File No: STD/1207

7 December 2007

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)**

# FULL PUBLIC REPORT

## Peroxide, bis(1,1-dimethylpropyl)

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| | |
|---|---|
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**Director**
**NICNAS**

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### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
ARKEMA Pty Ltd
Ground Floor 600Victoria Street,
RICHMOND Victoria 3121
ABN 44 000 330 772

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Import Volume
Details of use
Residuals and impurities of the notified chemical
Spectral data
Purity of the notified chemical
Customer(s) name and site

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

Variation to the schedule of data requirements is claimed as follows:
Boiling point
Water solubility
Density
Hydrolysis as a function of pH
Partition coefficient
Adsorption/Desorption
Dissociation constant
Particle size
Acute inhalation
Repeat Dose Toxicity
Genotoxicity – bacteria
Algal growth inhibition test
Inhibition of microbial activity tests

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC/622
CEC/705

NOTIFICATION IN OTHER COUNTRIES
Europe – EINECS, EC Nr.: 234-042-8
USA – TSCA listed
Canada – NDSL listed
Japan – ENCS listed: 2-367

### 2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Peroxide, bis(1,1-dimethylpropyl)

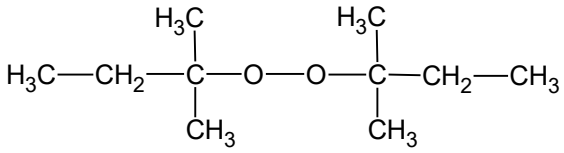
OTHER NAME(S)
Di-tert-Amyl Peroxide,
Di-t-Amyl Peroxide

MARKETING NAME(S)
Luperox DTA

CAS NUMBER
10508-09-5

MOLECULAR FORMULA
$C_{10}$ $H_{22}$ $O_2$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
174.3

## 3. COMPOSITION

DEGREE OF PURITY
97%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
Three hazardous impurities are present at < 1%.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)
None
ADDITIVES/ADJUVANTS
None

## 4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be brought into Melbourne or Sydney by sea freight from Europe or the USA in 15kg containers.

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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | < 10 | 10 - 30 | 10 - 30 | 10 - 30 | 10 - 30 |

USE
Free radical polymerisation initiator

## 5. PROCESS AND RELEASE INFORMATION

### 5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Confidential

TRANSPORTATION AND PACKAGING
The notified chemical in 15 L drums will be transported from the port of entry to Arkema Pty. Ltd. warehouse or delivered directly to the end users by road.

As the notified chemical is a Class 5.2 Dangerous Good (Organic Peroxide) it must be transported in accordance with the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code).

The notified chemical will be stored in a cool (below 38°C) area to maintain stability and active oxygen content. The storage areas should be out of direct sunlight in a cool, well-ventilated place away from combustibles and incompatible materials. Detached storage is preferred. Containers should be kept closed when not in use and securely sealed and protected against physical damage.

### 5.2. Operation description

At the sites polymer manufacture there may be two slightly different operation processes in which the notified chemical will be used. The basic steps of operation process in one site are described in the scheme below:

| | | | | | | |
|---|---|---|---|---|---|---|
| reactants and solvents charged to reactor and feed vessels. | → | initiator charged to initiator feed vessel storage | → | initiator fed into reactor. | → | polymer filtration and |

Depending of the site of use of the notified chemical the operator will take a container of the chemical, remove the lid and pour the chemical through a funnel into the initiator feed vessel. Then (s)he will close and bolt shut the lid of the feed vessel. (S)he will fill the initiator container with water, and empty that water in to the 200 L waste water drum for subsequent incineration. The empty container will be placed in a segregated waste bin for off site disposal by a licensed contractor.

Once the notified chemical has been added to the initiator feed vessel, its addition to the resin reactor is automatically controlled. The initiator feed vessel is rinsed with solvent, which is also added to the reactor. The resin cook is held at temperature for approximately one and a half hours during which time any initiator remaining in the reactor decomposes.

The operation process at an alternative site where the notified chemical will be used may vary in that raw materials are loaded together with the notified chemical into the resin reactor under vacuum. An operator will bring the notified chemical from the Class 5.2 Peroxide Store (approx 200m from the resin plant) to the resin reactor. The material will then be decanted into the resin reactor along with other raw materials for the resin batch. When loading is complete the reactor is sealed and heat is applied. The reaction is controlled by controlling the temperature of the reactor. Resin is sampled for quality control and then diluted into a final resin solution that is sent to a bulk storage tank and filled into 200 litre drums.

## 5.3. Occupational exposure

*Number and Category of Workers*

| *Category of Worker* | *Number* | *Exposure Duration hours* | *Exposure Frequency Days/year* |
|---|---|---|---|
| Operator | 2 | 0.25 | 250 |
| Experienced Operator | 2 | 0.25 | 250 |
| Quality control staff | 2 | 0.25 | 250 |

*Exposure Details*
*Transportation and storage:*

Exposure of workers involved in transport and storage of the notified chemical is possible only in the case of accident. If all the necessary measures are in place, this scenario that would involve dermal, ocular and inhalation exposure is unlikely.

In case of accidental spill or release, all sources of ignition must be removed and ventilation increased and all unnecessary personnel evacuated. Personal Protective Equipment (PPE) as described in the MSDS must be worn at all times when in contact with the material to ensure sufficient respiratory protection and minimisation of skin exposure.

*At the polymer synthesis sites:*

The reactor operator manually pours the notified chemical from the 15L containers into the initiator feed vessel or directly into the reactor tank under vacuum. During this process dermal, ocular and inhalation exposure may be possible but would be prevented by the use of PPE.

The rest of the operation steps are performed in a closed system (sealed reactor) and no exposure of the workers to the notified chemical is envisioned except in the case of an unlikely accident.

The notified chemical decomposes and is consumed during the polymerisation process, so there are no further opportunities for occupational exposure.

Material Safety Data Sheets are available for all chemicals used in the manufacturing process. The company runs internal training courses for all employees who handle chemicals. This occurs at commencement of employment and then at regular intervals during the year. Health and Safety Committees operate on all sites.

New Resin Plant Operators are given standard induction training, which includes basic safety rules and procedures on site. New operators then work for a minimum of 6 weeks under direct supervision from an experienced senior operator. Operators then work for a period of time at a given level before being promoted to a higher level. Handling of peroxides is done by experienced operators.

During handling and use of the notified chemical appropriate PPE are worn, including full-face shield, gloves of impervious material and chemical resistant suit or aprons, clothing as appropriate and chemically resistant boots.

Quality control testing personnel will take 500 mL samples approximately once a month. Exposure is very unlikely, as the notified chemical is consumed during the polymerisation synthesis.

## 5.4. Release

RELEASE OF CHEMICAL AT SITE
*At the first site*
The notified chemical will be imported from overseas and used directly as an initiator in the polymerisation process. There is scope for accidental spillage to occur whilst loading the initiator to the feed vessel prior to polymer manufacture. Should a spill occur it would be contained to the plant by bunding. Due to the closed reactor, there would be negligible release to the atmosphere.

It is expected that up to 0.2% of the residues will remain in a 15 L container. The used container will be rinsed with water which is fed into an on site incinerator for complete disposal. The empty container will then be placed in a segregated waste bin for off site disposal by a licensed contractor.

*At the second site*

Release of chemicals or by-products can occur at the reflux condenser and at the vacuum pump. All vapour emissions are discharged via an incinerator (also referred to as an after burner). The incinerator was installed to comply with NSW EPA directive 8201103D2.

The same amount of residues as in the first site is expected to remain in the import container. However, the rinsed water containing the residues will be placed into a drum to be transported to a service provider for incineration. Empty and cleaned containers are disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
The notified chemical is decomposed and consumed during the polymerisation process, so there are no further environmental implications from the proposed use.

**5.5. Disposal**

*At the first site*
Waste initiator will be collected and incinerated in the thermal oxidiser at an approved waste disposal site only.

*At the second site*
All empty peroxide containers are washed with caustic soda solution and punctured to prevent reuse prior to disposal. Caustic used to rinse empty containers is disposed of to the Resin Plant Waste Water Tank. This is diluted to approximately 1% by other streams in the tank. The combined stream is then disposed of to Waste Services' Lidcombe Plant as regulated waste.

**5.6. Public exposure**

The notified chemical will not be available to the public. It will be consumed during the polymerisation reaction and will not be present in goods that reach the public.

## 6. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance at 20ºC and 101.3 kPa** Colourless liquid

**Melting Point/Freezing Point** <-55ºC

| | |
|---|---|
| METHOD | In house method |
| Remarks | Notified chemical was tested by placing a 5g sample in a 16mm diameter test tube and while stirring with a 1/16" diameter thermocouple was immersed in a bath of dry ice/isopropanol. The sample was held below –55°C for more than a minute with no signs of solids forming. The freezing point was recorded as < -55°C. |
| TEST FACILITY | Arkema (2005) |

**Boiling Point** 166.30 ºC

| | |
|---|---|
| Remarks | Estimated by KOWIN Program (v1. 67) modeling |
| TEST FACILITY | SRCECC (1999) |

**Density** 8182 kg/m$^3$ at 25ºC

| | |
|---|---|
| Remarks | Information from MSDS |

**Vapour Pressure** 5.73 kPa at 20ºC

| | |
|---|---|
| METHOD | ASTM2879 *Measured*: Isoteniscope<br>No details of the measuring method were reported |
| Remarks | *Measured at different temperatures*:<br>4.00kPa (30 Torr) at 0ºC<br>4.80 kPa (36 Torr) at 10ºC<br>5.73 kPa (43 Torr) at 20ºC<br>7.60 kPa (57 Torr) at 38ºC<br>11.33 kPa (85 Torr) at 66 ºC |
| TEST FACILITY | Phoenix Chemical (1998) |

**Vapour Pressure** Estimated 0.33 kPa at 25°C

METHOD KOWIN Program (v1. 67) Results
TEST FACILITY SRCECC (1999)

Remarks The notifier indicates that the possible reason for the difference between the measured and the estimated vapour pressures for the notified chemical may be the presence of residual chemicals like mixed amylenes, isopentenes and amyl alcohol.

**Water Solubility** Estimated 9.66 to 21.58 mg/L.

METHOD WSKOW v1.41 and WATERNT Program (v1.01)
Remarks Estimated using WSKOW (v1.41) and WATERNT Program (v1.01) to be 9.66 and 21.58 mg/L, respectively.
TEST FACILITY SRCECC (1999)

**Hydrolysis as a Function of pH** Not measured

METHOD The notified chemical is unlikely to hydrolyse at the environmental pH range of 4-9 due to its relatively low water solubility. However, it is unstable and will decompose in the presence of oxidising materials and acids.

**Partition Coefficient (n-octanol/water)** Estimated log Kow = 4.43

METHOD KOWWIN Program (v1.67)
Remarks Estimated log Kow using EPI suite.
TEST FACILITY SRCECC (1999)

**Adsorption/Desorption** Estimated Koc to be 2862.

METHOD PCKOC Program (v1.66)
Remarks Estimated Koc using PCKOCWIN Program (v1.66).
TEST FACILITY SRCECC (1999)

**Dissociation Constant** Not applicable

Remarks The notified chemical does not contain any dissociable groups and thus is not expected to dissociate under the environmental pH of 4-9.

**Particle Size** Not applicable, substance is liquid

**Flash Point** 29°C at 101.5 kPa

METHOD ASTM D3828-02 method B
Remarks ERDCO Rapid Tester Model RT-1. No details of the method were included.
TEST FACILITY Arkema (2005a)

**Flammability Limits** Upper: 21.47%
Lower: 0.82%

METHOD ASTM method E-681
Remarks Volume of glass vessel: 5L. Pressure 101.6 kPa
Due to the extremely violent nature of the reaction, the upper flammable limit testing was terminated at 21.47%
TEST FACILITY Chilworth (2006)

**Autoignition Temperature** 414°C

METHOD ASTM method E695
Autoignition temperature is measured in a 500 mL glass flask which is heated in an electrical furnace. A small sample of test material is injected into the heated flask using a syringe and its ignition behaviour is observed. The temperature and sample size are then varied to determine the lowest ignition temperature.

Remarks Auto ignition temperature depends on many factors, including the volume of the vessel in which the chemical is stored. Materials have lower autoignition temperatures in larger vessels.

TEST FACILITY Chilworth (2006)

**Explosive Properties** Explosive

Remarks The notified chemical is an organic peroxide and is unstable. Exposure to heat, flames, sparks, ignition sources and contamination will increase its instability and contact with strong acids, alkalis, oxidisers and reducing agents will cause violent reactions.

**Reactivity**

Remarks This material is chemically unstable and should only be handled under specific conditions.

The notified chemical will react with organic materials to cause fire. The Self Accelerating Decomposition Temperature has been noted by ARKEMA as $75^0$C and the product should be stored below this temperature.

## 7. TOXICOLOGICAL INVESTIGATIONS

Data for some of the toxicological endpoints were not available for the notified chemical. For these endpoints the following information was used:

* For repeat dose toxicity, the toxicological data for the analogue Luperox TBEC was provided by the notifier. This analogue is an organic peroxide that generates radicals identical to those of the notified chemical.

** For bacterial genotoxicity, the notifier provided Category justification/test plan for organic dialkyl peroxides submitted to the US EIP (SPI; 2002). The summary results of the bacterial genotoxixity tests were negative in the bacterial reverse mutation tests and ambiguus in the SOS chromotest..

| *Endpoint and result* | *Test with notified chemical* | *Test with analogues* | *Assessment Conclusion* |
|---|---|---|---|
| Rat, acute oral LD50 >5000 mg/kg bw | √ | | low toxicity |
| Rat, acute dermal LD50 >2000 mg/kg bw | √ | | low toxicity |
| Rat, acute inhalation | - | | not performed |
| Rabbit, skin irritation | √ | | moderately irritating |
| Rabbit, eye irritation | √ | | slightly irritating |
| Guinea pig, skin sensitisation – adjuvant test/non-adjuvant test. | √ | | no evidence |
| Rat, repeat dose oral gavage toxicity – 28 days. | | √* | NOAEL = 150 mg/kg bw/day |
| Genotoxicity – in vitro human lymphocytes | √ | | non clastogenic |
| Genotoxicity – in vivo Micronucleus test in Mice | √ | | clastogenic |

### 7.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: In house method. Protocol and references were provided. A statement of compliance with Good Laboratory Practice as per FDA, EPA and OECD Annex 2 C(81)30, was also provided.

Species/Strain: Rat/ Sprague-Dawley Crl:CD BR VAF/Plus

Vehicle: None. Notified chemical 100%

Remarks - Method: A single dose of 5000 mg/kg bw administered orally. Animals were clinically observed on day 0 two times, after dosage on day 1 and daily thereafter up to day 14. Body weights were obtained prior to dosing and on days 7 and 14. Animals were sacrificed on day 14 and necropsies performed.

Room temperature and relative humidity were slightly increased during the study. Also animals were fed expired feed from day 0 to 2. These modifications of the protocol are considered not to have significant effect on the test results.

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| 1 | 5/sex | 5000 | none |

LD50: > 5000 mg/kg bw

Signs of Toxicity: Soft stools, decreased defecation and faecal/urine stain.

Effects in Organs: No significant gross internal findings were observed at necroscopy on study day 14.

Remarks - Results: None

| | |
|---|---|
| CONCLUSION | The notified chemical is of low toxicity via the oral route. |
| TEST FACILITY | SLS (1995) |

### 7.2. Acute toxicity – dermal

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | In house method. Protocol and references were provided. A statement of compliance with Good Laboratory Practice as per FDA, EPA and OECD Annex 2 C(81)30, was also provided. |
| Species/Strain | Rat/ Sprague-Dawley Crl:CD BR VAF/Plus |
| Vehicle | None. 100% notified chemical was applied. |
| Type of dressing | Occlusive |
| Remarks - Method | One day prior to dosing, the fur was removed from the dorsal trunk area amounting to >10% of the animal's body surface area (BSA), avoiding abrasion. On day 0, a dose of 2000 mg/kg bw of the test substance was administered dermally to approximately 10% of the BSA, spread evenly and held in contact with the skin using occlusive binding. After approximately 24 hours the dressings and test substance were removed and the animals observed clinically until day 14. Animals were examined for erythema and oedema after test substance removal on day 1 and thereafter on days 2-14. Body weights were obtained on days 0, 7 and 14. Animals were sacrificed at day 14 and necropsies performed.<br><br>Room temperature and relative humidity were slightly increased during the study. This modification of the protocol is considered not to have significant effect on the test results. |

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| 1 | 5/sex | 2000 | none |

| | |
|---|---|
| LD50 | > 2000 mg/kg bw |
| Signs of Toxicity - Local | Dermal irritation was noted at the site of test substance application. |
| Signs of Toxicity - Systemic | No mortality occurred during the test.<br><br>Body weight loss was noted for two female rats during the study day 0-7 and for one female during the day 7-14. Body weight gain was noted for all other animals during the test. |
| Effects in Organs | No significant gross internal findings were observed at necroscopy on study day 14. |
| Remarks - Results | Urine stain and dark material around facial area, which occurred during the 24-hour exposure period. |
| CONCLUSION | The notified chemical is of low toxicity via the dermal route. |
| TEST FACILITY | SLS (1995a) |

### 7.3. Acute toxicity – inhalation

| | |
|---|---|
| TEST | Not performed |
| Remarks | Due to the estimation of low vapour pressure no significant exposure is estimated. |

### 7.4. Irritation – skin

TEST SUBSTANCE: Notified chemical

METHOD: In house method. Protocol and references were provided. A statement of compliance with Good Laboratory Practice as per FDA, EPA and OECD Annex 2 C(81)30, was also provided.

| | |
|---|---|
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 6 males |
| Vehicle | None. 100% notified chemical |
| Observation Period | 14 days |
| Type of Dressing | Semi-occlusive |
| Remarks - Method | The dorsal area of the trunk of the animals was shaved avoiding skin abrasion. The following day, 0.5mL of the test substance was applied to ~2.5 $cm^2$ of intact skin under a gauze patch. After 4 hours exposure, the dressings and the test substance were removed and the remains of the test substance removed with water-moistened gauze. Animals were examined for erythema and oedema at 1, 24, 48 and 72 hours and up to day 14 after patch removal. Animals were observed clinically. Any unusual observations were recorded. Body weights were obtained for each animal prior to dosing. Animals were sacrificed at day 14. |

RESULTS

| *Lesion* | *Mean Score** | *Maximum Value* | *Maximum Duration of Any Effect* | *Maximum Value at End of Observation Period* |
|---|---|---|---|---|
| *Erythema/Eschar* | 3.9 | 4 | 10 days | 0 |
| *Oedema* | 1.2 | 2 | 10 days | 0 |

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

Remarks - Results: None.

CONCLUSION: The notified chemical is severely irritating to the skin.

TEST FACILITY: SLS (1995c)

### 7.5. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD: In house method. A statement of compliance with Good Laboratory Practice as per FDA, EPA and OECD Annex 2 C(81)30, was also provided.

| | |
|---|---|
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 6 male rabbits |
| Observation Period | 7 days |
| Remarks - Method | On day 0 both eyes of each animal were examined macroscopically for ocular irritation with an auxiliary light source. The corneal surface was examined using fluorescein sodium dye. All animals found to be acceptable were dosed with 0.1ml into the conjunctival sac of the right eye no more than 1 hour after this examination. The contralateral eye remained untreated to serve as a control. Eyes were macroscopically examined using a auxiliary light source at 1, 24, 48 and 72 hours and up to 7 days after dosing. Examination using fluorescein dye was repeated at 24 hours on all test and control eyes and if possible any residual test substance was rinsed from eyes with saline solution. Fluorescein examination was repeated at each interval until negative dye retention was obtained. Animals were observed clinically. Body weights were |

obtained prior to dosing on day 0. Animals were sacrificed following final observation.

RESULTS

| *Lesion* | *Mean Score** | *Maximum Value* | *Maximum Duration of Any Effect* | *Maximum Value at End of Observation Period* |
|---|---|---|---|---|
| *Conjunctiva: redness* | 0.9 | 2 | 72 hours | 0 |
| *Conjunctiva: chemosis* | 0.2 | 1 | 48 hours | 0 |
| *Conjunctiva: discharge* | 0 | 1 | 1 hour | 0 |
| *Corneal opacity* | 0 | 0 | n/a | 0 |
| *Iridial inflammation* | 0 | 0 | n/a | 0 |

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

Remarks - Results: Exposure to the test substance produced conjunctivitis (redness, swelling and/or discharge) in 6/6 test eyes at the 1-hour scoring interval. The conjunctival irritation resolved completely in all animals by study day 7. No corneal opacity, iritis or conjunctivitis was observed in the control eyes.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: SLS (1995d)

### 7.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 406 Skin Sensitisation - Maximisation method
EC Directive 96/54/EC B.6 Skin Sensitisation.

Species/Strain: Guinea pig/ Hartley CRL: (HA) BR (COBS-VAF)

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 25%
topical: 100%

MAIN STUDY

Number of Animals: Test Group: 10/sex Control Group: 5/sex

INDUCTION PHASE: Induction Concentration:
intradermal: 25% in corn oil
topical: 100%

Signs of Irritation: None observed before both challenges.

CHALLENGE PHASE

1st challenge – day 22: topical: 50% in acetone

2nd challenge – day 39: topical: 10% and 5% in acetone

Remarks - Method: No significant variations from protocol.

RESULTS

| *Animal* | *Challenge Concentration %* | *Number of Animals Showing Skin Reactions after:* | | | |
|---|---|---|---|---|---|
| | | *1st challenge* | | *2nd challenge* | |
| | | *24 h* | *48 h* | *24 h* | *48 h* |
| *Control Group* 1st challenge | 50 | 3/10 | 7/10 | - | - |
| *Control Group2*nd challenge | 10 | - | - | 1/10 | 1/10 |
| *Control Group2*nd challenge | 5 | - | - | 1/10 | 0/10 |
| *Test Group* 1st challenge | 50 | 11/20 | 17/20 | - | - |
| *Test Group2*nd challenge | 10 | - | - | 0/20 | 0/20 |
| *Test Group2*nd challenge | 5 | - | - | 1/20 | 0/20 |

| | |
|---|---|
| Remarks - Results | *Skin reactions grade 1after first challenge:*<br><br>At 24 hours:<br>Control group 3/3 (100%)<br>Test group 8/11 (72%)<br><br>At 48 hours:<br>Control group 4/7 (57%)<br>Test group 13/17 (76%)<br><br>After second challenge all the detected reactions were grade 1<br><br>More than 50% of the dermal reactions observed after first challenge and all after second challenge were grade 1, discrete or patchy erythema. The percentage of total number of skin reactions is somewhat higher in the test group compared to the controls at 48 hours after first challenge. However no significant reaction is observed after the second challenge with 10% or 5% of notified chemical. Therefore, it is concluded that the excess of postives responders (25% of animals at 24 hours and 50% challenge with notified chemical; 15% of animals at 48 hours and 50% challenge with notified chemical are probably irritant responses). |
| CONCLUSION | There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test. |
| TEST FACILITY | CIT (2006) |

### 7.7. Repeat dose toxicity

| | |
|---|---|
| TEST SUBSTANCE | Analogue Luperox TBEC |
| METHOD | OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents |
| Species/Strain | Wistar Albino Rats |
| Route of Administration | Oral – gavage |
| Exposure Information | Total exposure days: 28 days<br>Dose regimen: 7 days per week<br>Post-exposure observation period: none |
| Vehicle | Mineral oil |
| Remarks - Method | All animals were dosed orally with the test article or vehicle using a syringe and 16 gauge ball-tipped feeding needle, every day for 28 days except on day 20 due to insufficient quantity of test substance).<br><br>A Functional Observation Battery was conducted on days 23 and 26 to assess specific neurotoxicity and behavioural changes.<br><br>On day 29 all surviving animals were sacrificed with ether and exsanguinated. Whole blood, plasma and serum were analysed for selected hematologic and clinical chemistry parameters.<br><br>All animals were examined for gross pathology. |

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw/day* | *Mortality* |
|---|---|---|---|
| I (control) | 5 /sex | 0 | 0 |
| II (low dose) | 5 /sex | 150 | 0 |
| III (mid dose) | 5 /sex | 550 | 2 |
| IV (high dose) | 5 /sex | 1000 | 2 |

*Mortality and Time to Death*
Group II (two females at day 8 and 22)
Group III (female and male, day 10 and 23, respectively)

*Clinical Observations*
There were no significant differences in food consumption and body weights between groups. Only one of the females in the high dose group showed marked weight loss before death.

Functional Observational Battery – There were no significant differences ($p \leq 0.05$) between group means in the Orientation/Sensory Responsiveness, Posture, Locomotive/Patterned Movement and Integrated Movements subtotals as well as the summed scores.

*Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*
No significant changes were observed in most parameters of the clinical chemistry tests. Compared to controls and using two statistical tests (ANOVA and Dunn Multiple Comparison) chloride levels were higher in mid and low dose group males; albumin levels were increased in high and mid dose females; total protein was higher in females of the mid dose group. These changes were considered biologically unremarkable.

The mean haemoglobin concentration in males in the high dose group was significantly lower compared to controls.

*Effects in Organs*
Significantly higher liver to body weight ratio was observed in high dose females compared to controls at necropsy.

No significant differences were observed in all surviving animals at necropsy. Microscopic examination revealed no treatment related to microscopic changes in any of the low dose animals.
.
The prematurely dead animals had abnormalities in various organs consistent with inadvertent gavage accidents.

Remarks – Results
Treatment related changes were observed in kidneys of male rats in the high and mid dose groups and in the stomach of male and female rats in the high and mid dose groups. The incidence and severity of these treatment related changes occurred in a dose related manner. The pathologic changes noted in the stomach are considered to be biologically significant. However, the kidney pathology noted in the kidneys of the male rats is not considered to be relevant to human exposure since the enzyme system responsible for the hyaline droplet formation are unique to the male rat.

CONCLUSION
The No Observed Adverse Effect Level NOAEL was established as 150 mg/kg bw/day in this study, based on absence of any significant adverse effects at this dose.

| | |
|---|---|
| TEST FACILITY | MB Research Laboratories (1999) |

### 7.9. Genotoxicity – in vitro

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 473 In vitro Mammalian Chromosome Aberration Test. |
| Species/Strain | Human |
| Cell Type/Cell Line | Lymphocyte primary cultures |
| Metabolic Activation System | Liver post-mitochondrial fraction (S9) from Sprague-Dawley rats induced with Aroclor 1254 |
| Vehicle | Ethanol |
| Remarks - Method | Two independent experiments using duplicate cultures were carried out both with and without the metabolising system. A vehicle control and the appropriate positive controls were included: mitomycin C at 3μg/ml for 3 hours, or at 0.2μg/ml for the continuous treatment without S9 mix; |

Cyclophosphamide at 12.5 or 25 μg/ml with S9 mix.

The highest dose level of notified chemical for treatment in the first experiment was selected on the basis of pH, osmolality and solubility. For the second experiment, any toxicity indicated by the reduction of mitotic index (MI) in the first experiment was taken into account.

*First experiment*:

Lymphocyte cultures were exposed to the test or control items (with or without S9 mix) for 3 hours then rinsed. Cells were harvested 20 hours after the beginning of treatment, corresponding to approximately 1.5 normal cell cycles.

*Second Experiment*:

Without S9 mix, cells were exposed continuously to the test and control items until harvest

With S9 mix, cells were exposed to the test or control items for 3 hours, rinsed and harvested 20 hours and 44 hours after the beginning of treatment, corresponding to approximately 1.5 normal cell cycles and 24 hours later, respectively.

Each culture was treated with 10 μg/mL colcemid, 1.5 hours before harvest.

Mitotic Index was determined without blind scoring.

All metaphase analyses were performed blind.

| *Metabolic Activation* | *Test Substance Concentration (μg/mL)* | *Exposure Period* | *Harvest Time* |
|---|---|---|---|
| *Present* | | | |
| Test 1 | 19.5, 39.1, 78.1, 156.3, 312.5*, 625*, 1250* and 2236 | 3 hours | 20 hours |
| Test 2 | 78.1, 156.3, 312.5, 625^, 1250^** and 2236^ | 3 hours | 20 hours |
| Test 2 | 78.1, 156.3, 312.5, 625^, 1250^** and 2236^ | 3 hours | 44 hours |
| *Absent* | | | |
| Test 1 | 19.5, 39.1, 78.1, 156.3, 312.5, 625*, 1250* and 2236* | 3 hours | 20 hours |
| Test 2 | 78.1, 156.3, 3125, 625^, 1250^ and 2236^** | continuously | 20 hours |
| Test 2 | 78.1, 156.3, 3125, 625^, 1250^ and 2236^** | continuously | 44 hours |

*Cultures selected for metaphase analysis Test 1.
^ Cultures selected for metaphase analysis Test 2 at 20 hours harvest time.
** Cultures selected for metaphase analysis Test 2 at 44 hours harvest time.

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (μg/mL) Resulting in:* | | | |
|---|---|---|---|---|
| | *Cytotoxicity in Preliminary Test* | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Present* | | | | |
| Test 1 | - | ≥ 39.1 | n/a | no |
| Test 2 | - | > 1250 | n/a | no |
| Test 2 | - | @ 2236 | n/a | no |
| *Absent* | | | | |
| Test 1 | - | - | n/a | no |
| Test 2 | - | - | n/a | no |
| Test 2 | - | - | n/a | * |

Remarks - Results

* Some increase was detectable compared to negative control. However the increase was within the range of the historical data for vehicle control. No positive control was included for the 44-hour exposure time point in test 2.

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

TEST FACILITY CIT (2005)

### 7.10. Genotoxicity – in vivo

TEST SUBSTANCE Notified chemical

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain Mice/Swiss Ico: OF1 (IOPS coe)
Route of Administration Intraperitoneal injection
Vehicle Corn oil
Remarks - Method Animals were treated with notified chemical during a period of two days (1h, 4h and 24h) and once with the positive control. For each animal, the number of the micronucleated polychromatic erythrocytes (MPE) was counted in 2000 polychromatic (PE) erythrocytes. The PE and normochromatic (NE) erythrocytes ratio was established by scoring a total of 1000 erythrocytes (PE+NE).

Three animals of each sex were treated with the highest dose of the notified chemical to determine its plasma levels after treatment.

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Sacrifice Time Hours after last treatment* |
|---|---|---|---|
| I (vehicle control) | 5/sex | 0 | 24 |
| II (low dose) | 5/sex | 500 | 24 |
| III (mid dose) | 5/sex | 1000 | 24 |
| IV (high dose) | 5/sex | 2000 | 24 |
| V (positive control, CP) | 5/sex | 50 | 24 |

CP = cyclophosphamide.

RESULTS
Doses Producing Toxicity No systemic toxic effects were observed at any dose treatment with notified chemical.
Genotoxic Effects The proportion of micronucleated polychromatic erythrocytes (MPE) in the total number of immature polychromatic erythrocytes (PE) was increased in a dose dependent manner in females and males above the 1000 mg/kg bw/day dose 1.4; 1.5; 2.8 and 3.7 for vehicle control, 500; 1000 and 2000 mg/kg bw/day, respectively). The ratio of PE/NE was unchanged in the animals treated with notified chemical compared to that in the vehicle control.
Remarks - Results The plasma levels of the notified chemical were not determined due to the clear positive result with the MPE/1000 PE ratio

CONCLUSION The notified chemical was clastogenic under the conditions of this in vivo in Mammalian Erythrocyte Micronucleus Test.

TEST FACILITY CIT (2006a)

## 8. ENVIRONMENT

### 8.1. Environmental fate

No environmental fate data were submitted. However, based on the STP Fugacity model, the predicted fate of the notified chemical in a wastewater treatment facility is unlikely to undergo biodegradation. It is estimated that approximately 34% is removed in sludge, 54% as aeration off gas and 8% removed in water. However, as noted above, it will react with oxidising materials and acids and these predictions should be treated with caution.

#### 8.1.2. Bioaccumulation

Based on the calculated BCF value of 514.3 using BCF Program (v2.15), the relatively low molecular weight and the log Kow of 4.43, the notified chemical is considered to be potentially bioaccumulative. However, release to aqueous compartment will be very low.

### 8.2. Ecotoxicological investigations

Di-tert-butyl peroxide was used as the analogue chemical for the notified chemical for toxicity test in fish. The proposed analogue chemical is considered to be acceptable, though its higher water solubility may reduce its aquatic toxicity.

#### 8.2.1. Acute toxicity to fish

| | |
|---|---|
| TEST SUBSTANCE | Analogue chemical |
| METHOD | OECD TG 203 Fish, Acute Toxicity Test – Semi-static condition.<br>EC Directive 92/69/EEC C.1 Acute Toxicity for Fish |
| Species | Guppy (*Poecilia reticulata*) |
| Exposure Period | 96 h |
| Auxiliary Solvent | None |
| Water Hardness | 231 mg $CaCO_3$/L |
| Analytical Monitoring | None |
| Remarks – Method | The test was performed as a semi-static test with the solution being renewed after 48 h. In the preliminary test it was found that the use of acetone did not improve the solubility of the notified chemical. Consequently, in the definitive test, nominal concentrations of 210, 460 and 1000 mg/L were prepared by direct addition of the test substance to the diluting water. Due to the relatively low water solubility of the test substance, a two phase mixture of water and the test substance was obtained. This mixture was stirred for 24 h at room temperature to reach equilibrium. The test substance remained visible as a film on the surface of the test medium at all concentrations during the test. Ten fish per concentration and control were used in the test. Mortality of fish was observed daily. Water quality (dissolved oxygen, pH and temperature) was determined during the test. |

RESULTS

| *Concentration mg/L* | *Number of Fish* | *Mortality* | | | | |
|---|---|---|---|---|---|---|
| *Nominal* | | *0 h* | *24 h* | *48 h* | *72 h* | *96 h* |
| Control (0) | 10 | 0 | 0 | 0 | 0 | 0 |
| 210 | 10 | 0 | 0 | 0 | 0 | 0 |
| 460 | 10 | 0 | 0 | 0 | 0 | 0 |
| 1000 | 10 | 0 | 0 | 0 | 0 | 0 |

| | |
|---|---|
| LC50 | >1000 mg/L at 96 hours |
| NOEC | 1000 mg/L at 96 hours |
| Remarks – Results | The fish survived at all concentrations up to 1000 mg/L during 96 h |

exposure. However, given that the test substance has a relatively low solubility in water (180-250 mg/L) and remained visible during the test as a film layer on the surface at all concentrations, the 96 h LC50 should be treated with caution. No other sub-lethal effects were observed. Water quality (dissolved oxygen, pH and temperature) was determined to be within acceptable limits.

CONCLUSION The test substance is considered to be non-toxic to fish up to its limit of water solubility, but this result should be treated with caution.

TEST FACILITY Akzo Research Laboratories (1989)

The aquatic toxicity of the notified chemical was also evaluated using the SAR (Structure activity relationship) method. On this basis, the ECOSAR Class Program used the Peroxy Acids class to estimate 96 h LC50 of 0.556 mg/L for fish and 48 h LC50 of 0.673 mg/L for Daphnia. The Neutral Organic SAR class gave baseline toxicity for fish, daphnia and alga as shown in the following table.

| Organisms | Duration | End point | Predicted result (mg/L) |
|---|---|---|---|
| Fish | 96 h | LC50 | 0.672 |
| | 96 h | LC50 | 0.498 |
| | 30 day | Chronic value | 0.128 |
| Daphnia | 48 h | LC50 | 0.851 |
| | 16 day | EC50 | 0.126 |
| Mysid shrimp | 96 h | LC50 | 0.034 |
| Green Algae | 96 h | EC50 | 0.612 |
| | 96 h | Chronic value | 0.249 |

While these results suggest high toxicity they should be treated with some caution as the appropriateness of the model (especially peroxy acids class) is unclear.

## 9. RISK ASSESSMENT

### 9.1. Environment

#### 9.1.1. Environment – exposure assessment

The notified chemical is a relatively low molecular weight molecule (MW = 174) which will be used as a free radical initiator for the synthesis of polymers. During the polymerisation process, it is expected that the notified chemical will decompose and be consumed in the process.

The likely route of environmental exposure is from accidental spillage and washing of the used import container. In the case of spillage, it would be contained to the plant by bunding during the manufacture of the polymer. The residues from the washing of containers will be collected and eventually incinerated.

Under the proposed use pattern, the exposure to the aquatic compartment is likely to be very low.

Incineration of the wastes will destroy the compound with the generation of water vapour and carbon dioxide.

#### 9.1.2. Environment – effects assessment

On the basis of the modelling data and fish toxicity data provided, the most sensitive toxicological end point would be 96 h LC50 = 0.034 mg/L for mysid shrimp (based on neutral organic SAR). However, aquatic exposure is expected to be minimal during the manufacture of the polymers. Therefore, there is unlikely to be an environmental risk in the aquatic compartment.

### 9.1.3. Environment – risk characterisation

The majority of the notified chemical will be consumed during the polymerisation process and thus minimal environmental exposure is likely to occur during the manufacture of the polymers. Wastes generated during the manufacturing process will eventually be incinerated producing water vapours and carbon dioxide.

If spilt on land, the notified chemical is expected to become immobilised in the soil layer due to its relatively high estimated Koc value and be degraded by the abiotic and biotic processes.

The very limited exposure of the notified chemical to the aquatic compartment due to its industrial settings and consumption in the industrial process is unlikely to have an adverse effect on aquatic organisms.

Given its limited environmental exposure, the notified chemical is unlikely to pose an environmental risk under the proposed use pattern.

## 9.2. Human health

### 9.2.1. Occupational health and safety – exposure assessment

Transportation of the notified chemical will be in accordance with the *Australian Code for the Transport of Dangerous Goods by Road and Rail*. During import and transport of the notified chemical, there is unlikely to be any worker exposure, except in the event of an accidental spill. In addition, drivers of vehicles of dangerous goods are trained in emergency procedures. Exposure after a spill of organic peroxide would be controlled by using the emergency procedures described in the *Initial Emergency Response Guide Number 32* (Standards Australia, 1997).

The notified chemical is transported to two customer sites for use in a purpose built reactor for the production of acrylic polymers. The reactor operators are most likely to be exposed to the notified chemical as they will manually pour the notified chemical from the 15L containers into the initiator feed vessel or directly into the reactor tank under vacuum. During this process dermal, ocular and inhalation exposure is possible but would be prevented by the use of PPE.

Laboratory testing involves small amounts of resin mixtures (about 500 mL) that contain negligible amounts of notified chemical as it will be consumed during the polymerisation process. In addition, QA workers wear laboratory coat, safety shoes, safety glasses and rubber gloves that will further minimise exposure.

The polymer produced using the notified chemical is subsequently blended into coatings for use on metal substrates. The exposure of painting workers coming into contact with the notified chemical in these coatings is also negligible.

### 9.2.2. Public health – exposure assessment

The public is not likely to be exposed to the notified chemical as it will be consumed during the polymerisation reaction and will not be present in goods that reach the public.

Accidental exposure (eg as a result of an industrial accident) is possible, but unlikely.

### 9.2.3. Human health – effects assessment

*Acute toxicity*

The notified chemical is of low acute toxicity through the oral and dermal routes with LD50 > 5000 mg/kg bw/day and 2000mg/kg bw/day, respectively. Acute inhalation studies were not conducted due to negligible vapour pressure of the notified chemical.

*Irritation and Sensitisation*

The notified chemical is severely irritating to the skin of rabbits and slightly irritating to rabbit eyes. Based on the mean scores for erythema and duration of the irritating effects in the skin irritation test, the notified chemical is classified as Irritating to the skin - R38, according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (2004).

There was no evidence of skin sensitisation by the notified chemical in the Guinea Pig

Maximisation test provided.

*Repeated Dose Toxicity* (sub chronic):
Based on a repeat oral dose toxicity study for the analogue Luperox TBEC a NOAEL of 150 mg/kg bw/day can be estimated for the notified chemical. The NOAEL was based on absence of any treatment related effects in the animals dosed with 150 mg/kg bw/day. Treatment related changes were observed in kidneys of male rats in the high and mid dose groups and in the stomach of male and female rats in the high and mid dose groups.

*Mutagenicity*
The mutagenicity of organic peroxides is hard to test as they show high cytotoxicity to bacteria. The data provided for the notified chemical indicate that it does not significantly increase chromosomal aberrations in vitro in human lymphocytes. However, the notified chemical was clearly clastogenic in vivo in a mouse micronucleus test as the proportion of micronucleated polychromatic erythrocytes (MPE) in the total number of immature polychromatic erythrocytes (PE) was increased in a dose dependent manner in females and males above the 1000 mg/kg bw/ day dose. Therefore, the notified chemical is classified Mutagenic, Category 3, according to the NOHSC *Approved Criteria* (2004).

*Effects on health of humans*
No adverse effects have been reported during the use of the notified chemical in Australia under the Commercial Evaluation permit.

Hazard classification for health effects.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

Xi – Irritant
R38 Irritating to Skin
Xn - Harmful
R68 Possible risk of irreversible effects

### 9.2.4. Occupational health and safety – risk characterisation

The notified chemical is an organic peroxide classified as Class 5.2. dangerous good (Standards Australia, 1993). Therefore transport, storage and handling will be in accordance with the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (FORS, 1998) and AS2714-1993 *The Storage and Handling of Hazardous materials – Class 5.2 Substances (Organic Peroxides).* These measures will minimise the risk of explosions and flammability for the transportation and storage workers. In addition, drivers of vehicles of dangerous goods are trained in emergency procedures. Exposure after a spill of organic peroxide would be expected to be controlled by the emergency procedures described in the *Initial Emergency Response Guide Number 32* (Standards Australia, 1997).

During its use as an initiator in the production of polymers, inhalation exposure to the notified chemical is expected to be negligible, because of the low volatility, low frequency and duration of exposure opportunities during charging and reactor sampling, and the use of local exhaust ventilation at points of emission. Occupational exposure will be limited to 0.25 hours per day on only 1 day per year in any single worker case, during manual addition of the notified chemical to the manufacturing process. According to Marquart et al. (2006), a typical dermal exposure of the hands when loading and filling large containers with large amounts of liquids over a 30 minute period is estimated to be 410 mg per scenario or 14 mg/cm$^2$ skin on the hands. Assuming 1g = 1mL of notified chemical and the fact that 0.2 mL/cm$^2$ causes severe dermal irritation in rabbits, the risk of skin irritation during the handling of the notified chemical is high. However, the risk would be minimized by the use of long PVC or rubber gloves and protective clothing .

Eye contact and therefore the risk of eye irritation will be minimised by the wearing of safety goggles.
Under the described conditions of use and regulations on the storage, handling and transport of

organic peroxides and worker education and training, the risk of adverse health effects from occupational exposure to the notified chemical is expected to be low.

#### 9.2.5. Public health – risk characterisation

Based on the toxicity profile and use pattern of the notified chemical, there is negligible risk for the public posed by the notified chemical.

## 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:

Xi – Irritant
R38 Irritating to Skin
Xn - Harmful
R68 Possible risk of irreversible effects

and

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

| | ***Hazard category*** | ***Hazard statement*** |
|---|---|---|
| Skin Irritant | 2 | Causes skin irritation |
| Germ Cell mutagenicity | 2 | Suspected of causing genetic defects |

### 10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

### 10.3. Human health risk assessment

#### 10.3.1. Occupational health and safety

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

#### 10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

## 11. MATERIAL SAFETY DATA SHEET

### 11.1. Material Safety Data Sheet

The MSDS of the 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 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

### 11.2. Label

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

## 12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - *R38* Irritating to Skin
  - *S24* Avoid contact with skin
  - S25 Avoid contact with eyes
  - 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 water.
  - S36/37/39- Wear suitable protective clothing, gloves and eye/face protection.
  - *R68* Possible risk of irreversible effects

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Conc ≥20%: R38 - Irritating to Skin
  - Conc ≥ 1%: R68 - Possible risk of irreversible effects

- The notified chemical should be classified as follows under the ADG Code:
  - *Class* 5.2 Organic Peroxide

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical:
  - Manufacture of the chemical in closed systems
  - Transfer procedures should be automated where possible.
  - Exhaust ventilation should be used when the product containing the notified chemical is repacked or dispensed.

- Employers should implement the following safe work practices to minimise occupational exposure and ensure safety during handling of the notified chemical as introduced, and in the product as supplied to end-users
  - Avoid spills and contamination of the product containing the notified chemical
  - Wash spills from protective clothing promptly.
  - Dispose of cleaning rags safely.
  - Do not allow the product containing the notified chemical to dry on clothing or combustible material, in order to avoid fire.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Safety goggles
  - Industrial clothing
  - Impermeable gloves
  - Occupational footwear

  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.

- The label for products containing the notified chemical should be prepared in accordance with the Australian Dangerous Goods Code and the NOHSC *NOHSC National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]*.
  - Label claims should be consistent with those applicable to industrial chemicals.

Environment

Disposal

- The notified chemical should be disposed of by incineration.

Storage

- The storage and handling of the notified chemical and other organic peroxides to be in accordance with Australian Standard 1940 *The Storage and Handling of Hazardous Chemicals and Materials* (Standards Australia, 1993).

  Reference should also be made to all State and Federal regulations.

- The following precautions should be taken by storage managers regarding storage of the notified chemical:

  - temperature below 38°C
  - out of direct sunlight
  - well-ventilated place
  - away from combustible materials
  - detached storage pattern
  - containers should be kept closed when not in use and securely sealed and protected against physical damage
  - appropriate fire extinguishers should be available in and near the storage area
  - precautions should be taken against static electricity discharges

Emergency procedures

- Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal
- In case of spills or accidental release of the notified chemical all sources of ignition should be removed and ventilation increased. Unnecessary personnel should be evacuated.
- Appropriate Personal Protective Equipment, PPE, must be worn at all times when in contact with the material to ensure sufficient respiratory protection and minimisation of skin exposure.

Transport and Packaging

- The transportation of the notified chemical and other organic peroxides to be in accordance with the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (FORS, 1998).

### 12.1. Secondary notification

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

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

The Director will then decide whether secondary notification is required.

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