation and sensitisation studies.

The notified chemical has been used in Australia for one year under a Commercial Evaluation Permit (Permit No.: 287). There are no records of injuries or disease resulting from exposure to the notified chemical during its use in Australia.

Occupational Health and Safety

Skin contact will be the main route of exposure, although eye contact is also possible. Given the molecular weight distribution of the chemical absorption through intact skin cannot be excluded. Exposure to neat chemical may occur during manual transfer of neat chemical from the 200 L drums into the mixing vessel. Exposure to the mixed chemical at < 80% may then occur during manual filling and loading/unloading of mould assemblies from filling machines into ovens, because waste liquid resin containing the notified chemical is generated. Exposure to the notified chemical may also occur when handling the finished plastic lenses, given that 3.5% and 2.5% of the uncured chemical and unreacted residual monomers, respectively, remain in the cured lenses.

Exposure to the chemical during manufacturing is controlled through the use of semi-automatic equipment, engineering control measures, such as sealed vessels and local exhaust ventilation and good industrial hygiene. In the event that workers should become contaminated with the chemical, they are unlikely to experience adverse health effects, namely risk of skin/eye irritation, given the known low toxicity of the chemical. Workers handling the notified chemical are required to wear appropriate personal protective equipment such as gloves, cotton laboratory coats and safety spectacles with side shields to protect against skin and eye contact.

The risk of skin and/or eye irritation during R & D operation is considered low, given the small amounts handled and the low potential for exposure.

According to the notifier, workers involved in the manufacturing operation are trained in aspects of health and safety practices and use of personal protective equipment.

Exposure to the notified chemical is not expected during transport or storage provided the packaging remains intact. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier. The risk of adverse health effects for transport and storage workers is considered low.

Adequate control measures should also be implemented for workers involved in the reconditioning of empty drums and the disposal of the notified chemical and acetone washings to ensure that exposure to these is avoided.

Public health
Members of the public will make dermal contact with articles formed from the polymerised form of the notified chemical. Exposure is anticipated to be minimal, as the majority of the chemical is in a polymerised form, with little remaining as unchanged monomer. Theer is little direct contact between the skin or eyes and sunwear or ophthalmic lenses, which further decreases exposure.

Based on the toxicity profile and use pattern of the notified chemical, it is considered that the

notified chemical will not pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to 1,4-cyclohexanedicarboxylic acid, di-2-propenyl ester, polymer with 1,2-propanediol the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

- Local exhaust ventilation should conform to AS 1668.2 (Standards Australia, 1994);

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion; and

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Secondary notification under Section 64 of the Act will be required if:

i) the method of use changes in such a way as to greatly increase the environmental exposure of the notified chemical; or

ii) if additional information becomes available on adverse environmental effects of the chemical; or

iii) if the conditions of use are varied, greater exposure of the public to the product may occur. In such circumstances, further information may be required to assess the hazards to public health; or

iv) any of the circumstances stipulated under subsection 64(2) of the Act arise.

No other specific conditions are prescribed.

16. REFERENCES

Coleman, D. (1998). DA 101- Skin sensitisation in the Guinea pig, Huntingdon Life Sciences Ltd.

Draize, J., Woodard G., and Calvery, H. (1944). Methods for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes. Journal of Pharmacology and experimental Therapy 82: 377.

Draize, J. H. (1959). Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US 49: 2-56.

Jolly, N. (1999a). DA 101- Physico-chemical properties, Huntingdon Life Sciences Ltd.

Jolly, N. (1999b). DA 101- Determination of hydrolysis as a function of pH, Huntingdon Life Sciences Ltd.

Lyman, W., Reehl W. and Rosenblatt, D (1982). Handbook of chemical property estimation methods. Environmental behavior of organic compounds, McGraw-Hill Inc.

Magnusson, B. and Kligman A. (1970). Allergic Contact Dermatitis in the Guinea-pig: Identification of Contact Allergens. Illinois, Thomas C C.

McCall, P., Swann, R., Laskowski, D., Unger, S., Vrona, S. and Dishburger, H. (1980). Estimation of chemical mobility in soil from liquid chromatography retention times. Bulletin of Environmental Contamination and Toxicology 24: 190-195.

Mensink, B., Montforts M., Wijkhuizen-Maslankiewicz, L., Uibosch, H. and Linders, J. (1995). Manual for summarising and evaluating the environmental aspects of pesticides, national Institute of Public Health and the Environment, Netherlands.

NOHSC (1994). National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Canberra, Australian Government Publishing Service.

NOHSC (1995). Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment, [NOHSC:1003(1995)]. Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards. Canberra, Australian Government Publishing Service.

NOHSC (1999). Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Canberra, Australian Government Publishing Service.

Parcell, B. (1998a). DA-101 Skin irritation to the rabbit, Huntingdon Life Sciences Ltd.

Parcell, B. (1998b). DA101-Eye irritation to the rabbit, Huntingdon Life Sciences Ltd.

Sato, F. (1994). Oral acute toxicity study of DA 101, an aryl ester resin, in rats, Safety Evaluation Team, Biochemical Research Institute, SHowa Denko KK.

Standards Australia (1987). Australian Standard 2919-1987, Industrial Clothing. Sydney, Standards Association of Australia.

Standards Australia (1990). Australian Standard 3765.1-1990, Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals. Sydney, Standards Association of Australia.

Standards Australia (1994). Australian Standard 1336-1994, Eye protection in the Industrial Environment. Sydney, Standards Association of Australia.

Standards Australia (1994). Australian Standard 1668.2, Mechanical Ventilation and Air Conditioning Code Part 2 - Ventilation Requirements. Sydney, Standards Australia.

Standards Australia/Standards New Zealand (1992). Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Sydney/Wellington, Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994). Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Sydney/Wellington, Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1998). Australian/New Zealand Standard 2161.2-1998, Occupational Protective Gloves, Part 2: General Requirements. Sydney, Standards Association of Australia.

Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize et al., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

MSDS