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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

RAV 7 NG

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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
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Sola Optical Australia
Sherriffs Road
LONSDALE SA 5160

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: chemical name, CAS No., molecular weight, molecular and structural formulae, composition, spectral data, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
- Physicochemical data
- Toxicological data
- Ecotoxicological data
- Biodegradation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
RAV 7 NG

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	HPLC
Remarks	
TEST FACILITY	Great Lakes Chemical Corporation

3. COMPOSITION

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer is in a liquid form where the residual monomers are available for release. However, once the polymer has been cured, a solid matrix is produced and residual monomers are no longer available for release.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a liquid raw material for the manufacture of opthalmic plastic lenses in 205 L drums.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-100	10-100	10-100	10-100	10-100

USE
The notified chemical will be used as a lens casting monomer in the production of ophthalmic lenses.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Adelaide

IDENTITY OF RECIPIENTS
Sola Optical Australia, Sherriffs Road, Lonsdale, South Australia 5160

TRANSPORTATION AND PACKAGING
The notified chemical will be transported in 205 L lined steel drums.

5.2. Operation Description

The notified polymer is transferred from the drums to a 150 L stainless steel blending vessel via hose and pumping equipment. The notified polymer is blended with other liquid resins and additives within the fully enclosed blending vessel that is fitted with a mechanical stirrer.

The blending vessel is directly connected to a semi-automated and enclosed filling machine which houses the re-usable glass moulds. The reformulated resin mixture is then transferred to the glass moulds which are then transferred via a conveyor onto a tray. The tray is then manually placed into an oven which, when full is closed and heated to 80ºC for approximately 21 hours. This curing process takes place under local exhaust ventilation.

When curing is complete the moulds are allowed to cool and are removed for cleaning and disassembly. The cleaning process takes place first with water and detergent and finally with acetone. The rinsed moulds are then opened and the cured lens removed.

Equipment used is dedicated to the manufacture of ophthalmic lenses and is cleaned on a daily basis. Residual monomers including residues present in solvent rinsate may be reused or collected into drums and cured prior to disposal via landfill. Solvent rinsate may also be disposed via cement kiln fuel blending.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Storage	3-6	2 hours/day	10-15 days/year
Plant operators	50-60	2 hours/day	241 days/year
Laboratory Staff	2-4	0.5 hours/day	241 days/year
Maintenance	1	1 hour/day	241 days/year

Exposure Details

Transport and Storage (2 hours/day, 10-15 days/year)

The notified substance will be imported in 200 L drums. The material will be transported from the dockside to the Sola Optical warehouse facility where it will be stored prior to being transported to the customer site. It is anticipated that waterside workers, transport drivers and warehouse workers would only be exposed to the material in the event of an accident.

Plant Operators (2 hours/day, 241 days/year) and Laboratory Staff (0.5 hours/day, 241 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. The manufacturing process is described above. The system is designed to minimise exposure of the plant operators and laboratory staff, particularly during transfer and cleaning operations. Laboratory staff are responsible for the blending operation. The blending, filling and curing process take place in a purpose-built, isolated and bunded area which is supplied with local ventilation. Safety glasses and safety clothing must be worn within the work zones.

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 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 from handling and disassembling the cured assemblies and plastic lenses is not 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.

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. During transfer and cleaning, workers must also wear impervious gloves and respirator if required.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported for use in the manufacture of plastic ophthalmic lenses. The notified substance will be imported in 200 L drums. The manufacture of the lenses is described in Section 5.2. When curing is finished, the moulds are cleaned with water and detergent and finally with acetone. Any unused monomer, including residues in solvent rinsate may be reused. The waste generated during mould filling will account for approximately 2% of the import volume. These wastes will be collected with cloth and will be disposed of by incineration. If other wastes are not suitable for use, they are collected into drums and heat cured prior to disposal to landfill. Solvent rinsate may also be disposed of by incineration.

RELEASE OF CHEMICAL FROM USE

Release to the environment will occur from residues in empty transport containers (0.5% of import volume) and cleaning of the equipment (0.5% of import volume). Empty drums are rinsed with solvent and sent to a drum recycling company. Release to sewer will be minimal and may occur from the release of aqueous washings. Approximately 225 kg of the notified chemical per year is expected to be released to the sewer. The notifier indicates that most of the notified chemical is expected to end up in the sediment on the basis of the low water solubility of the notified chemical. The sediment will be collected as required for disposal to a liquid waste facility by a licensed waste contractor. The bulk of the notified chemical will be in a cured form and will not be available for release to the environment. The ultimate fate of the lenses at the end of their useful life is that they are likely to be disposed of to landfill.

5.5. Disposal

Wastes are heat cured prior to disposal to landfill or by incineration.

5.6. Public exposure

The notified chemical will be used only for industrial applications and will not be sold to the public. The public may be exposed to the chemical indirectly as a result of accidental spills and from release to the environment. The main form of exposure of the consumers to the notified chemical will be to the cured form which is not bioavailable.

6. PHYSICAL AND CHEMICAL PROPERTIES

No data for the notified chemical were provided. Most of the data available were for the analogue diallyl diglycol carbonate [CAS no. 142-22-3] (DAGC), extracted from Robust Summaries compiled by Great Lakes Chemical Corporation and PPG Industries Inc for the US EPA High Production Volume (HPV) Challenge program (Great Lakes and PPG, 2001). The notified chemical is similar chemically to DAGC but with an overall higher average molecular weight.

Appearance at 20ºC and 101.3 kPa Colourless to light amber mobile liquid.

Melting Point/Freezing Point Not determined

Remarks Test not performed; notified chemical is a liquid.

Boiling Point >160ºC

METHOD Not provided.
Remarks The boiling point for DAGC was measured to be 160ºC at 2.7 hPa

Density 1194 kg/m^3 at 20ºC (DAGC).

METHOD Not stated
Remarks

Vapour Pressure < 0.00146 hPa at 25ºC

Remarks The vapour pressure for DAGC was estimated using the EPIWIN/MPBPWIN Program (v1.40). The vapour pressure calculation used a boiling point of 300°C as an input. The calculation was done by the Antoine, Modified Grain and Mackay methods, with the Modified Grain Method preferentially adopted. Vapour pressure for diallyl diglycol carbonate was calculated to be 0.00146 hPa at 25ºC.

Water Solubility < 0.1 g/L at 20°C

Remarks Water solubility for DAGC was calculated to be < 0.1 g/L. No details of the study were provided. Note that precipitation of the test substance occurred in the algal growth inhibition studies at a concentration of > 10 mg/L using triethylene glycol as solvent. Again the original reference was not available.

Hydrolysis as a Function of pH Not determined

Remarks The notifier indicates that hydrolysis was not conducted due to the low water solubility. Given the right circumstances (higher temperature, acidic or caustic conditions), hydrolysis of carbonate ester groups will occur. At ambient, uncatalysed conditions, such a reaction will be slow, predominantly due to the low water solubility. Specific hydrolysis rates cannot be provided but reference was made to Streitwieser (1956) and Ingold (1969). Resulting hydrolysis species will be the mono-hydrolysed species of the diallyl carbonate component, carbon dioxide and allyl alcohol. With full hydrolysis, diethylene glycol will be formed as well.

Partition Coefficient (n-octanol/water) log Pow at 20ºC = 2.05-5.24 (calculated) (DAGC)

METHOD ACD Labs Software
Remarks No details of the report was provided. Weighted average of log Pow values was calculated to be 2.56 for the 3 main components. The Log Pow for diallyl diglycol carbonate was calculated to be 1.543 (EPIWIN/KOWWIN program). This program calculates log K_{ow} contributions from individual molecular fragments and then summing up these contributions.

Adsorption/Desorption – screening test log K_{oc} = 2.05-4.20 at 20°C (calculated) (DAGC).

METHOD ACD Labs Software
Remarks No details of the report was provided. Weighted average of log Koc values was calculated to be 2.76 at 20°C for the 3 main components of the notified substance.

Dissociation Constant Not applicable

Remarks Test was not performed. The notified polymer does not contain any functional groups which can undergo dissociation.

Particle Size Not applicable – polymer is liquid

Flash Point > 150ºC

METHOD Not specified
Remarks The flash point for the notified chemical is derived from information contained in the MSDS (Great Lakes Chemical Corporation, 2001). The flash point of DAGC is 173 ºC.
TEST FACILITY Not specified

Flammability Limits Not performed.

Remarks Combustible but not expected to be flammable.

Autoignition Temperature Not performed.

Remarks Not expected to undergo autoignition.

Explosive Properties Not performed.

Remarks Not expected to have explosive properties.

Reactivity Not performed.

Remarks The notified chemical is not thermally stable and undergoes polymerisation when heated.

7a. TOXICOLOGICAL INVESTIGATIONS

No toxicological data were submitted for the notified chemical. Robust summaries were submitted for the analogue Diallyl diglycol carbonate (CAS No. 142-22-3). These were compiled by the manufacturers PPG Industries Inc. and Great Lakes Chemical Corporation for the US EPA HPV Challenge program (Great Lakes and PPG, 2001).

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	LD50 349.5 - 515 mg/kg bw - Harmful
Rabbit, acute dermal	LD50 3038 – 10,250 mg/kg bw - Not harmful
Rabbit, skin irritation	Severely irritating
Human, skin irritation (MSDS)	Severely irritating

Rat, acute inhalation (1 hour)	LC50 >0.73 mg/L (maximum attainable concentration)
Rabbit, eye irritation	Non-irritating
Human, eye irritation (MSDS)	Moderate to severely irritating
Guinea pig, skin sensitisation -non-adjuvant test.	No evidence of sensitisation.
Rat, dermal repeat dose toxicity - 14 days.	LOAEL = 2 mL/kg bw/day NOAEL = 457mg/kg bw/day
Genotoxicity - bacterial reverse mutation	Ambiguous
Genotoxicity – in vitro <UDS> in primary rat hepatocytes	Negative
Developmental toxicity	No malformations. Foetotoxicity and maternotoxicity were observed at 0.5 mL/kg/day and above (NOEL at 114 mg/kg/day)

7.1. Acute toxicity – oral

TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Not stated
Species/Strain	Fischer 344
Vehicle	Corn oil
Remarks – Method	20 male and 20 female rats were divided into 4 groups of 5/sex and dosed via gavage. Animals were observed twice daily for 14 days for signs of toxicity and mortality. Animals were weighed the day before dosing, the day of dosing and 7 and 13 days following dosing. Necropsies were performed on all animals upon death or 14 days after dosing. LD50 values were calculated based on method of Litchfield and Wilcoxan (1949).

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 male, 5 female	100	0
2	5 male, 5 female	400	2/5 females
3	5 male, 5 female	600	1/5 males, 5/5 females
4	5 male, 5 female	800	5/5 males, 5/5 females

LD50	515 mg/kg bw
Signs of Toxicity	Not reported
Effects in Organs	Not reported
Remarks – Results	
CONCLUSION	The notified chemical is harmful via the oral route.
TEST FACILITY	Wil Research Laboratories (1981)
TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Not stated
Species/Strain	Rat/Charles River
Vehicle	Corn oil
Remarks – Method	Rats were observed for 5 days prior to treatment. Groups of 4 rats (2 of each sex) were dosed via gavage. All doses except the high dose were administered as a 10% (W/v) solution in corn oil. The high dose was administered undiluted. Animals were then individually housed and observed for 14 days. Necropsies were conducted on all animals The

LD50 value was calculated using the moving average method of Weil (1952) and Thompson (1947).

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	2 male, 2 female	177.8	0
2	2 male, 2 female	266.70	2/4
3	2 male, 2 female	400	2/4
4	2 male,2 female	600	3/4
5	2 male, 2 female	900	4/4

LD50	349.4 mg/kg bw
Signs of Toxicity	Not reported.
Effects in Organs	All animals which died showed pale livers and haemorrhage in the GI tract. No gross effects on organs were noted in surviving animals.
Remarks – Results	No sex differences.

CONCLUSION The notified chemical is harmful via the oral route.

TEST FACILITY Industrial Bio-Test Laboratories, Inc. (1971)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Diallyl diglycol carbonate

METHOD Not stated

Species/Strain	Rabbit/New Zealand White
Vehicle	None
Type of dressing	Occlusive
Remarks – Method	Rabbits were observed for 13 days prior to treatment. Back fur was clipped 24 hours before treatment. Each test site was occluded with a layer of gauze. Residual test material was removed after 24 hours and animals were examined for skin reactions and mortality for 4 additional days. Animals were weighed one day prior to dosing, on day of dosing, and 6, and 13 days after dosing. Necropsies were performed on visceral and thoracic cavities of all survivors.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	4M/4F	10 mg/kg	3/8

LD50	>10 mg/kg bw
Signs of Toxicity - Local	Slight to moderate erythema and oedema were noted on days 1-3.
Signs of Toxicity - Systemic	None reported.
Effects in Organs	Two of the animals which died exhibited haemorrhage of GI tract. Pale and irregular foci were observed on the liver in 2 of the surviving animals.
Remarks – Results	

CONCLUSION Test results are inconclusive.

TEST FACILITY Wil Research Laboratories (1981a)

TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Not stated
Species/Strain	Rabbit/New Zealand White
Vehicle	None
Type of dressing	Occlusive
Remarks - Method	The skin test site was abraded just prior to application of test material. Six rabbits (4 males, 2 females) were tested with 5ml/kg test material. Each test site was occluded with a layer of gauze. Residual test material was removed after 24 hours and animals were examined for skin reactions and mortality for 13 additional days. Animals were weighed one day prior to dosing, on day of dosing, and 3, 9, and 13 days after dosing. Necropsies were performed on visceral and thoracic cavities of all survivors.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	4M/2F	5 ml/kg	0

LD50	> 5mL/kg bw
Signs of Toxicity - Local	Slight to moderate erythema and oedema were noted from days 1-5, slight eschar formation on days 6 – 13, scaling on days 3-13, and cracking on days 4-7.
Signs of Toxicity - Systemic	
Effects in Organs	One rat had diffuse intermingled pale white to yellow foci on the liver upon necropsy.
Remarks - Results	No deaths occurred
CONCLUSION	The test substance was not harmful by the dermal route.
TEST FACILITY	Wil Research Laboratories (1981b)

TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Not stated
Species/Strain	Rabbit/New Zealand White
Vehicle	None
Type of dressing	Occlusive
Remarks – Method	Rabbits were observed for 7 days prior to treatment. Backs were shaved 24 hours before treatment. Each test site was occluded with impervious plastic sheeting taped into place. Residual test material was removed after 24 hours and animals were examined for skin reactions and mortality for 14 additional days. Initial and final body weights were recorded. Necropsies were performed on all animals.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	2M/2F	3,088	1/4
2	2M/2F	10,250	3/4

LD50	3038 < LD50 < 10,250 mg/kg bw
Signs of Toxicity - Local	Skin irritation characterized by red, well defined erythema and severe oedema was found at the application site 24 hours after test material administration. Dryness was evident after 14 days.
Signs of Toxicity - Systemic	Not reported.

Effects in Organs	Not reported
Remarks – Results	
CONCLUSION	The test substance is not harmful via the dermal route.
TEST FACILITY	Industrial Bio-Test Laboratories, Inc. (1971)

7.3. Acute toxicity – inhalation (1hour)

TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Not stated
Remarks - Method	
RESULTS	
LC50	>0.73 mg/L
CONCLUSION	The LC50 was determined to be greater than 0.73 mg/L, the maximum attainable concentration.
TEST FACILITY	PPG Industries, Inc. (1997)

7.4. Irritation – skin

TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Not stated
Species/Strain	Rabbit/(Strain unknown)
Number of Animals	6
Vehicle	None
Observation Period	13 days
Type of Dressing	Occlusive.
Remarks – Method	Undiluted test material (0.5 mL) was applied at one intact and one abraded site on rabbits (3/sex), and test material diluted with 0.2 mL of sterile physiological saline was applied to the other intact and abraded sites. The test material was applied under a surgical gauze patch and then covered with robber dental damming. The patches were removed and residual sample was removed after 6 hours with a moistened towel. Reactions were scored immediately after removal, and at 24, 48 and 72 hours, and on days 7, 9, 11, and 13.
RESULTS	
Remarks – Results	All except 2 rabbits had a score of 0 for erythema and oedema. Rabbit 1 showed very slight to slight erythema and very slight oedema at 48 hours. By day 11 necrosis and slight oedema were noted in this rabbit. Rabbit 2 exhibited very slight erythema at 24 hours. However, this progressed to moderate to severe erythema at 48 hours and necrosis at 72 hours. Reddening and blackened skin were noted for this rabbit on day 5.
CONCLUSION	Severe irritation and skin necrosis were observed in 2/6 animals. The notified chemical is severely irritating to skin.
TEST FACILITY	Hill Top Research Inc. (1979)
TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Not stated

Species/Strain	Rabbit/
Number of Animals	4
Vehicle	None
Observation Period	72 hours
Type of Dressing	Occlusive.
Remarks – Method	Test material was applied to the shaved back and flanks of four rabbits at two test sites located lateral to the midline of the back (approximately 10cm apart). One of the two sites was abraded Undiluted test material (0.5 mL) was applied to each test site. Gauze was placed over the test material and secured with masking tape and the trunk of each animal wrapped with impervious sheeting. After 24 hours the wrapping and gauze were removed and the test sites examined and scored separately for erythema and oedema on a graded scale of 0-4.. Sites were re-examined and scored after 72 hours.

RESULTS

Remarks – Results	Severe erythema and oedema were observed in 3 animals at 24 and 72 hours. Superficial burns were noted in 2 animals.

CONCLUSION Severe irritation (in 3 animals) and skin necrosis (in 2 animals) were observed. The notified chemical was determined to be severely irritating to skin by the test facility.

TEST FACILITY Industrial Bio-Test Laboratories, Inc. (1971)

7.5. Irritation – eye

TEST SUBSTANCE Diallyl diglycol carbonate

METHOD Draize Method.

Species/Strain	Rabbit
Number of Animals	5
Observation Period	7 days
Remarks – Method	

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2		72	0
Conjunctiva: chemosis	0		N/A	0
Conjunctiva:discharge	1.2		72	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks – Results	The irritation score calculated by the Draize method was 6.4/1100 (minimally irritating).

CONCLUSION The notified chemical is minimally irritating to the eye.

TEST FACILITY Industrial Bio-Test Laboratories, Inc. (1971)

7.6. Skin sensitisation

TEST SUBSTANCE Diallyl diglycol carbonate

METHOD Not stated

Species/Strain	Rabbit

MAIN STUDY	
Number of Animals	Test Group: 3 male and 3 female Control Group: 0
INDUCTION PHASE	Induction Concentration: topical application 100% test substance
Signs of Irritation	3/20 animals showed irritation with a score of 1 or 2 after the second or third induction.
CHALLENGE PHASE	
1st challenge	topical application: 100% test substance
2nd challenge	topical application: 100% test substance
Remarks – Method	Rabbits (3/sex) were acclimated for 6 days prior to study initiation. Four application sites were prepared on each rabbit by clipping the hair from the saddle area of the rabbits. Undiluted test material (0.5 mL) was applied at one intact and one abraded site. Test material diluted with 0.2 mL of sterile physiological saline was applied to the other intact and abraded site. Test sites were occluded for 6 hours after which residual test material was removed with a moistened towel. Reactions were scored immediately after removal (6 hours) and at 24, 48 and 72 hours and on days 7, 9, 11 and 13. Twenty-six days following the initial application, the abdomens of each of the six rabbit6s were clipped. Test material (0.5 mL) was then applied to the centre of the shaved area. In one rabbit that was severely affected by the first application (rabbit 2), 25 µL of test material was applied to another test site anterior to the central; site. Sites were occluded for 6 hours af6ter which residual sample was removed as above. Reactions were scored immediately after removal (6 hour reading) and at 24, 48, and 72 hours. A third trial was performed 21-days after the second application of test material. A different batch of sample was used for this test. The abdomens of the six rabbits were shaved again and two application sites (lateral to the ventral longitudinal midline of the rabbit) were prepared. One patch site on each rabbit was left intact, and was abraded. Test sites were occluded for 6 hours after which residual test material was removed with a moistened towel. Reactions were scored immediately after removal (6 hours) and at 24, 48 and 72 hours and at 7 days. Selected biopsies were taken for histopathologic and immunofluorescent examination.
RESULTS	
Remarks – Results	The test substance caused sporadic irritation. Tissue samples showed no IgG deposits in arterial walls. Thus, the irritation was not related to an immune response.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Hill Top Research Inc. (1979)
TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Non adjuvant method (Buehler).
Species/Strain	Guinea pig/ Dunkin Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration:

	topical:	100% (slight patchy erythema in 1/4 guinea pigs)
MAIN STUDY		
Number of Animals	Test Group: 10 males 10 females	Control Group: 5 males 5 females
INDUCTION PHASE	Induction Concentration: topical application 100%	
Signs of Irritation	No signs of irritation.	
CHALLENGE PHASE		
1st challenge	topical application: 100%	
Remarks – Method	Twenty Hartley Guinea pigs (10 per sex) served as test animals and 10 (5 per sex) served as controls. They were acclimated for 4 days before treatment. The upper left quadrant of the backs of the guinea pigs was clipped using electric clippers. On the following day, a patch moistened with 0.4 mL of test material was applied to the shaved area. The test area was occluded for 6 hours after which the test animals were returned to their cage. The patches were reapplied to the same site of test animals once/week for a total of 3 applications. The same site was shaved the day before each application was made After a 2-week rest period, a fresh application for primary challenge was prepared on the lower left quadrant of the backs of the guinea pigs . On the following day a challenge patch was applied to all animals (including) controls using the technique previously described. On the next day the sites were depilated and scored within 2-3 hours (24 hour reading). The sites were scored again after 48 hours (without additional depilation).	

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	0	0	N/A	N/A
Control Group	100%	0	0	N/A	N/A

Remarks – Results	There were no signs of irritation following the challenge.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Hill Top Research Inc. (1979)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Non OECD or EC method
Species/Strain	Rats/Charles River CD
Route of Administration	Dermal
Exposure Information	Total exposure days: 14 days; Dose regimen: 7/7 days per week; Post-exposure observation period: None
Vehicle	None

Physical Form	Liquid
Particle Size	Not applicable
Remarks – Method	Test material was applied to the backs (clipped free of hair) of 3 groups of 5 rats per sex at doses of 80, 400, and 2000 µL/kg for 14 consecutive days. Rats were observed daily for toxicity. Rats were weighed weekly and dose volumes were adjusted accordingly. Terminal body weights were taken at necropsy. Major organs were examined grossly at necropsy. Organs were not examined microscopically. Urine was collected from the bladders of 4 rats at necropsy and was macroscopically examined for the presence of protein and ketones.

RESULTS

Group	*Number and Sex of Animals*	*Dose µl/kg bw/day*	*Mortality*
I (control)	1M/1F	0	0
II (low dose)	5M/5F	80	0
III (mid dose)	5M/5F	400	0
IV (high dose)	5M/5F	2000	1

Mortality and Time to Death

One high dose male died on day 8.

Clinical Observations

Average weight gains of rats treated with 400 µL were less than controls during the first week but similar in the second week.

High dose animals accumulated red material around the nose, eyes, and mouth. Following the fifth day of application, food consumption and defecation was reduced in all high dose animals. High dose animals lost an average of 18g over the first week and gained 19g from days 7-10.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No clinical chemistry, haematology were conducted. Urine samples were taken from bladders of 4 high dose rats at necropsy and examined for the presence of ketones and protein. There was some ketones (1+) and protein (1-2+) in the urine.

Effects in Organs

In the high dose male which had died, necropsy showed extreme emaciation with total lack of fat tissue. The bladder was filled with a coffee-coloured fluid. The mucosa of the hindstomach was hyperaemic and some post-mortem autolysis had taken place. Surviving high dose animals were sacrificed on day 10 of the study. A red material was caked around the eyes and external nares and emaciation.

Remarks – Results

Collars were used to prevent ingestion of the test material, however, these were not placed on the animals until after the second day and some animals slipped out of their collars overnight (number not stated). Some toxicity may therefore be due to ingestion of the material.

CONCLUSION

The LOAEL was 2000 µl/kg bw/day (equivalent to 2286 mg/kg/day) and the NOAEL was 400 µl/kg bw/day (equivalent to 457 mg/kg/day). R48 is not applicable to the test substance since the NOAEL > 100 mg/kg/day via the dermal route.

TEST FACILITY	Wil Research Laboratories (1980)
TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Non OECD or EC method
Species/Strain	Rats/Charles River CD

Route of Administration	Dermal
Exposure Information	Total exposure days: 14 days Dose regimen: 2x per day, 7/7 days per week; Post-exposure observation period: None
Vehicle	None
Physical Form	Liquid
Particle Size	Not applicable
Remarks – Method	10 rats (5 per sex) were treated with test material with another 10 serving as controls. The backs of all rats were shaved prior to treatment. Test material was applied to the test animals in a split dose (2mL/kg/day) five hours apart for 14 consecutive days. Shaved skin of control animals was rubbed daily with a glass rod.

RESULTS

Group	*Number and Sex of Animals*	*Dose µl/kg bw/day*	*Mortality*
I (control)	5M/5F	0	0
II (high dose)	5M/5F	2000	0

Mortality and Time to Death
None.

Clinical Observations
Mean body weight was 8.1% and 14.6% lower than in control group at the end of week 1 and 2, respectively. Water consumption was 21% lower in treated females during the second week.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No effect of treatment on urinalysis or serum chemistries.

Effects in Organs
Brownish colouration of the shaved hair area, red encrustation around the eye lids and general absence of fatty tissue were noted in 4/5 treated animals at necropsy. The brain/body weight ration was higher in treated (0.844) compared with controls (0.74) which was probably due to emaciation. Spleen and heart weights (not reported if relative to bodyweight or absolute organ weights) were lower than controls. Microscopic examination of standard organs was unremarkable.

Remarks – Results
This study was the range-finding test which preceded the full study above. The LOAEL was 2000 µl/kg bw/day (equivalent to 2286 mg/kg/day). A NOAEL was not established in this study.

CONCLUSION Results are inconclusive.

TEST FACILITY Wil Research Laboratories (1980)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Diallyl diglycol carbonate

METHOD	Non OECD or EC method. Ames Test with pre-incubation
Species/Strain	*S. typhimurium*/ TA98, TA100, TA1535, TA1537, TA1538.
Metabolic Activation System	Arochlor 1254 induced S9 (rat male)
Concentration Range in Main Test	a) With metabolic activation: 0.003% to 0.3% (300 µg/plate) b) Without metabolic activation: 003% to 10% (10,000 µg/plate)
Vehicle	Acetone
Physical Form	Liquid

Remarks – Method Test were preformed in triplicate

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present		0.3%		0.003% (TA98)
Absent		10%		None

Remarks – Results The test substance produced a dose-dependent increase in revertants which > 3 times solvent controls in strain TA98 in the presence of S9.

CONCLUSION There were no increases in revertants in any of the other strains both in the presence or absence of metabolic activation. Thus, the results are ambiguous.

TEST FACILITY Microbiological Associates (1980)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE

METHOD Unscheduled DNA Synthesis in primary rat hepatocytes in vitro.
Species/Strain Rat
Cell Type/Cell Line Hepatocytes
Metabolic Activation System None
Vehicle Acetone
Physical Form Liquid
Remarks – Method Maximum concentration tested 0.01 µg/mL

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	N/A	0.0025		None

Remarks – Results

CONCLUSION The test substance did not cause an increase in unscheduled DNA synthesis in primary rat hepatocytes treated in vitro under the conditions of the test.

TEST FACILITY Litton Bionetics Inc. (1980)

ADDITIONAL INVESTIGATIONS

7.14T. Developmental toxicity

TEST SUBSTANCE

METHOD

Species/Strain	Rabbit/New Zealand White
Route of Administration	Dermal – non-occluded.
Exposure Information	Exposure period: Days 6 to 18 of gestation Duration of exposure (dermal): 6 hours/day.
Vehicle	None
Physical Form	Liquid
Particle Size	Not applicable
Remarks – Method	Observation period was to day 29 of gestation

RESULTS

Group	*Number of Animals*	*Dose ml/kg bw/day*	*Mortality*
I	18	0	0
II	18	0.1 (114 mg/kg/day)	0
III	18	0.5 (572 mg/kg/day)	0
IV	18	1.0 (1143 mg/kg/day)	7

Mortality and Time to Death

Six rabbits in the high dose group died during the study and one was in moribund condition and was sacrificed.

Effects on Dams

There was a decrease in bodyweight gain in the mid and high dose groups. Some animals were sacrificed before the termination of the study due to abortion or early littering. The incidence was 2, 0, 3 and 8 rabbits in the control, low dose, mid dose and high dose groups, respectively.

In the high dose group animals that had died, pale foci, firmness and/or irregular surface were noted in the liver. There were also pale foci on the heart, kidneys and/or mesentery in these animals. In the mid dose group one animal had firmness and irregular surface of the liver and another had pale foci on the mesentery.

The pregnancy rate was at least 99.9%. There was a high incidence of resorptions in animals that died or were sacrificed prior to end of study. However, the uterine parameters were similar to controls in the 3 surviving females in the high dose group.

Effects on Foetus

The incidence of visceral or skeletal malformations was similar to controls. However, ocular effects (small or oval lenses and/or opacity) were observed in 1, 0, 6 (from 3 litters), 4 (from 2 litters) foetuses in the 0, 0.1, 0.5 and 1.0 ml/kg/day groups, respectively.

Remarks – Results

The significance of the ocular effects was unclear as the incidence was low and not dose-related. Furthermore, these effects occurred at the higher doses, which were maternotoxic and foetotoxic.

CONCLUSION

The NOEL for maternotoxicity, foetotoxicity and teratogenicity was 0.1 mL/kg/day (114 mg/kg/day).

TEST FACILITY BioResearch Laboratories Ltd (1986)

7.15T. Experience with Human Exposure

TEST SUBSTANCE Diallyl diglycol carbonate (DAGC)/ Diallyl carbonate (DAC)

RESULTS
Referenced information was supplied in the robust summaries regarding the induction of irritant contact dermatitis after exposure to DAGC. Among those exposed to DAGC, skin lesions appeared within hours of first contact in some cases, and after a few days in others. Severity of reaction ranged from oedema and infiltration of extending further than the site of application to swelling of the eyelids, arms, thighs, abdomen, mid-back and neck after 9 days in the case of one worker exposed during lens manufacture processes. Concentrations above 10% DAC were reported to be irritating in 100% of test subjects while 5/22 subjects exposed to a 1% solution of the test substance experienced reactions.

CONCLUSION Diallyl diglycol carbonate is irritating to human skin

SOURCE Lacroix M et al., (1975) in Great Lakes Chemical Corporation and PPG Industries, Inc. (2001).

7a. METABOLISM

In information presented in the robust summaries, diallyl diglycol corbonate is metabolised (by hydrolysis) to diallyl carbonate and monoallyl diglycol carbonate.

8. ENVIRONMENT

In no case were full test reports for the following provided, for which the information has been taken from the robust summaries for diallyl diglycol carbonate (DAGC) prepared for the US EPA HPV program (Great Lakes Chemical Corporation and PPG Industries Inc, 2001)). As this is the major component with the lowest molecular weight in the notified polymer these results may be accepted as worst case.

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Mixed population
Exposure Period	28 days
Auxiliary Solvent	Methylene chloride
Analytical Monitoring	BOD
Remarks – Method	For COD measurement a 4% (w/v) solution of test material in methylene chloride was prepared. 25 mL of the solution were transferred to COD test tubes and the solvent evaporated to dryness. 20 mL of distilled water were added to give a final concentration of 50 mg/L. A blank control was also made up using distilled water. After reflux, the excess dichromate was titrated with ammonium iron (II) sulphate using ferroin as the indicator. The COD (mg O_2/mg test substance) was calculated based on the volume of the ammonium iron (II) sulphate titrated with the test substance. For the BOD test a 4% (w/v) solution of the test material in methylene chloride was prepared. 16 mL of the solution was transferred to BOD bottles and the solvent evaporated to dryness. Fully aerated mineral medium was added so the final test concentration was 2 mg/L. The test substance and positive control (sodium acetate, 2 mg/L) were also tested to determine if the test substance inhibited BOD. All tests were performed in duplicate. Tubes were inoculated with micro-organisms from a mixed population and kept in closed bottles in the dark at 20ºC. The concentrations of dissolved oxygen was calculated by the Winkler method at immediately, 7, 14, 21, and 28 days. The BOD was calculated as mg O_2 uptake of test substance. Biodegradability was calculated as BOD/COD X 100%.

RESULTS

Test substance		*Reference Substance*	
Day	*% degradation*	*Day*	*% degradation*
7	4.4	7	67.3
14	9.6	14	73.1
21	47	21	88.4
28	73.2	28	97

Remarks – Results	Average COD was 1.147 mg oxygen/mg. The average BOD on days 7, 14, 21 and 28 was 0.055, 0.11, 0.54 and 0.84 mg oxygen/mg, respectively.
CONCLUSION	While there is insufficient information to conclude that 60% biodegradation was attained within 10 days of reaching 10%, it would appear from the results that the test substance can be classed as ready

biodegradable.

TEST FACILITY RBM Instituto di Richerche Biomediche (1994)

8.1.2. Bioaccumulation

Bioaccumulation data are not available. Log Pow estimates indicate that the notified chemical would have moderate potential for bioaccumulation. However, exposure to water will be very low.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Diallyl diglycol carbonate

METHOD Non OECD or EC method. Fish acute toxicity – static conditions
Species Bluegill *(Lepomis macrochirus)*
Exposure Period 96 hours
Auxiliary Solvent None
Water Hardness 16 - 24 mg $CaCO_3$/L
Analytical Monitoring None
Remarks – Method Fish were held in a 500 L fibreglass tank under a photoperiod of 16 h light and 8 h darkness for 14 days and were fed daily (except for 48 h prior to testing). The solutions were prepared to give final test concentrations of 0.22, 0.36, 0.60, 1.0 and 1.7 mg/L. Ten bluegill fish were allocated to each test jar. Fish were not fed during exposure. The physical conditions of the fish were determined on a daily basis. Water quality parameters of temperature and pH were monitored throughout the test.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		10		0	0	0	0
0.22		10		0	0	0	0
0.36		10		0	1		
0.60		10		0	0	3	4
1.0		10		3	10		
1.7		10		10			

LC50 0.57 mg/L (CI: 0.45-0.73 mg/L) at 96 hours.
NOEC (or LOEC) 0.22 mg/L at 96 hours.
Remarks – Results None of the controls or fish exposed to 0.22 mg/L died. The NOEL through 96 h was 0.22 mg/L. The 24- and 48-h LC50s and CIs were estimated by by binomial probability to be 1.0 (CI: 0.6-1.7) and 0.77 (CI: 0.6-1.0) mg/L, respectively. The 72- and 96-h LC50s and CIs were estimated by moving average angle analysis to be 0.6 (0.4-0.76) and 0.57 (0.45-0.73) mg/L, respectively. The low oxygen saturation did not appear to adversely affect the fish as all controls survived. Test concentrations were not verified analytically. No observations on sub-lethal effects are available.

CONCLUSION The notified chemical is highly toxic to bluegill.

TEST FACILITY EG & G Bionomics (1982a)

TEST SUBSTANCE Diallyl diglycol carbonate

METHOD	Non-OECD or EC method. Fish acute toxicity – static conditions
Species	Sheepshead minnow *(Cyprinodon variegatus)*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	None
Remarks – Method	Nominal test concentrations of 0.125, 0.25, 0.5, 1.0 and 2.0 mg/L. Tests were conducted in 13.8 L covered glass jar, each of which contained a final volume of 3.0 L of test solution, vehicle solution or control seawater. Ten fish were placed in each jar and treatments were duplicated. Test water was not aerated and fish were not fed during the test. Lethality was determined on a daily basis. Water quality parameters of temperature, dissolved oxygen and pH were determined during the test. Both the dissolved oxygen and pH range were considered acceptable throughout the test.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		10		0	0	0	0
0.125		10		0	0	0	0
0.25		10		0	0	0	0
0.5		10		0	0	0	0
1.0		10		0	6	10	
2.0		10		6	10		

LC50	0.707 mg/L (CI: 0.384-0.713 mg/L) at 96 hours.
NOEL	0.5 mg/L at 96 hours.
Remarks – Results	The 24-, 48-, 72- and 96-h LC50s and CIs were estimated by moving average angle analysis to be 1.8 (1.8-1.87), 0.976 (0.620-1.01, 0.707 (0.384-0.713) and 0.707 (0.384-0.713) mg/L, respectively. Test concentrations were not verified analytically. No observations of sub-lethal effects are available.

CONCLUSION	The notified chemical is highly toxic to Sheepshead minnow.
TEST FACILITY	EG & G Bionomics (1982b)

8.2.2. Acute/Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Non-OECD or EC method. Static conditions.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Triethylene glycol
Water Hardness	Not reported
Analytical Monitoring	None
Remarks – Method	Nominal test concentrations of 6.4, 11, 18, 30 and 50 mg/L were used in the test. Three control beakers containing dilution water were also prepared. Five water fleas were placed in each test beaker. Mortalities and condition of fleas and water were recorded after 24 and 48 h of exposure. The water hardness, alkalinity and specific conductance were measured prior to testing. The temperature, pH and dissolved oxygen were measured at 0 and 48 h in each flask from each test concentration and control.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
0	5		0
6.4	5		0
11	5		0
18	5		1.65
30	5	5	
50	5	5	

LC50	18 mg/L (CI: 11-30 mg/L) at 48 hours
NOEL	11 mg/L at 48 hours
Remarks – Results	The 24 and 48-h LC50s and CIs were estimated by binomial probability to be 23 (18-30) and 18 (11-30) mg/L, respectively. Concentrations of the test substance were not verified analytically.

CONCLUSION The notified chemical is moderately toxic to *Daphnia magna*.

TEST FACILITY EG & G Bionomics (1982c)

TEST SUBSTANCE Diallyl diglycol carbonate

METHOD

Species	Mysid shrimp (*Mysidopsis bahia*)
Exposure Period	96 hours
Auxiliary Solvent	Triethylene glycol
Water Hardness	Not reported
Analytical Monitoring	None
Remarks – Method	Nominal test concentrations of 6.25, 12.5, 25, 50 and 100 mg/L were used in the test. Tests were conducted in 1.6 L covered glass bowls. Ten shrimps were placed in each bowl and treatments were duplicated. Ten shrimps were also exposed in duplicate to a solvent control of triethylene glycol. Test water was not aerated during tests. Lethality was determined at 24, 48, 72 and 96 h. Test water was natural seawater which was diluted with freshwater to 20 parts per thousand. Initial pH and dissolved oxygen were determined.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h	*96 h*
0	10	0.5	0
6.25	10	0	0
12.5	10	0	0
25	10	0.5	1.5
50	10	1	3
100	10	0	7

LC50	70.7 mg/L (CI: 55.6-77.6 mg/L) at 96 hours
NOEL	12.5 mg/L at 96 hours
Remarks – Results	The LC50s and CIs calculated by the moving average angle method were >100 ppm for 24 and 48 h, 84.7 (81.4-88.2) mg/L for 72 h and 70.7 (55.6-77.6) mg/L for 96 h. Concentrations of test material were not verified analytically.

CONCLUSION	The notified chemical is moderately toxic to shrimps.
TEST FACILITY	EG & G Bionomics (1982d)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Non-OECD and EC method. Alga, Growth Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	96 hours
Concentration Range Nominal	0.625 to 10 mg/L
Auxiliary Solvent	Triethylene glycol
Water Hardness	Not reported
Analytical Monitoring	None
Remarks – Method	Nominal test concentrations of 0.625, 1.25, 2.5, 5.0 and 10.0 mg/L were used in the test. Freshwater algae were added to test flasks at approximately 2 X 10^4 cells/mL. The composition of the test medium was referred to as "algal assay procedure medium". Three replicates were used for each of the test concentrations and controls (medium and solvent). Cultures were incubated at 24°C under constant illumination for 96 h. In vivo chlorophyll content was measured each day with a fluorimeter. Cells were counted at the end of the test using a hemacytometer and compound microscope. Initial and final pH was recorded.

RESULTS

Biomass		*Growth*	
Test substance mg/L at 96 h	*Cell numbers % Change over solvent control*	*Test substance mg/L at 96 h*	*Chlorophyll fluorescence % Change over solvent control*
0 (growth medium)	-14	0 (growth medium)	-7
0.625	-10	0.625	-12
1.25	- (5-10)	1.25	+9
2.5	- (5-10)	2.5	+35
5.0	- (5-10)	5.0	
10.0	- (5-10)	10.0	

Remarks – Results	Precipitation of the test substance occurred at > 10mg/L. There was no dose-dependent decrease in cell number or chlorophyll fluorescence in cells treated with the test substance. Thus, the NOEC was 10 mg/L and E_bC50 was >10 mg/L.
CONCLUSION	The acute toxicity E_bC50 of the test substance to freshwater algae cannot be determined accurately but is greater than its water solubility.
TEST FACILITY	EG & G Bionomics (1983a)
TEST SUBSTANCE	Diallyl diglycol carbonate
METHOD	Non-OECD and EC method. Alga, Growth Inhibition Test
Species	Algae (*Skeletonema costatum)*
Exposure Period	96 hours
Concentration Range Nominal	0.357 to 11.43 mg/L
Auxiliary Solvent	Triethylene glycol
Water Hardness	Not reported

Analytical Monitoring	None
Remarks – Method	Nominal test concentrations of 0.357, 0.714, 1.43, 2.86, 5.72 and 11.43 mg/L were used in the test. Saltwater algae were added to test flasks at approximately 2 X 10^4 cells/mL. Test medium was artificial seawater adjusted to a salinity of 30 parts per thousand and enriched with nutrients. Three replicates were used for each of the test concentrations and controls (medium and solvent). Cultures were incubated at 20°C under constant illumination for 96 h. In vivo chlorophyll content was measured each day with a fluorimeter. Cells were counted at the end of the test using a hemacytometer and compound microscope. Initial and final pH was recorded.

RESULTS

Biomass		*Growth*	
Test substance mg/L at 96 h	*Cell numbers % Change over solvent control*	*Test substance mg/L at 96 h*	*Chlorophyll fluorescence % Change over solvent control*
0 (growth medium)	0	0 (growth medium)	+14
0.357	-	0.357	-
0.714	0	0.714	-
1.43	0	1.43	+9
2.86	-	2.86	-21
5.72	-15	5.72	-9
11.43	-7	11.43	-5

Remarks – Results	Precipitation of the test substance occurred at >10 mg/L. There was no dose-dependent decrease in cell number or chlorophyll fluorescence in cells treated with the test substance. Thus, the NOEC was 11.43 mg/L and E_bC50 was >11.43 mg/L. Concentrations of test material were not verified analytically.
CONCLUSION	The acute toxicity E_bC50 of the test substance to saltwater algae cannot be determined accurately but is greater than its water solubility.
TEST FACILITY	EG & G Bionomics (1983b)

ADDITIONAL TESTS

8.4E. Photodegradation

TEST SUBSTANCE	Diallyl diglycol carbonate

METHOD

Light source and Spectrum	Sunlight
Relative Intensity	Based on intensity of sunlight
Spectrum of Test Substance	
Exposure Period	
Remarks - Method	The photodegradation half-life was calculated using the EPIWIN/AOPWIN Program (v1.90). The hydroxyl radical rate constant was calculated to be 73.28 E^{-12} cm^3/molecule-sec, based on the sum of contributions of individual rate constants for each active functional group on the molecule. The overall rate constant was then used to calculate the half-life assuming the hydroxyl radical concentration is constant and assuming first order reaction kinetics.

RESULTS

Remarks - Results	The photo-degradation half-life was calculated to be ca 1 day.

CONCLUSION The data indicate that the notified chemical is readily degradable in the air through OH radicals.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Based on the environmental release, it is estimated that 225 kg of the import volume may be discharged to sewer as a result of washings of equipment. Using a worst case scenario, it will be assumed that 225 kg of the notified polymer is discharged through sewerage systems from a single manufacturing site in Adelaide and none is attenuated within these systems. Assuming an average 150 ML of water in the sewage system in Adelaide, the predicted concentration in sewage effluent is estimated as (225 kg/150 ML of water) 1.5 mg/L.

Based on the dilution factor of 10 for ocean discharge of effluent, the PEC of the notified polymer in marine water may approximate 0.15 mg/L.

On the basis of data available for DAGC, DEH was not able to perform calculations for partitioning and losses in sewage treatment plants (European Commission, 1996) based on the SIMPLETREAT model. However, Based on the Mackay Level III Fugacity modelling for DAGC it may be assumed that ca 50% of the notified polymer will be adsorbed to the sludge and the remaining 50% may potentially stay in solution, passing through the STP.

It is assumed 225 kg of the notified polymer would be discharged to sewer per year. Based on the assumption that 0.1 tonnes of biosolids is generated for each ML of STP effluent, this may result in an average biosolid concentration of 8×10^3 mg/kg [(0.5 X 225 kg)/(1.42 X 10^6 ML X 0.1 X 1000 kg)] assuming 50% attenuation in sludge during the STP process. Biosolids are applied to agricultural soils, with an average rate of 10 tonnes/ha/year. Assuming a bulk density of 1000 kg/m^3 and a soil mixing zone of 0.1 m, the concentration of the notified polymer may approximate 8×10^2 mg/kg (8 X 10^3 mg/kg X 10 X 10^3 kg X 10/(1000 X 1000 kg)) in the applied soil, assuming accumulation of the notified polymer in soil for 10 years under repeated biosolids application. Thus an estimated worst case PEC for the notified polymer in soils following application of biosolids would be 8×10^2 mg/kg.

The effluent re-use (eg irrigation purposes) concentration of the notified chemical may potentially approximate 1.5 mg/L, assuming no attenuation during the STP process. STP effluent re-use for irrigation in Australia occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m^3). Using these assumptions, irrigation with a concentration of 1.5 mg/L may potentially result in a soil concentration of approximately 1.5×10^2 mg/kg assuming accumulation of the notified chemical in soil for 10 years under repeated irrigation. Thus 1.5×10^2 mg/kg is an estimated worst case PEC for the notified chemical in soils following effluent irrigation.

Fate

On the basis of the available data for DAGC, it is expected that the notified polymer is readily biodegradable. Data for photodegradation are estimated for DAGC indicating an atmospheric half-life of <1 day. Macckay level III Fugacity modelling indicates that DAGC should partition primarily to water (46.7%) and soil (52.9%) with smaller percentages (<1%) in air and sediment. Therefore, following release to sewer, the notified polymer is expected to adsorbed to sludge where abiotic or slow biotic processes are largely responsible for the degradation of the notified polymer. Considering the calculated log Pow of 2.05-5.24, the notified chemical would have moderate bioaccumulation potential (Connell 1990).

9.1.2. Environment – effects assessment

In summary the aquatic toxicity for the analogue diallyl diglycol carbonate (DAGC) indicates:

Bluegill sunfish (*Lepomis macrochirus*): 96 h LC50 0.57 mg/L

Sheephead minnow (*Cyprinodon variegates*): 96 h LC50	0.707 mg/L
Daphnia magna: 48 h LC50	18 mg/L
Mysid shrimp (*Mysidopsis bahia*): 96 h LC50	70.7 mg/L
Algae (*Skeletonema capricornutum*): EC50	>10 mg/L
Algae (*Skeletonema costatum*): EC50	>11.4 mg/L

Using the lowest 96 h LC50 of 0.57 mg/L for bluegill sunfish, a predicted no effect concentration (PNEC) of 5.7 µg/L has been derived by dividing the LC50 value by a safety factor of 100 since toxicity data are available for three trophic levels.

9.1.3. Environment – risk characterisation

Although the notified polymer is largely cured with limited discharge to sewer, the worst case PEC/PNEC ratio for the aquatic environment assuming a single site usage in Adelaide is 150 /5.7=26.3 for ocean discharge. This value is significantly greater than 1 indicating immediate concern to the aquatic compartment and indicates lens manufacturing aqueous washings should not be discharged to the sewer.

Leaching in landfill is unlikely to occur as it is predicted that the notified polymer likely to adsorb to soil matrix components and will be heat cured prior to release to landfill with further possibility of abiotic or biotic processes largely responsible for the degradation of the notified polymer.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Skin contact will be the main route of exposure, although eye contact is also possible. Given the molecular weight distribution of the polymer, absorption through intact skin cannot be excluded. Exposure to the notified polymer may occur during transfer of neat chemical from the 200 L drums into the mixing vessel via residual or leaking polymer solution from hoses, fittings and/or pumps.

Mixing occurs mechanically in a closed system and thus exposure is limited. Exposure to the chemical during manufacturing is controlled through the use of semi-automatic equipment, engineering control measures, such as sealed vessels and the use of PPE such as safety glasses, gloves, protective clothing and respirator if required. Inhalation exposure may also occur, however, the latter is expected to be low, given the chemical's low vapour pressure and the use of general exhaust ventilation.

Exposure to the reformulated polymer is not expected to occur during automated filling of mould assemblies. 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.

Dermal and ocular exposure to the notified polymer in a dilute solution may occur during solvent rinsing of manufacturing equipment and the collection of this rinsate into drums.

Exposure to the notified chemical is not expected when handling the finished plastic lenses as no residual polymer or residual constituents were identified. Exposure to the notified chemical is not expected during transport or storage provided the packaging remains intact.

9.2.2. Public health – exposure assessment

Consumers of the ophthalmic lenses are expected to make dermal and ocular contact with the notified polymer in its polymerised form that is not bioavailable. Residual monomers are present only at very low concentrations. Exposure to the notified chemical is therefore assessed as low due to the inert nature of the notified polymer in its cured form.

9.2.3. Human health - effects assessment

No toxicological data were provided for the notified chemical. However, a report containing robust summaries of toxicological studies for the suitable analogue diallyl diglycol carbonate were submitted. It was reported that the analogue was metabolised to the mono derivative and diallyl carbonate. Acute toxicity studies in the rat and rabbit indicated that the analogue was harmful by the oral route but of low toxicity by the dermal route, respectively. Information to indicate that the analogue could be harmful by the inhalation route was submitted although no robust summary was available for this endpoint.

A number of skin irritation studies in rabbits indicated severe irritation. This was confirmed in data in humans, where workers exposed to the analogue experienced severe irritation. In one study, a 10% solution was highly irritating to all persons exposed, a 2% solution was irritating to 9 of 12 persons exposed, and a 1% solution was irritating to 5/22. A single eye irritation study in rabbits indicated slight irritation only. The MSDS for the analogue states that the chemical is severely irritating to the eye in humans. In skin sensitisation studies, the analogue tested negative in a rabbit study, a Buehler study in guinea-pigs and in a human patch test.

In a 14-day repeated dose dermal study in rats, the NOAEL was 457 mg/kg/day, based on general systemic toxicity at the higher dose. No particular organ toxicity was identified in the study, however, no microscopic examination was conducted. In a developmental toxicity study in rabbits by the dermal route, ocular effects were observed in foetuses, but only at the level of maternotoxicity and general foetotoxicity (114 mg/kg/day).

In genotoxicity *in vitro* tests, the analogue tested negative in an Ames test and an unscheduled DNA synthesis test in primary rat hepatocytes.

Summarising, the analogue is harmful by the oral route and irritating to the skin and eyes. By analogy, the notified chemical is expected to be harmful by the oral route and irritating to the skin. The notified chemical is therefore classified as a hazardous substance on the basis of its acute toxicity and irritant effects.

9.2.4. Occupational health and safety – risk characterisation

Workers responsible for the transfer of material from the drum to the blending vessel and quality control workers responsible for testing of the incoming polymer solution may be exposed to small amounts of the notified chemical in concentrated form. The notified chemical is severely irritating to the skin and eye, therefore exposure to small amounts may be sufficient to cause injury to exposed workers. Impervious gloves, protective clothing, and chemical goggles are therefore recommended during these operations. The notified chemical is also harmful via the oral route, and as such, good industrial hygiene is important.

Exposure to the notified chemical in dilute solvent solution may also occur during rinsing of manufacturing equipment and the packaging of rinsate, however the concentration of notified chemical in these solutions is expected to be low. The OHS risk associated with these activities is assessed as low due to the expected low concentration of notified polymer in the solvent solution. Nevertheless, all workers in involved in these rinsing activities should wear safety glasses, gloves, and protective clothing.

The likelihood of exposure during import, storage and transport of the notified chemical is considered negligible and therefore the health risk is low. The risk to workers associated with the transport storage and handling of fished ophthalmic lenses is considered to be low due to the low likelihood of exposure in the polymerised form.

Overall, there is some risk of skin and eye irritant effects when handling the notified chemical, particularly in its more concentrated forms. However, the engineering controls employed such as semi-automation, enclosure of blending equipment and local exhaust ventilation, are expected to reduce the risk of irritant effects. Nevertheless, the use of personal protective equipment is recommended in order to mitigate the risk sufficiently.

9.2.5. Public health – risk characterisation

The risk to public health is assessed as low based on the low levels of residual polymer and monomers present in the finished lenses and the inert nature of the polymer.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R22 Harmful if swallowed
R36/R38 Irritating to the eyes and skin

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 categorised as **Acute I**.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

The chemical is considered to pose a risk to the aquatic environment based on its reported use pattern, and aqueous wastes from lens manufacturing should not be discharged to the sewer.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is moderate concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is negligible concern to public health when used in the intended manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2002). 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 (and products containing the chemical) provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health, hazard classification for the notified chemical:
  - R22 Harmful if swallowed
  - R36/38 Irritating to eyes and skin

- Use the following risk and safety phrases for products/mixtures containing the notified chemical:
  - ≥25% R22 Harmful if swallowed
  - R36/38 Irritating to eyes and skin
    S13 Keep away from food, drink and animal feeding stuffs
    S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
    S28 After contact with skin, wash immediately with plenty of soap suds
    S 37 Wear suitable gloves
    S 39 Wear eye/face protection

  - ≥5% R36/38 Irritating to eyes and skin
    S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
    S28 After contact with skin, wash immediately with plenty of soap suds
    S 37 Wear suitable gloves
    S 39 Wear eye/face protection

  - ≥1% S24/25 Avoid contact with skin and eyes

- Suppliers should label the notified chemical with the signal word 'Hazardous' and the risk phrases listed above.

Health Surveillance

- The notified chemical should be considered by NOHSC for development of health surveillance guidelines.

- As the notified chemical is a skin irritant and analogue material has been shown to cause irritant contact dermatitis, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of irritant contact dermatitis.

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 chemical:
  - Protective clothing
  - Chemically resistant gloves or gauntlets
  - Chemical goggles or safety glasses

  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

- Do not allow material or rinsates from lens manufacturing equipment to enter drain, sewers or water course.

Disposal

- The notified chemical should be disposed of to landfill or be incinerated

Emergency procedures

- Spills/release of the notified chemical should be handled by diking area to contain spill. Recover neutralised material on adsorbents, such as sand or vermiculite, and sweep into closed containers for disposal. If area of spill is porous, remove as much earth and gravel, etc. as necessary and place in closed containers for disposal.

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 subsection 64(1) of the Act; if
- the importation volume exceeds one tonne per annum notified chemical;
- when further toxicological studies are available; or

Existing studies on repeated dose toxicity (14 days) are not sufficient. The submitted test plan (Great Lakes Chemical Corporation and PPG Industries, Inc., 2001) recommends conductance of a repeated dose toxicity study of a 90-day duration, which will incorporate toxicity to reproductive organs. Additionally, studies on stability in water, chromosomal toxicity are also to be performed. These studies are to be supplied as part of a secondary notification for this polymer.

(2) Under subsection 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.

No additional secondary notification conditions are stipulated.

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