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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Peroxide in Trigonox 301

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Director
Chemicals Notification and Assessment

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1. APPLICANT

Akzo Nobel Chemicals Pty Ltd of 6 Grand Avenue, Camellia NSW 2142 has submitted a standard notification statement in support of their application for an assessment certificate for Peroxide in Trigonox 301.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of composition and details of exact import volume and amount used in process have been exempted from publication in the Full Public Report and the Summary Report.

2.1 Marketing Name

Trigonox 301

3. PHYSICAL AND CHEMICAL PROPERTIES

The physicochemical properties listed below were measured using two batches of the product Trigonox 301 (also referred to as Initiator D-129), whereby one consisted of 44.6% total peroxide and the other consisted of 41% total peroxide. The latter was used only for determining explosive properties.

Appearance at 20°C and 101.3 kPa:	Clear colourless liquid
Boiling Point:	Not determined (see comments below)
Relative Density:	0.883 at 20°C
Vapour Pressure:	4.1×10^{-3} kPa at 25°C
Particle Size:	Not relevant (chemical is a liquid)
Water Solubility:	13.1 mg/L at 20°C and pH ~ 6
Partition Co-efficient (n-octanol/water):	log P_{ow} = 4.84
Hydrolysis as a Function	

of pH:	Not determined (see comments below)
Adsorption/Desorption:	log K_{oc} = 3.16
Dissociation Constant:	Not determined (see comments below)
Flash Point:	71°C
Flammability Limits:	Explosive; Not pyrophoric or flammable in contact with water
Autoignition Temperature:	291°C
Explosive Properties:	Explodes under effect of flame and sources of ignition. Under certain circumstances, explosion of fire can be caused by direct contact with incompatible substances or by thermal decomposition. No more mechanically sensitive to shocks than m-dinitrobenzene.
Reactivity/Stability:	Reactive, organic peroxide- oxidising. Self-accelerating thermal decomposition reaction can occur $\geq$ 100°C or by direct contact with acid, alkali, heavy metals and reducing agents. Reactive with water.
Surface Tension:	70.9 mN/m at 21.5°C (1.51 x 10^{-2} g/L solution); considered not to be surface-active

3.1 Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice (Mullee & Bartlett 1997).

The notified chemical Trigonox 301 is never isolated and is always present in organic solvent (petroleum distillates).

The boiling point of Trigonox 301 was not determined. The notifier indicated that the notified chemical undergoes a self-accelerating decomposition at 100ºC. The notifier indicated that this value is experimentally derived, however, no report was supplied to confirm this. The notified chemical is a cyclic triperoxide and would be expected to be unstable on heating.

The vapour pressure of Trigonox 301 was determined to be 4.1 Pa at 25ºC using a vapour pressure balance according to EEC method A.4 of guideline 92/69/EEC (Tremain & Bartlett 1997). The notified chemical is considered moderately volatile to volatile (Mensink et al 1995).

The maximum water solubility of Trigonox 301 was determined to be 13.1 mg/L at 20ºC using the flask shaking method according to EEC method A.6 of guideline 92/69/EEC.

The hydrolytic stability of the notified chemical was not determined. The notified substance

contains no readily hydrolysable groups and has very low solubility in water 13.1 mg/L. Therefore, hydrolysis is unlikely under environmental conditions (4 < pH < 9).

The partition coefficient log P_{OW} of Trigonox 301 between n-octanol and water was determined to be 4.84 by HPLC according to EEC method A.8 of guideline 92/69/EEC. The retention time of the test compound on a Sperisorb 5 OD5 (2) column was compared with those of six reference compounds whose values for log P_{OW} ranged from 0.9 to 5.7. The reference compounds included aniline, benzene, toluene, naphthalene, phenanthrene and triphenylamine. The dead time of the column was determined by measuring the retention time of thiourea. The retention time of the test compound was found to lie between phenanthrene and triphenylamine with partition coefficients log P_{OW} of 4.5 and 5.7, respectively. The notified substance is hydrophobic.

The adsorption coefficient log K_{OC} of Trigonox 301 was determined to be 3.16 by an HPLC screening method used for the determination of the adsorption-coefficient on soil-comparison of different stationary phases. The retention time of the test compound on a Hypersil 5µ CN BDS column was compared with those of 13 reference compounds whose values for log P_{OW} ranged from 1.77 for simazine to 4.53 for cyfluthrin. The dead time of the column was determined by measuring the retention time of formamide. The retention time of the test compound was found to lie between endosulfan-alcohol and monceren with adsorption coefficients log K_{OC} of 2.99 and 3.53, respectively. The high value for the adsorption coefficient for the notified chemical indicated that the notified chemical will bind strongly to the organic component of soils and sediments and will have a low mobility in soil.

The dissociation of the notified chemical was not determined. The notified chemical has no dissociable groups and is poorly water-soluble.

The surface tension of Trigonox 301 was determined to be 70.9 mN/m at 21.5ºC using a White Electrical Institute interfacial tension balance according to EEC method A.5 of guideline 92/69/EEC. The notified chemical cannot be considered a surface-active material.

The notified chemical is an organic peroxide and is classified according to the ADG Code as a Class 5.2 dangerous good. The notifier has indicated that Trigonox should be a Type D substance [assigned UN number 3105]. This designation is satisfactory if the concentration of notified chemical in Trigonox is maintained at 40-45%, however if the concentration is above 45% (and ≤ 52%), Trigonox becomes a Type B substance [assigned UN number 3101], and labelled as 'Explosive' and 'Corrosive' (FORS, 1998). Organic peroxides are assigned to Packing Group II.

The notified chemical is also oxidising and explosive. Therefore, the risk phrase 'R7 – May cause fire' is appropriate.

4. PURITY OF THE CHEMICAL

Degree of Purity: 41.2-48% (typical concentration 44.6%)

Hazardous Impurities: Contains two impurities identified as hazardous:

the first impurity is present at < 1%; the classification is Irritant: Xi- R36/37 (cut-off concentration > 20%), and has the following exposure standards: 445 mg/m^3 Time Weighted Average (TWA); 890 mg/m^3 Short Term Exposure Limit (STEL)[¥]; and

the second impurity is present at 2.2% and is on NOHSC *List of Designated Hazardous Substances*, not classified* - NOHSC exposure standard 0.2 ppm (peak limitation), and

Poison by intraperitoneal route; moderately toxic by ingestion and inhalation; a moderate eye and skin irritant[#].

- **List of Designated Hazardous Substances [NOHSC: 10005 (1999)]* (National Occupational Health and Safety Commission 1999a)
- [#]*SAX's Dangerous Properties of Industrial Materials* (Sax & Lewis 1996)
- [¥]*Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC: 1003 (1995)]* (National Occupational Health and Safety Commission 1995)

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

Additives/Adjuvants:

Chemical name:	Petroleum distillates
CAS No.:	64742-47-8
Weight percentage:	Typical 54% (52-56%)
Toxic properties:	On NOHSC *List of Designated Hazardous Substances*, R65 (cut-off concentration ≥ 10%); this preparation is outside the kinematic viscosity criteria required for classification as a hazardous substance.

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia, but will be imported by sea as a component of the commercial product Trigonox 301 (41-48%) in sealed 30 L high density polyethylene containers packed on shrink-wrapped pallets. The commercial product will be used mainly as an initiator in polypropylene manufacture. It will also be used similarly in polyacrylate production and as a cross-linking agent in rubber compounding. Up to 50 tonnes of the notified chemical will be imported each year over the next five years.

Polypropylene pellets will be used in the manufacture of plastic end-use products including food wraps, laundry fittings, automobile parts and outdoor furniture. Cross linked rubber products will include rubber seals and gaskets.

6. OCCUPATIONAL EXPOSURE

Transport and storage:
The notified chemical will be imported in 16 or 25 kg Dangerous Goods approved packaging (plastic drums) within a container by sea or air in rare circumstances. The container will be transported from the dockside by road or rail to the warehouse contractor's site where the contents will be emptied for storage in a dangerous goods store. Approximately four workers will be involved in this process and may be handling the drums for a maximum of 4 hours/day, six days/year.

The drums are then distributed to customer warehouses. Twelve workers are expected to handle the drums for approximately 2 hours/day, 240 days/year. At the warehouse, store personnel (four) transport the drums as required, using a forklift or hand trolley from the store to the process peroxide storage and pumping shed, where they will be added to a fully enclosed peroxide storage vessel. The peroxide solution, containing 41-48% of the notified chemical, is semi-automatically pumped via a dip tube from the drums into a storage vessel with capacity of 150L. Workers may be contaminated with the peroxide solution as they manually empty the containers or as they connect/disconnect the dip tube and pump to the drums. Incidental exposure to the notified chemical may occur via skin or eye contact from spills and drips or by inhalation of peroxide vapours. Transfer of peroxide solution may occur on 30 days/year, with a maximum of 4 hours/day. Workers involved in transfer will wear overalls, goggles and PVC or rubber gloves.

Waterside, transport and other storage workers would only be exposed to the notified chemical in the event of a spill. The nature of the packaging used for transport minimises the likelihood of release or loss of the chemical in incidents.

Polymer manufacture and rubber compounding
The manufacturing processes are similar for polypropylene, polyacrylate and rubber compounds. Typically, polymeric products are manufactured in two stages, primary manufacture (polymerisation) and secondary manufacture (formulation and conversion into plastic products). This section describes exposure during primary manufacture. Polymerisation is an enclosed process where the additives, including the notified chemical, are introduced to the reactor either manually or via an automatic dosing system. The additives are usually weighed and mixed before dosing.

Prior to addition to the reactor, the peroxide solution containing 41-48% of the notified chemical is transferred and weighed into a mixing vessel, either from the peroxide storage vessel or directly from the drum. Exposure during weighing and transfer to the notified chemical would mainly occur via skin or eye contact from spills and drips or by inhalation. Dosing of the peroxide into the reactor is achieved by contained automatic dosing thereby reducing the potential for spills to occur. Worker exposure during this operation is assumed to be negligible. Four and 12 process workers in polypropylene and polyacrylate/rubber compounding, respectively, may come in contact with the chemical over a maximum of 4 hours/day, 30 days/year.

After use, the process workers would also rinse the plastic drums of peroxide solution before collection by drum recyclers for disposal. Inhalation and dermal exposure may occur during

rinsing.

Exposure estimates were determined by use of the EASE[1] model, information provided by the notifier and information provided in the corresponding risk assessment conducted by the Dutch assessment authority. No personal protection is assumed in the estimates. Assuming the following:

use pattern	-	non-dispersive
pattern of control	-	direct handling, dilution ventilation
volatility	-	low (< 1.5 kPa)
aerosol formation	-	none

Exposure to vapours (inhalation) by process workers is estimated to be 10-50 ppm (108-541 mg/m^3 at 25^{o}C and 101.3 kPa). However, on the basis of very low volatility (vapour pressure 0.004 kPa), 10 ppm is taken to be a reasonable worst-case estimate. Direct handling of the notified chemical has been assumed as the possible use of local exhaust ventilation during weighing and transference procedures has not been indicated by the notifier.

Then, using a respiratory rate of 1.3 m^3/h, the inhalation dose from handling the chemical over a maximum of 4 hours/day is calculated to be 8-mg/kg bw/day (assuming an average body weight of worker as 70 kg).

Similarly, dermal exposure is estimated using the EASE model to be 0.1-1 mg/cm^2/day, assuming non-dispersive, direct handling and intermittent use. The calculated dermal dose, assuming exposure to both hands with skin surface area estimate of 840 cm^2 (following standard US EPA values), is 0.54-5.4 mg/kg bw/day for a solution containing approximately 45% of the notified chemical. In the absence of data, 100% skin absorption was assumed.

Workers handling the notified chemical wear elbow length rubber gloves, eye goggles and rubber aprons. The notifier stated that safe job handling procedures have been developed for production tasks, and workers involved in formulation are trained in the safe handling and use of peroxides.

After reaction, the notified chemical will be either consumed during the polymerisation process or bound within the polymer matrix. At this point, the notified chemical will not be available for exposure or absorption. Therefore, workers involved in the filling and packing operations are not likely to be exposed to the notified chemical.

Laboratory analysis: 4 hours/day, approximately 30 days per year
Exposure to the notified chemical may occur mainly via skin contact or inhalation while sampling and testing the peroxide solution, however exposure is expected to be minor as small samples will be handled. In addition, testing is performed in fume hoods and laboratory personnel are required to wear personal protective equipment. Sixteen laboratory technicians, in all manufacturing processes, are responsible for conducting the analysis.

Drum recycling
The empty plastic containers are either pierced and disposed of to an industrial landfill, or are

[1] The EASE model is the second version of the knowledge based system in development by the UK Health and Safety Executive (HSE), and was formerly called EES (Exposure Expert System). For a further description of EES, see: Marquart et al., Evaluation of Methods of Exposure Assessment for Premarket Notifications, TNO Report V 94.229 TNO Nutrition and Food Research (Zeist), 1994.

collected by contractors who shred and granulate them. It is estimated that 12 and 36 workers in polypropylene and polyacrylate/rubber compounding, respectively, may be involved with exposure expected for a maximum of 4 hours/day over 30 days/year. Residues of peroxide in empty containers are expected to be minimal as the drums are rinsed by process workers before collection and recycling or disposal. Therefore, inhalation and dermal exposure are not expected during these operations.

Plastic product production
This is described as secondary manufacture. As the notified chemical is either consumed during the polymerisation process or bound within the polymer matrix, it will not be available for worker exposure during plastics production. Any residues of the notified chemical will be consumed in the compounding or extrusion processes, under heat (temperatures range between 50-185°C depending on process) and pressure. Exposure to the notified chemical in this instance is not expected.

7. PUBLIC EXPOSURE

The notified chemical is for industrial use and will not be sold to the public. It reacts with the polypropylene, polyacrylate or rubber compounds and is consumed in the polymerisation process, so that none is available for exposure or absorption. No degradation products have been identified. Exposure of the public by handling the finished goods is considered to be negligible.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The notifier expects that no Trigonox 301 will be released to the environment at the site of processing as the chemical is consumed in the extrusion process, chemically degrading at high the temperatures of the polymerisation process.

Spilled polypropylene pellets at customer sites containing only residual amounts of the notified chemical would typically be collected with a broom and bagged. The polymer maybe remelted and reprocessed for recycling operations. Otherwise, the material will be bagged and disposed of to landfill as industrial waste *via* a waste contractor.

The notifier estimates that up to 120 kg of the imported material will be wasted as residues left in import containers and washed and disposed of via a licensed contractor. Waste generated by plastic production is expected to be minor, overall 600 kg per annum will require disposal as waste product to landfill.

8.2 Fate

The fate of any residual chemical will share the fate of the plastic articles into which it is incorporated. These will be disposal either to landfill or incineration at the end of their useful lifetimes. Incineration would destroy the chemical, and create typical decomposition products of water and oxides of carbon.

Approximately 120 kg of the notified chemical will be disposed of to landfill as waste from empty containers. The low water solubility of the chemical indicates it is unlikely to leach from landfill.

The biodegradability of the notified substance was investigated in a Ready Biodegradability CO_2 Evolution Test OECD 301B with bacteria activated sludge from a domestic wastewater treatment plant (Mead 1997c). Trigonox 301 attained a 9% biodegradation after 28 days. The control chemical, sodium benzoate, attained a 97% biodegradation after 28 days. The pass level of 60% for this test was not achieved within 10 days of passing the 10% level. Thus, the notified chemical was found not to be readily biodegradable.

A study of the potential for Trigonox 301 to bioaccumulate was not conducted. The notifier states that since the notified chemical is not readily soluble in water, has a high log P_{OW} and log K_{OC} and is not readily biodegradable it has the potential to accumulate in the environment. Care should be taken not to release the notified chemical into the environment. As the notified chemical is to be used as an additive to plastic processes, it will be chemically reacted within the polymer matrix. It is expected that either leaching or extraction from the polymer would be very low. Therefore, under normal use and handling of the notified substance there should not be a significant release into the environment.

9. EVALUATION OF TOXICOLOGICAL DATA

All toxicity studies were conducted on the product Trigonox 301 also known as Initiator D-129 (total peroxide content of 44.6%).

9.1 Acute Toxicity

Summary of the acute toxicity of Trigonox 301

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50}> 2 000 mg/kg bw	(Sanders 1997a)
acute dermal toxicity	rat	LD_{50}> 2 000 mg/kg bw	(Sanders 1997b)
skin irritation	rabbit	Moderately irritating	(Sanders 1997c)
eye irritation	rabbit	Slightly irritating	(Sanders 1997d)
skin sensitisation	guinea pig	non-sensitising	(Sanders 1997e)

9.1.1 Oral Toxicity (Sanders 1997a)

Species/strain:	Rat/Sprague-Dawley (Crl:CD® BR)
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	Oral (gavage); single dose of 2 000 mg/kg bw of undiluted test substance (dose volume 2.27 mL/kg bw)

Test method:	OECD TG 401 (limit test)
Mortality:	None
Clinical observations:	With the exception of two females, all animals appeared normal throughout the study period. The two females showed signs of systemic toxicity, which included a hunched posture and lethargy. An isolated incident of ataxia was also observed in one of these females within the first day after dosing.
Morphological findings:	None
Comment:	No abnormalities were noted at necropsy conducted on animals in the main study.
LD_{50}*:*	> 2 000 mg/kg bw
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Sanders 1997b)

Species/strain:	Rat/Sprague-Dawley (Crl:CD® BR)
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	Single 24 hours, semi-occluded dermal application to an area of shorn intact skin (equivalent to ~ 10% of total body surface area) at a dose level of 2 000 mg/kg bw (2.27 mL using a syringe). Following exposure, residual test material was removed with cotton wool moistened with distilled water.
Test method:	OECD TG 402 (limit test)
Mortality:	None
Clinical observations:	None
Morphological findings:	None
Comment:	No signs of systemic toxicity, skin irritation or abnormalities at necropsy were observed.
LD_{50}*:*	> 2 000 mg/kg bw

Result: the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

The notifier claimed that this toxicological end-point may not be relevant as the substance is described as a liquid of low volatility, and therefore of low potential for inhalation.

9.1.4 Skin Irritation (Sanders 1997c)

Species/strain: Rabbit/New Zealand white

Number/sex of animals: 3 males

Observation period: 14 days

Method of administration: 0.5 mL of undiluted test substance was applied to an area of shorn intact skin on the back of each rabbit and held under semi-occlusive dressing. After 4 hours, residual test substance was removed by gentle swabbing with cotton wool soaked in 74% industrial methylated spirits.

Test method: OECD TG 404

Draize scores:

	Observation time					
Animal #	***1 hour***	***1 day***	***2 days***	***3 days***	***7 days***	***14 days***
Erythema						
1	2[a]	2	2	2	0	0
2	1	2	2	2	1	0
3	2	2	2	2	0	0
Oedema						
1	1	1	1	1	0	0
2	0	1	1	1	0	0
3	1	1	1	1	0	0

[a] see Attachment 1 for Draize scales

Comment: One hour after patch removal, well-defined and very slight erythema was observed in two and one animal, respectively.

All animals had well-defined erythema persisting up to three days after patch removal. Only one animal had very slight erythema on day 7.

Similarly, very slight oedema was observed in two animals one hour after patch removal, and in all animals up to day 3.

Also reported was loss of skin elasticity and flexibility observed in one animal on day 3; slight desquamation and moderate desquamation were observed in two and one animal on day 7, respectively.

The primary irritation index was 3. All signs of skin irritation disappeared by day 14.

Result: the notified chemical was moderately irritating to the skin of rabbits

9.1.5 Eye Irritation (Sanders 1997d)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 1 female; 2 males

Observation period: 72 hours

Method of administration: In one animal (female), 0.1 mL of undiluted test substance was instilled into the conjunctival sac of the left eye; the right eye served as a control. To minimise pain reaction, one drop of local anaesthetic was instilled into the eyes of the remaining two males 1-2 minutes prior to test substance administration.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

Time after instillation

Animal	***1 hour***			***1 days***			***2 days***			***3 days***		
Cornea	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***
1	0[1]			0		0	0		0	0		0
2	0			0		0	0		0	0		0
3	0			0		0	0		0	0		0
Iris												
1	0			0			0			0		
2	0			0			0			0		
3	0			0			0			0		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	0	0	0	0	0	0	0	0	0	0	0
2	2	1	0	1	0	0	0	0	0	0	0	0
3	2	1	1	1	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales

o = opacity a = area r = redness c = chemosis d = discharge

Mean scores (24, 48, 72 hours observation):

Animal	*Corneal opacity*	*Iridial inflammation*	*Conjunctival redness*	*Conjunctival chemosis*
1	0	0	0	0
2	0	0	0.3	0
3	0	0	0.3	0

Comment: Inflammation of the cornea and iris were not observed in any of the animals during the observation period. However, moderate and slight conjunctival irritation was observed in two males and female, respectively, one hour after instillation of the test substance.

Only slight conjunctival irritation was observed in the males at 24 hours, which resolved by 48 hours.

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

9.1.6 Skin Sensitisation (Sanders 1997e)- Magnusson and Kligman Maximisation Test (Magnusson & Kligman 1970)

Species/strain: Guinea pig/Dunkin Hartley (albino)

Number of animals: Main study: 10 males (test) and 5 males (control)

Main study:

Induction procedure:

test group:

day 0 three pairs of *i.d.* injections (0.1 mL) into the skin of the shoulder:

FCA 1:1 in distilled water;
the test substance, diluted to 10% w/v in arachis oil BP;
the test substance diluted to 10% w/v in a 1:1 mixture of FCA and distilled water;

day 7 filter paper saturated with the undiluted test substance was applied to the treated area and held under occlusive dressing for 48 hours.

day 21 filter paper saturated with undiluted test substance and a 75% v/v in arachis oil were applied to shorn sites on the right and left flanks respectively, and held under occlusive dressing. After 24 hours, residual test substance was removed by swabbing with cotton wool soaked in diethyl ether.

control group: treated similarly to test animals omitting the test substance from the intradermal injections; nothing was applied to filter paper in topical applications.

Test method: OECD TG 406

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
75%	0**/10	0/10	0/5	0/5
100%	8/10	6/10	3/5	2/5

* time after patch removal
** number of animals exhibiting positive response

Comments on Main study:

i.d. induction Intradermal induction sites in all test animals revealed well-defined to moderate to severe erythema, which persisted up to 48 hours after *i.d.* injection. Very slight erythema was detected at the *i.d.* injection sites in three and two animals at 24 and 48 hours, respectively.

topical induction Very slight to well-defined erythema and very slight oedema were observed in test group animals one hour after patch removal, which persisted in the majority of animals over 24 hours. Also observed at 24 hours were desquamation, crust formation, fissuring of the skin and hardened dark brown/black-coloured scabs. Control group animals revealed no signs of skin reactions at the one or 24-hour observations.

topical challenge Besides erythema and oedema, which were observed at 24 hours, haemorrhage of the dermal capillaries in one animal was observed with 100% challenge. At 48 hours, erythema and oedema were also noted and small superficial scattered scabs were observed in two animals and desquamation in another. Skin reactions were also observed in control animals at both the 24- and 48-hours observations, with one case of small-scattered superficial scabs.

No skin reactions were observed in animals challenged with 75% of the test substance at 24-or 48-hours observations. Similarly, control animals had no skin reactions at both intervals.

Comment: It was concluded that reactions observed at 100% resulted

from irritancy effects rather than sensitisation, since control animals were not previously exposed to the test substance.

It is worth noting that in the sighting study, similar skin reactions were observed with the 100% and 75% v/v dilution of the test substance. However, a clear distinction in the severity of skin reactions was noted between the two concentrations in the main study.

It was not possible to determine the incidence of sensitisation in animals previously induced with the test substance and challenged with 100% topical application due to skin irritation.

One animal was euthanised following the 24-hour observation due to ill health.

Result: At the highest non-irritating concentration (75%), the test substance was non-sensitising to the skin of guinea pigs.

9.2 28-Day Repeated Dose Oral Toxicity (Thomas et al 1997)

Species/strain: Rat/Sprague-Dawley Crl:CD®BR

Number/sex of animals: Range finding study: 3/sex/dose;
Main study: 5/sex/dose

Method of administration: Oral (gavage); vehicle: arachis oil BP;
dose volume: 2 mL/kg bw;

Dose/Study duration: 0, 15, 150, 1 000 mg/kg bw /day for 28 consecutive days;
0, 1 000 mg/kg bw/day for 14 days in recovery groups;
control group animals received the vehicle only.

Test method: Commission Directive 92/69/EEC- method B7 (similar to OECD TG 407)

Clinical observations:

No mortalities resulted from dosing with the test substance. No treatment related clinical findings were observed in animals dosed with 15 and 150 mg/kg bw/day during the study period.

Both males and females in the high dose group showed increased salivation before or approximately two minutes after dosing, which started on day 2 and persisted throughout the treatment period. Increased salivation was also reported to occur approximately one hour after dosing, together with red/brown staining or wetting of the external body surface and fur loss. Pilo-erection, hunched posture, noisy respiration and red/brown staining around the mouth or the ano-genital region were observed briefly in only a few animals.

A reduction in body weight gain at the high dose treatment during the first three weeks and the first week was observed in males and females, respectively. Males also showed a reduction in dietary intake during the first three weeks and a reduction in food efficiency in week 1 of the treatment period. Although females at the high dose group showed reduced dietary intake in the first two weeks of treatment, the extent of such effect was not as pronounced. No such effects were observed in treatment-free recovery animals. Water consumption, measured for the last week of treatment and for the recovery period, was reportedly increased for animals of either sex at the high dose group between days 22 and 28 in comparison to control animals, but regressed during the recovery period, though slowly in the males.

Animals treated with the low and medium doses showed no abnormal clinical signs and no inter-group differences were reported.

All clinical signs, with the exception of fur loss in two males at the high dose, were reported to have regressed completely during the treatment-free recovery period.

Haematology

A statistically significant reduction in haemoglobin, erythrocyte count and haematocrit was observed in the males of the high dose group. Besides reduced haemoglobin and haematocrit, females at the 1 000 mg/kg bw/day also showed increased neutrophil counts when compared to controls, which was possibly a secondary stress response. However, differences were not always statistically significant. These changes were not detectable in the high-dose recovery group animals following the 14 day treatment-free period. No treatment-related haematological changes were detected in the animals at the medium and low doses.

Although statistically significant differences in mean corpuscular haemoglobin and mean corpuscular volume were observed in the high dose recovery animals compared to the controls, these changes were considered toxicologically irrelevant in light of the absence of any supporting changes in haematological data for non-recovery animals or histopathological correlates.

Clinical chemistry

Increased plasma aspartate aminotransferase (ASAT), alanine aminotransferase (ALAT) and bilirubin levels were noted in all animals treated with 1 000 mg/kg bw/day. Differences in ASAT and ALAT values were not always statistically significant, but nonetheless they were outside the normally accepted ranges for rats of the strain and age used. The high dose treatment group also revealed increased plasma urea and creatinine in the males and elevated triglycerides in the females.

None of these changes were reported to occur in recovery group animals or in animals treated with low and medium doses.

Other inter-group statistically significant differences were reportedly detected among high dose non-recovery and/or recovery animals. For example, plasma potassium concentrations were significantly higher in both the recovery and non-recovery females treated at the high dose, when compared to the control animals. Similarly, all high dose recovery group animals showed a significant increase in plasma calcium coupled with

reduced plasma bilirubin, together with increased plasma cholesterol and reduced albumin/globulin ratio in females, when compared to the controls. However, these differences may be toxicologically irrelevant since all the individual values for the relevant parameters fell well within the expected respective ranges for rats of the strain and age used. In addition, the changes were neither accompanied by toxicological correlates nor, as in the case of recovery animals, detectable in the non-recovery animals at the end of the treatment period.

No treatment-related changes were reported in the urinalysis parameters investigated.

Pathology:

Organ weights
All animals treated with 1 000 mg/kg bw/day of the test substance showed increased liver weight, absolute and relative to terminal body weight when compared to control animals. Increased relative kidney weight was also noted in these animals. Differences in individual weight values, though not always statistically significant, fell outside the normally expected respective ranges for rats of the strain and age used. These findings persisted in the recovery females at the high dose throughout the treatment-free period. No treatment-related changes were observed in organ weights of recovery males at high dose or in other treatment group animals (mid and low doses).

A minimal, but statistically significant, increase in relative brain weight was detected in males treated at the high dose, which was attributed to the reduced terminal body weight in these animals.

Necropsy (macroscopic)
Animals treated with the low or medium doses of the notified chemical revealed no treatment-related macroscopic abnormalities at terminal kill. However, animals at the high dose treatment had enlarged and/or dark livers that persisted in all recovery animals, one female excepted, throughout the treatment-free period. Dark kidneys were also observed in several animals at high dose treatment.

No other significant treatment-related macroscopic changes were observed.

Histopathology
All animals of the high dose group and males of the medium dose treatment revealed hepatocyte enlargement, bile duct proliferation and pigment accumulation in the liver. Hepatocyte enlargement was also identified in animals at the low (2 males/1 female) and medium (2 females) dose treatments. Only partial regression of hepatocyte enlargement and bile duct proliferation occurred during the 14-day treatment free period.

Treatment associated effects on the kidneys of rats in the high dose groups consisted of eosinophilic and/or pigmented globular accumulations in the proximal tubules, which appeared to partially regress amongst recovery males following the treatment free period.

Although special staining techniques were applied, the nature of the deposited pigment in the liver and kidneys was not identified.

All other histopathological changes observed were reportedly characteristic of the strain

and age used.

Comment
At 1 000 mg/kg bw/day the treatment resulted in significant toxicological effects including clinical, haematological and pathological, macroscopic and microscopic, parameters as described above, whereas at 150 mg/kg bw/day microscopic hepatic lesions were the only effects caused by the treatment. Treatment-related effects at 15 mg/kg bw/day involved minimal hepatic changes.

The gross pathological effects observed, namely increased liver weights and enlarged and dark livers, appeared to correlate with the histopathological changes observed, ie. hepatocyte enlargement, bile duct proliferation and pigment deposition.

Although staining failed to identify the nature of the pigment, it is possible that it represented deposition of the test substance or its metabolites. If so, this would explain bile duct proliferation, a phenomenon observed with the aggregation of xenobiotics, which causes biliary obstruction. Increased plasma bilirubin, a significant indicator of hepatic damage and perturbation to hepatic excretory function, lends further support to the latter.

Similarly, elevated triglyceride levels are indicative of cholestatic episodes that may be associated with the absence of bile flow from the liver. Increased ASAT levels cannot be conclusively correlated with effects on the liver since this enzyme is ubiquitous and may indicate damage to other tissues.

Kidney sections also revealed treatment-related effects at the highest dose, which appeared to correlate with the accumulation of the test substance and induce renal dysfunction.

Treatment-related effects described above were also observed in a range finding study conducted with 150, 400 and 1 000 mg/kg bw/day doses. No mortalities were reported with the range finding study.

Result:	Given the toxicologically significant changes observed at all treatment doses, it was not possible to determine a No Observed Adverse Effect Level (NOAEL) for the test substance. Based on the changes observed at the lowest dose treatment of 15 mg/kg bw/day, which were confined to hepatocyte enlargement, the Lowest Observed Adverse Effect Level (LOAEL) for the test substance is determined to be 15 mg/kg bw/day.
Addendum:	Additional expert review was supplied, which provided quantitative assessment of the severity of the histopathological changes, namely clarification of the changes described as “minimal” and “moderate” in the study (Gopinath & Harling, 2000).

9.3 Genotoxicity

9.3.1 Salmonella typhimurium and Escherichia coli Reverse Mutation Assay- Ames Test (Thompson 1997)

Strains:	*S. typhimurium*: TA 1535, TA 1537, TA 98 and TA 100; *E. coli*: WP2uvrA$^-$
Concentration range:	Two independent experiments were conducted at the following concentrations: 0, 50, 150, 500, 1 500 and 5 000 μg/plate, with or without S9 mix; triplicate cultures were used for each concentration. Positive controls: N-ethyl-N'-nitro-N-nitrosoguanidine (ENNG) at 2 μg/plate for WP2uvrA$^-$, 3 μg/plate for TA 100 and 5 μg/plate for TA 1535; 9-Aminoacridine (9AA) 80 μg/plate for TA 1537; 4-Nitroquinoline-1-oxide (4NQO) 0.2 μg/plate for TA 98; All without S9 mix; 2-Aminoanthracene (2AA) at 1 μg/plate for TA 100, 2 μg/plate for TA 1535 and TA 1537, 10 μg/plate for WP2uvrA$^-$ and 0.5 μg/plate for TA 98; with S9 mix Negative control: Acetone (vehicle control)
Metabolic activation:	liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Test method:	OECD TG 471, 472
Comment:	A preliminary toxicity study revealed that the test substance was not toxic to TA 100 or WP2uvrA$^-$ strains at concentrations up to 5 000 μg/plate with or without metabolic activation. Test substance precipitation was observed at 1 500 and 5 000 μg/plate, however, this did not appear to interfere with the scoring of the revertant colonies. In the main study, no significant increase in the frequency of revertant colonies was observed in any of the bacterial strains, at any concentration, with or without S9 metabolic activation. All positive controls used in the study confirmed the sensitivity of the various strains and the efficacy of the S9-mix. Acetone was used as the vehicle because the test substance

was insoluble at 50 mg/mL in both sterile distilled water and DMSO. The vehicle solvent was dried prior to incorporation of test substance in experiments using molecular sieves.

Result: The test substance was considered non-mutagenic in the bacterial strains tested in the presence or absence of metabolic activation.

9.3.2 Chromosomal Aberration Assay in Chinese Hamster Lung Cells in vitro (Wright & Jenkinson 1997)

Cell line: Chinese Hamster Lung cells

Metabolic activation system: liver fraction (S9 mix) from rats pretreated with Aroclor 1254

Test method: Similar to OECD TG 473; Japanese New Chemical Substance Law and updated Annex V B10 method

Experimental Design: Two independent experiments were conducted in duplicate. The experimental design and concentrations tested are as follows:

Metabolic Activation	Experiment	Test substance concentration (μg/mL)	Positive Control
-S9	Experiment 1	treatment/harvest time: 12/12 hours 0*, 1.22, 2.44, 4.88*, 9.77*, 19.53* & 29.3* μg/mL	MM C 0.075* μg/mL

	Experiment 2	treatment/harvest time:12/12 hours 0*, 2.44, 4.88*, 9.77*, 19.53*, 24.42* & 29.3 µg/mL treatment/harvest time: 6/24 hours 0*, 2.5, 5*, 10*, 20*, 30* & 40 µg/mL treatment/harvest time: 24/24 hours, 48/48 hours 0*, 2.5, 5*, 10*, 20*, 30* & 40 µg/mL	MM C 0.075* µg/mL; CP 10* µg/mL MM C 0.05* µg/mL & 0.025* µg/mL for 24 & 48 respectively
+S9	Experiment 1	treatment/harvest time: 4/12 hours 0*, 156.25, 312.5*, 625*, 1 250*, 2 500* & 3 750 µg/mL	CP 10* µg/mL
	Experiment 2	treatment/harvest time: 4/12 hours 0*, 156.25, 312.5*, 625*, 1 250*, 1 875* & 2 500 µg/mL treatment/harvest time: 6/24 hours 0*, 312.5, 625*, 1 250*, 2 500*, 3 750* and 5 000 µg/mL	CP 10* µg/mL CP 10* µg/mL

- CP – cyclophosphamide, MM C – mitomycin C
- acetone (solvent) was the negative control
- * cultures selected for metaphase analysis

Comment:

The test substance showed a dose-related increase in cell toxicity in the absence and presence of metabolic activation by S9 mix, with one exception seen in 4/12 hours treatment cultures. Metaphases were detectable and scored at concentrations up to 2 500 µg/mL in the presence of S9 mix, but only at concentrations up to 19.53 µg/mL in the absence of S9 mix.

Cytotoxicity of the test substance was further confirmed in

experiment 1, with a 50% mitotic inhibition reported at 1 250 μg/mL in the presence of S9 and a sudden and total mitotic inhibition at 29.3 μg/mL without S9 mix. In Experiment 2 in the absence of activation by S9, a dose-related increase in mitotic inhibition achieving 50% inhibition at 19.53 μg/mL and total inhibition at 24.42 μg/mL was reported.

In both, Experiment 1 and 2, the test substance did not induce a statistically significant or dose-related increase in the frequency of cells with aberrations, though a small increase was detectable, or in the number of polyploid cells.

All vehicle control cultures had frequencies of chromosome aberrations within the expected range. Positive controls induced significant increases in the frequency of aberrant cells indicating that the activity of the S9 fraction was satisfactory and that the test method was operating as expected.

Result: the test substance was non-clastogenic in CHL cells under the test conditions applied.

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity in rats with LD_{50} > 2 000 mg/kg bw and of low acute dermal toxicity in rats (LD_{50} > 2 000 mg/kg bw). The notified chemical was a moderate irritant to the skin of rabbits and a slight irritant to the eyes of rabbits. At the highest non-irritating concentration, the notified chemical was non-sensitising to the skin of guinea pigs.

Oral administration of the notified chemical to rats in a 28-day repeated dose toxicity study resulted in significant toxicological effects at all doses, including organ specific (liver and kidney), clinical and haematological effects. These effects were found to be partially reversible after a 14-day recovery period. An expert review clarified some of the changes observed in the study and concluded that these changes were not severe nor an indication of marked organ dysfunction. It was not possible to determine a NOAEL for the test substance since minimal, but treatment related, effects on the liver were observed at 15 mg/kg bw/day. Based on minimal hepatocyte enlargement, the LOAEL for this 28-day study was determined to be 15 mg/kg bw/day.

The notified chemical was considered non-mutagenic to the bacterial strains tested and non-clastogenic *in vitro* in a chromosomal aberration assay.

The notified chemical is classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission 1999b) based on the findings of skin irritation observed in an acute dermal irritation study. The overall classification is Irritant (Xi) and the risk phrase R38 – Irritating to Skin is recommended.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has supplied the following ecotoxicity studies. The tests were carried out according to OECD Test Methods.

Test	*Species*	*Test concentrations (nominal) mg/L*	*Results (Measured) mg/L*
Acute Toxicity (Wetton & Bartlett 1997a) - (Semi-static Test) (OECD TG 203)	Rainbow Trout (Oncorhynchus mykiss)	2	96 h LC_{50} > 1.4
Acute Toxicity (Wetton & Bartlett 1997b) - Immobilisation (Static Test) (OECD TG 202)	Water Flea (*Daphnia magna*)	2	48 h EC_{50} > 2
Growth Inhibition (Mead & Bartlett 1997) - (Static Test) (OECD TG 201)	Green Algae (*Scenedesmus subspicatus*)	2	72 h E_rC_{50} > 1.4 72 h E_bC_{50} > 1.4 72 h NOEC > 1.4
Respiration Inhibition (Mead 1997b) (OECD TG 209)	Activated Sludge - Aerobic Waste Water Bacteria	1000	3 h EC_{50} > 1000

* NOEC - no observable effect concentration

Fish

Following a preliminary range-finding study, fish were exposed in two groups of 10 to an aqueous dispersion of the test material at a single nominal concentration of 2 mg/L of Trigonox 301. A semi-static test was conducted with renewal of test media every 24 hours because of the formation of oily globules of the test material on the water surface.

The test concentration of 2 mg/L was claimed to be the highest preparation attainable by the notifier given the limited solubility of the test material in water and the auxiliary solvent acetone. It is noteworthy that the claimed solubility of 2 mg/L is lower than that previously stated at 13.1 mg/L.

No mortalities or other significant adverse effects were observed. The 96 hour LC_{50} value, based on time-weighted mean measured concentrations, was determined to be > 1.4 mg/L. The study does not indicate any steps taken to ensure only dissolved material was analysed. The test material concentration in the test samples was determined by gas chromatography using an external standard technique.

Aquatic Invertebrates

Following a preliminary range-finding study, daphnia were exposed in four groups of 10 to an aqueous dispersion of the test material at a single nominal concentration of 2 mg/L of Trigonox 301 for 48 hours under static test conditions. The notifier also observed oily globules of the test material on the sample water surfaces of this test.

The test concentration of 2 mg/L was claimed to be the highest attainable preparation given the limited solubility of the test material in water and the auxiliary solvent acetone.

No mortalities and other significant adverse effects were observed. The 48 hour LC_{50} value was determined to be > 2 mg/L. Analysis of the test solutions showed the measured test concentrations to be in excess of the required 80% of the nominal test concentrations, so the results are based on nominal test concentrations only. The study does not indicate how the test samples were collected. The test material concentration in the test samples was determined by gas chromatography using an external standard technique.

Algae
Following a preliminary range-finding study, the algae *Scenedesmus subspicatus* in six replicate flasks was exposed to an aqueous dispersion of the test material at a single nominal concentration of 2 mg/L for 72 hours under constant illumination and shaking at 14ºC. The notifier also observed oily globules of the test material on the sample water surfaces of this test and the limited solubility was also noted in this test.

No significant adverse effects were observed. The 72 hour EC_{50} values for growth and biomass and the no observed effect concentration, based on time-weighted mean measured concentrations, was determined to be > 1.4 mg/L. The study does not indicate how the test samples were collected. The test material concentration in the test samples was determined by gas chromatography using an external standard technique.

Microorganisms
The inhibitory effect of the notified substance on aerobic wastewater bacteria activated sludge from a domestic wastewater treatment plant was investigated in a respiration test. The notified substance showed no toxic effects, with the respiration rate not inhibited when exposed to the test nominal concentration of 1000 mg/L over the exposure period of 30 minutes, with a final 3 hour EC_{50} > 1000 mg/L.

Conclusion
The ecotoxicity data for the notified chemical indicate that the chemical is not toxic to aquatic organisms up to the limit of its water solubility and does not affect sewage microorganisms at a nominal concentration of 1000 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will be used as an initiator in the production of polypropylene, polyacrylate and the cross linking of rubber compounds. Hence, any residues of the notified chemical will share the fate of the articles into which it is incorporated as part of the cross-linked matrix of the plastic polymer. Articles may be initially recycled but will eventually be disposed of either to landfill or by incineration. In landfill, residual notified chemical is expected to remain immobile within the plastic polymer matrix. Incineration would destroy the chemical and create typical decomposition products of water and oxides of carbon.

Predominant environmental exposure will result from landfill of residue in empty drums and waste from plastic products, which is expected to be less than 600 kg per annum. Unreacted notified chemical is expected to be immobile due to its water insolubility and chemical incorporated in the crosslinked matrix of the plastic polymer would be immobile and inert. While the chemical is not expected to readily biodegrade, it should not bioaccumulate because of its low solubility. The chemical is unlikely to present a hazard to the environment when it is incorporated into plastics and rubber compounds.

Hence, given the low environmental exposure, the overall environmental hazard of the chemical can be rated as low.

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

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard assessment

The notified chemical was of very low acute oral toxicity and low acute dermal toxicity in rats. It was a moderate skin irritant and a slight eye irritant in rabbits. At the highest non-irritating concentration, the notified chemical was non-sensitising to the skin of guinea pigs. However, its potential as a skin sensitiser when tested undiluted was equivocal.

Oral administration of the notified chemical to rats in a 28 day repeated dose toxicity study resulted in significant toxicological effects at all doses, which included organ specific (liver and kidney), clinical and haematological effects. Based on minimal hepatocyte enlargement observed at the lowest dose, it was not possible to determine a NOAEL for the test substance, so a LOAEL of 15 mg/kg bw/day was established for the study.

The notified chemical was considered non-mutagenic to the bacterial strains tested and non-clastogenic in vitro in a chromosomal aberration assay.

The notified chemical is classified as a hazardous substance according to the NOHSC Approved Criteria for Classifying Hazardous Substances (National Occupational Health and Safety Commission 1999b) based on the findings of skin irritation observed in an acute dermal irritation study. The notified chemical is therefore classified as Irritant (Xi) with the risk phrase R38 – Irritating to Skin recommended.

The notified chemical is a dangerous good Class 5.2 (organic peroxide), with Packing Group II assigned. If the concentration of notified chemical in Trigonox is > 40 to 45%, the product is a Type D organic peroxide with packing method OP5 assigned. If the concentration of notified chemical is > 45 to 52%, Trigonox is a Type B organic peroxide with packing method OP7 assigned. According to the ADG Code, Trigonox should be labelled as 'Explosive' and 'Corrosive' if Type B.

The notified chemical is an oxidising substance and explosive. The risk phrase 'R7 – May cause fire' is warranted, together with the safety phrases 'S3/7 – Keep container tightly

closed in a cool place' and 'S14 – Keep away from reducing agents, acids, alkalis and heavy metal compounds.

The imported product, Trigonox 301, containing the notified chemical is classified as a dangerous good as it contains an organic peroxide. Trigonox 301 is also a hazardous substance due to the presence of petroleum distillates, which are classified as hazardous substances. Accordingly, it will require the appropriate risk phrases for petroleum distillates under hazardous substances regulations.

Occupational Health and Safety

Transport and storage
Incidental exposure to Trigonox 301 (containing 41-48% of the notified chemical) may occur during transfer of the solution from drums to peroxide storage vessels as inhalation of vapours and skin and eye contact may occur when connecting pumps and transfer lines. Therefore, there is a risk of skin and eye irritation during this operation.

Exposure to the notified chemical is not expected during transport or other storage operations as long as the packaging remains intact and dangerous goods precautions are taken. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up given in the Material Safety Data Sheet (MSDS) supplied by the notifier. Organic peroxides should be stored, handled and disposed of according to AS 2714-1993 (Standards Australia 1993). The risk of adverse health effects for these workers is considered low.

Polymer manufacture and rubber compounding
Process workers may be exposed to the notified chemical during weighing of the peroxide solution before addition to the reactor, when transferring the solution from the drum or storage vessel to the mixing tank and when rinsing the empty containers. Exposure may occur by inhalation of vapours and from skin contact with the liquid during these operations. Exposure during polymerisation is negligible as the reactor is enclosed and additives are introduced to the reactor via a sealed automatic dosing system.

Considering the use pattern described by the notifier, the predicted inhalation exposure for process workers is estimated to be 8-mg/kg bw/day using the EASE model. This is considered a reasonable worst-case estimate as the notified chemical is of low volatility. The estimate assumed non-dispersive use, direct handling of the chemical (as a 45% solution), dilution ventilation and no aerosol formation. According to the EASE model, exposure would be reduced approximately 20 times if local exhaust ventilation were employed. Again using the EASE model, dermal exposure is estimated to be 0.54-5.4 mg/kg bw/day, assuming intermittent use, exposure to both hands and 100% skin absorption. Therefore, the combined estimated human dose (EHD) is 8.5-13.4 mg/kg bw/day. No personal protection is assumed in the estimates.

For the critical health effect, namely hepatic damage, the Margin of Exposure (MOE = LOAEL/ EHD) calculated for the process workers is 1.1-1.8, indicating that effective control measures must be in place to avoid health risk to workers. The data could be refined with atmospheric monitoring and skin absorption test data, although an assumption of 100% skin absorption is reasonable given the notified chemical is a skin irritant.

These estimates are based on the assumption that exposure to vapours or solution results from continuous direct handling of the chemical and represent the worst-case scenario. Polymer manufacture is a batch process and process workers may handle the chemical intermittently during the day. Nevertheless, as dermal exposure to the notified chemical may lead to skin irritation, control measures must be in place to minimise both dermal and inhalation exposure to prevent the risk of systemic and topical toxicity. These include the automation and enclosure of transfer processes and the use of appropriate personal protective equipment such as PVC or rubber gloves, industrial standard overalls and safety goggles. Workers potentially exposed to the notified chemical must be trained in the handling of organic peroxides.

The risk of adverse health effects arising from exposure to the notified chemical is low during the polymer filling and packing process as the notified chemical will be either consumed or bound to the polymer matrix during polymerisation and will not be available for absorption.

Laboratory analysis
As exposure is expected to be minor during laboratory sampling and testing, the risk of adverse health effects is low, however, as skin contact may occur, protective equipment such as gloves and laboratory coat should be worn to minimise irritant effects.

Drum recycling
As the empty drums are to be rinsed at the production site prior to collection by licensed contractors, the risk of adverse health effects is low for these workers.

Plastic product production
As the notified chemical is not be available for absorption during plastics production, the risk of adverse health effects arising from exposure to the notified chemical is negligible.

Public health

Trigonox 301 will be used for industrial purposes and will not be available for use by the public. Once reacted with polypropylene, polyacrylate or rubber, the notified chemical becomes chemically bound and will not be bioavailable. Consequently, the potential for public exposure to the notified chemical during all phases of its life cycle is considered to be negligible.

Based on the above information, it is considered that the organic peroxide in Trigonox 301 will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

It is recommended that the following health and physico-chemical hazard classification be referred to the NOHSC Chemicals Standards Sub-committee for consideration:

R7	May cause fire
R38	Irritating to skin
S3/7	Keep container tightly closed in a cool place
S14	Keep away from reducing agents, acids, alkalis and heavy metal compounds

The notified chemical is a dangerous good Class 5.2 (organic peroxide), with Packing Group II assigned. Therefore it is recommended that transport, storage and handling of the notified

chemical be in accordance with the Australian Dangerous Goods Code and Australian Standard (AS) 2714-1993 (Standards Australia 1993).

To minimise occupational exposure to the notified chemical, the following guidelines and precautions should be observed:

- Direct handling procedures such as weighing should be conducted under local exhaust ventilation;
- Transfer procedures should be enclosed and automated;
- Rinsing of empty drums should be conducted in a bunded area with effective general ventilation at the user's site;
- Workers must wear overalls, face/eye protection and rubber or PVC gloves when handling the notified chemical or mixtures containing the chemical; if inhalation exposure could occur, then respiratory protection such as a half-face respirator with organic vapour cartridge should be worn;
- Spillage of the notified chemical should be avoided; spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

If products and mixtures containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, then workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Guidance in selection of protective eyewear may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998); for respirators, in AS/NZS 1715 (Standards Australia/ Standards New Zealand, 1994a) and AS/NZS 1716 (Standards Australia/ Standards New Zealand, 1994b); or other internationally acceptable standards.

14. MATERIAL SAFETY DATA SHEET

The MSDS for Trigonox 301 was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission 1994).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

If the notifier or any person introducing the notified chemical becomes aware of any of the following circumstances, or any circumstances listed in subsection 64(2) of the Act, they must notify the Director in writing within 28 days. The Director will then decide whether secondary notification is required.

i) long-term (> 60 days) repeated dose toxicity studies become available;

ii) measured work exposure studies become available;

iii) the method of use changes in such a way as to greatly increase the environmental exposure of the notified chemical, particularly to natural waters; and

iv) the conditions of use are varied from its use in the manufacture of polypropylene such that greater exposure of the public may occur.

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Attachment 1

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

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

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

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

CONJUNCTIVAE

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

IRIS

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