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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Ultranox 641

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Ultranox 641

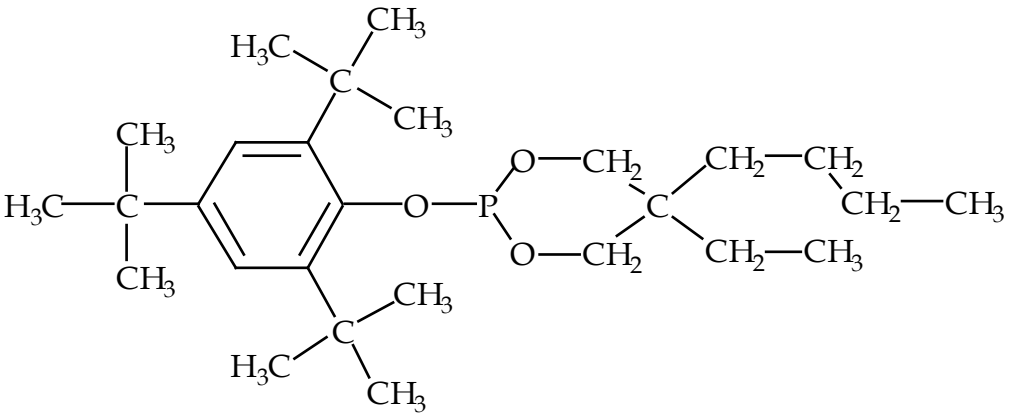
1. APPLICANT

Ultranox 641 is considered to be hazardous according to the Worksafe's *Approved Criteria for Classifying Hazardous Substances* (1). It has been shown to be a skin sensitiser in a guinea pig Maximisation test. The chemical name has been disclosed on the Material Safety Data Sheet (MSDS) in accordance with Worksafe Australia's *National Model Regulations for Control of Workplace Hazardous Substances* (2). At the request of the notifier, purity, identity of impurities, additives and adjuvants, methods of detection, spectral data, exact details and details of exact import volume have been exempted from publication in the Full Public Report and the Summary Report on the following basis:

- The chemical identity has been disclosed on the MSDS; in addition the relevant employee unions shall be informed of the conditions of use; and
- Confidentiality will expire after a 3 year period

Chemical Name:	(2,4,6-tri-t-butylphenol) 2-butyl 2-ethyl 1,3-propanediol phosphite
Chemical Abstracts Service (CAS) Registry No.:	161717-32-4
Other Names:	1,3,2-dioxaphosphorinane, 5-butyl-5-ethyl-2(2,4,6-tris(1,1-dimethyl-ethyl) phenoxy)- XR-2677
Trade Name:	Ultranox 641
Molecular Formula:	$C_{27}H_{47}O_3P$

Structural Formula:



Molecular Weight: 450

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white lumpy solid
Melting Point:	84-103°C
Specific Gravity:	1.057
Vapour Pressure:	3.0 x 10^{-5} KPa at 25°C
Water Solubility:	< 60 μg/L at 20°C
Partition Co-efficient (n-octanol/water):	log P_{ow} > 6 at pH 4
Hydrolysis as a Function of pH:	not determined (see below)
Adsorption/Desorption:	not determined (see below)
Dissociation Constant:	not determined (see below)
Flash Point:	not determined
Flammability Limits:	not highly flammable
Autoignition Temperature:	360°C (minimum autoignition temperature of dispersed dust)
Explosive Properties:	minimum explosive concentration 20 g/m^3
Reactivity/Stability:	reacts with water and strong oxidisers

Particle size:	99.4%	> 300 μm
	0.6%	150-300 μm
	0.0%	< 75 μm

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice.

The value of 60 µg/L for the water solubility represents the detection limit of the method used.

Hydrolysis as a function of pH was not provided. The notified chemical does not contain groups that would be expected to hydrolyse under environmental conditions. The partition coefficient was determined by the high performance liquid chromatography (HPLC) method. The value given by the notifier is a lower limit as the test sample was outside the range of the calibration curve. Extrapolation of the line of best fit for the standard curve yields a value of log P_{OW} of 7.8.

No information was provided on the adsorption/desorption properties of the chemical. Given the chemical's low water solubility and high partition coefficient it is anticipated that it will strongly adsorb to soils.

The notified chemical contains no dissociable hydrogens.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 90%

Toxic or Hazardous Impurities: none known

Non-hazardous Impurities: < 10%

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia but will be imported as Ultranox 641 containing a very high percentage of the notified chemical. Ultranox 641 will be used as an antioxidant/stabiliser in polymers. Applications include polyolefins, styrenics, engineering plastics, PVC, elastomers and adhesives.

Projected import volumes will be less than 100 tonnes per annum in the first five years.

6. OCCUPATIONAL EXPOSURE

It is envisaged that the notified chemical will be used by polymer producers and possibly by master batch manufacturers. During transport and storage exposure to the notified chemical is unlikely under normal handling conditions.

Laboratory staff may be exposed to the notified polymer during formulating and testing of polymer compounds. The concentration of Ultranox 641 involved is usually less than 0.1%. The most likely route of exposure is dermal, however these tasks will be carried out infrequently with exposure expected to be less than one hour.

Polymer manufacture

The polymer type and the specific polymerisation process will determine the physical form of the antioxidant, Ultranox 641 to be used. For some polymerisation processes the antioxidant has to be soluble in the monomer or in the polymerisation solvent. Ultranox 641 shows high solubility in hydrocarbon solvents, thus facilitating its incorporation by liquid dosing via metering pumps from stock solutions. In other polymerisation processes, the polymer is produced as a powder in a reactor. Antioxidants and additives are added in a solid form via automatic feeders and blended with powder prior to granulation extrusion.

Polymer manufacturing plants are fully automated, computerised and enclosed systems. There is the potential for occupational exposure to the notified chemical during the charging of the feeder tanks, when making up stock solutions or during the loading of feed hoppers. Dermal exposure is the most likely route of exposure during these operations. The potential for inhalational exposure is minimised by the low dusting pastille product form of the notified chemical and by the use of appropriate ventilation.

On completion of the polymer production process, Ultranox 641 will be completely dissolved and encapsulated in the polymer.

Masterbatch Manufacture

Ultranox 641 may also be used in masterbatch manufacture. A masterbatch is a solid mixture of one or more compounding ingredients in a suitable carrier polymer. The use of such master batch offers plastic processors accurate metering, ease of handling and completely dust free operation since the additives are encapsulated in polymer.

Often several additives, as well as colour, may be added by processors in one operation. The concentration of Ultranox 641 in masterbatch is expected to be less than 2%. Dermal exposure may occur during weighing and batch operations in the masterbatch manufacturing process. The manufacture of masterbatches is a sophisticated process using a variety of complex equipment: internal mixers, single-screw and twin-screw extruders, kneaders, blenders and pelletisers. The process essentially consists of weighing and blending of polymer (coarse powder and granules), additives (antioxidants, waxes, metal soaps, light stabilisers). Often pigment powders and fillers are also added.

Raw materials, as required, are selected from stock and weighed using mechanical scales or load cells. The weighed items are then transferred to the mixing area by fork lift trolley or by hand, and are loaded into the solid paste mixers and simultaneously checked against the manufacturing formulation. Solid phase mixing is carried out in impeller mixers. The heat generated by friction as the impeller blades rotate is sufficient to melt some of the ingredients and may often soften the polymer powder thus producing a homogenous mixture. All of the ingredients are solid and the machines used for mixing are closed to avoid dusting and minimise occupational exposure.

After discharge from the mixer, the pre-blend is fed from the hopper of an extruder into the feed zone of the screw(s), where heat softens and melts the polymer. During the mixing process the melted polymer is being compressed and forced under high pressure through the heat extrusion head. The hot extruded strands are water cooled, pelletised, dried and packed into bags. Once in this form the notified chemical is encapsulated in the polymer and occupational exposure to the notified chemical is unlikely to occur.

Process workers in the plastics industry are not expected to be exposed to the notified chemical. Ultranox 641 will be completely encapsulated in the polymer and will be present at low concentrations only (0.1% for polymer, less than 0.2% in masterbatch).

7. PUBLIC EXPOSURE

There will be widespread public contact with the finished articles including any plastic articles that contain the notified chemical. However, because the notified chemical is bound tightly to the material and is encapsulated in the polymer matrix, the potential for public exposure during use of the plastic articles is minimal. While public exposure to the notified chemical is possible following an accident, the likelihood is low in view of the quality accredited transport services and clean up and disposal services.

8. ENVIRONMENTAL EXPOSURE

Release

Under normal conditions it is not expected that the chemical would be released during storage and transportation. The MSDS contains adequate instructions for handling a spill should one occur.

The manufacturing process for polymers will involve the automatic transfer (via metering pumps for liquid additions or feeders for solid additions) of the required reactants, catalysts and other additives into a closed reactor system. Since these manufacturing processes are fully automated and closed, practically no loss of the notified chemical to the environment is expected to occur. The notifier estimates that a maximum of 10 kg of the notified chemical will be disposed of as waste to landfill as a result of polymer manufacture.

A masterbatch is a solid mixture of one or more compounds in a suitable carrier polymer. The concentration of the notified chemical in a masterbatch is expected to be below 2%. The process consists of weighing and blending of polymer, Ultranox 641 and other compounding ingredients. The blending is carried out in closed/sealed mixers. This preblending process is followed by an extrusion process that completely dissolves and encapsulates the notified chemical into the polymer. Waste from masterbatch formulation, consisting of dirty spilt material or purging material, is estimated to be less than 10 kg per annum. This material will be disposed of to landfill.

After incorporation into polymers by polymer or masterbatch manufacturers, the notified chemical will be completely dissolved and encapsulated in polymer. The manufacture of plastic articles by injection moulding or plastic extrusion is not expected to result in the release of significant amounts of the chemical. Plastic scrap is generally reprocessed into lower quality articles. Dirty spilt or purging material is generally sent to municipal landfill. The notifier estimates that such waste streams would be less than 2% of total throughput (containing <1 000 kg of the notified chemical).

• Fate

The substance was examined for biodegradation potential using EEC Directive 92/69, Part C.4-C (Modified Sturm Test), and OECD Test Guideline 301B. The substance exhibited no degradation after 28 days, indicating that it is not readily biodegradable under the conditions of the test. It was also found that the substance was not inhibitory to microorganisms under these conditions.

No testing of the bioaccumulation potential of the notified chemical was conducted. The notifier argues that the chemical has the potential to bioaccumulate, based on the high value of the partition coefficient and non-biodegradable nature of the notified chemical, which will be limited by the limited release of the chemical and its low water solubility. Any potential for bioaccumulation would be mitigated by the low environmental release and the low water solubility of the notified chemical. Further, as Log P_{OW} > 6 (at least 7.8 by extrapolation of notifier's data) the chemical is superhydrophobic and the bioaccumulation potential is diminished (3).

The notified chemical is intended for use as an antioxidant in plastics. As such, the fate of the majority of the chemical will share the fate of the plastic articles into which it is incorporated. The fate of which will be disposal 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 and phosphorous.
A small amount, less than 20 kg per year, will be disposed of to landfill as waste from the formulation of polymers or masterbatches. Any chemical which is not bound within a polymer matrix is not expected to be mobile within landfill due to its low water solubility and its high partition coefficient.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Ultranox 641

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg	(4)
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(5)
skin irritation	rabbit	slight irritant	(6)
eye irritation	rabbit	slight irritant	(7)
skin sensitisation	guinea pig	skin sensitiser	(8)

9.1.1 Oral Toxicity (4)

Species/strain:	rats/Crl:CD BR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	oral by gastric intubation, test substance administered in 0.5% methyl cellulose
Clinical observations:	red staining of the facial area and forelimbs was observed in 4 animals; yellow urinogenital staining was observed in 3 animals; there were no significant body weight changes and all animals appeared normal by day 3 or earlier
Mortality:	nil
Morphological findings:	none
Test method:	OECD Guidelines for Testing Chemicals (9)
LD_{50}:	> 5 000 mg/kg
Result:	the notified chemical is of low oral toxicity in the rat

9.1.2 Dermal Toxicity (5)

Species/strain:	albino rats/Crl: CD BR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	the test substance was applied in deionised water at a dose level of 2 000 mg/kg under a semi-occlusive dressing for 24 hours
Clinical observations:	no signs of systemic toxicity were observed
Mortality:	nil
Test method:	OECD Guidelines for Testing Chemicals (9)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical is of low dermal toxicity in the rat

9.1.3 Inhalation Toxicity

not conducted as the notifier considers it is unlikely to be a significant route of exposure

9.1.4 Skin Irritation (6)

Species/strain:	rabbit/New Zealand white
Number/sex of animals:	5 males/1 female
Observation period:	9 days
Method of administration:	500 mg of test material applied to intact skin under a semi-occlusive dressing for 4 hours
Test method:	OECD Guidelines for Testing Chemicals (9); the Draize method (10) was used to evaluate the irritation scores
Result:	very slight erythema and desquamation was observed in 1 animal until day 9 of the study; no signs of skin irritation were seen in the remaining animals the test material was a slight irritant to rabbit skin

9.1.5 Eye Irritation (7)

Species/strain:	rabbit/New Zealand white
Number/sex of animals:	7 males/2 females
Observation period:	14 days
Method of administration:	49 mg of test material (weight equivalent to 0.1 mL) instilled into the conjunctival sac of the right eye of each rabbit, the left eye serving as an untreated control; the right eyes of 6 animals in group 1 were irrigated 30 seconds after installation of the test material; the eyes of the remaining 3 animals in group 2 were not irrigated
Irrigated eyes:	positive (grade 2) conjunctival reactions were noted for all animals in group 1 and in 2 animals in group 2; one animal had grade 1 iridial irritation at one hour post installation; with the exception of grade 1 conjunctival redness in one animal in group 1 (which persisted until the end of the study), all signs of irritation had reversed by day 4 or earlier
Test method:	OECD Guidelines for Testing Chemicals (9); the Draize method (10) was used to evaluate the irritation scores
Result:	the notified chemical is a slight irritant to the rabbit eye

9.1.6 Skin Sensitisation (8)

Species/strain:	albino guinea pig/Dunkin Hartley Crl:(Ha) Br
Number of animals:	main study: 10/sex /test group 5/sex/ control group Challenge: 10/sex/group Rechallenge: 5/sex/group
Induction procedure:	Day 1: intradermal injection as follows: Freund's Complete Adjuvant (FCA)/distilled water (DW) 1:1 (v/v) test material diluted to 5% in mineral oil

test material diluted to 5% by an emulsion in a 1:1 (v/v) mixture of FCA and in mineral oil

Day 8: topical induction as follows:

test material (100%) moistened with mineral oil

Comments: one animal in the test group was found dead on day 24 but this was considered not to be treatment related; dichloronitrobenzene (DNCB) was used as the positive control

Challenge procedure: Day 22:

test material (100%) moistened with mineral oil;

a separate group previously treated with FCA and vehicle only were used as irritation controls

Rechallenge procedure: Day 29:

test material (50% w/v) in mineral oil;

a separate group previously treated with FCA and vehicle only were used as irritation controls

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
100%	8/19**	13/19	0/10	4/10

* time after patch removal
** number of animals exhibiting positive response (one test animal died on day 24, see above)

	Test animals		***Control animals***	
Rechallenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
50%	12/19**	9/19	1/10	0/10

* time after patch removal
** number of animals exhibiting positive response (one test animal died on day 24, see above)

Test method: OECD Guidelines for Testing Chemicals (9)

Result: moderate skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity and Neurobehavioural Study (11)

Species/strain:	rats/Sprague-Dawley CD
Number/sex of animals:	8/sex/group
Method of administration:	orally via gavage
Dose/Study duration::	dose levels of 100 (low dose), 300 (mid dose) and 1 000 (high dose) mg/kg or vehicle control (corn oil), administered daily for 28 days
Clinical observations:	all animals survived the course of the study and there were no adverse effects reported; body weight was unaffected; slight increases in food consumption were observed in both sexes in the mid and high dose groups; there was no evidence of a neurotoxic effects after a single dose or following repeated administration as measured by a functional observational battery of tests
Clinical chemistry/Haematology	slight but significant increases in total protein and albumin were reported in the females in the high dose group and in the males of this group significant increases in aspartate aminotransferase and alanine aminotransferase there were test related effects on coagulation parameters at termination that were more evident in the males than females; in mid and high dose groups prothrombin and activated partial thrombin time were significantly increased in the males compared to control animals; in the females significant increases in activated partial thromboplastin and platelet count were observed at the highest dose
Histopathology:	there were no treatment related macroscopic findings; however microscopic findings included hypertrophy of the central lobular hepatocytes which was observed in 3/5 males in the high dose group and in females at all treatment groups; increased absolute liver weight, liver/bodyweight and liver/brain weight ratios in mid and high dose groups were also observed; the liver/bodyweight ratio was significantly increased in the females in the low dose group and in males in the high dose

	group
Test method:	OECD Guidelines for Testing Chemicals (9)
Result:	increased liver weight and hepatocelluar hypertrophy was observed in males and females; the authors state this was due to metabolic adaptation; effects on haematological parameters were observed in both sexes in mid and/or high dose groups, however a recovery group was not included in the study and reversibility could not be determined; no signs of neurotoxicity were observed

9.3 Genotoxicity

9.3.1 Reverse Mutation Assay in *Salmonella typhimurium* and *Eschericia coli* (12)

Strains:	*S.typhimurium* TA 98, TA 100, TA 1535 and TA 1537; *E.coli* WP2 *uvr* (pKM101) and WP2 (pKM101) in the presence and absence of arochlor-induced rat liver S9
Concentration range:	5 000 μg/plate for the test material
Test method:	OECD Guidelines for Testing Chemicals (9)
Result:	the notified chemical was not mutagenic under the conditions of the assay; the positive controls gave the appropriate responses

9.3.2 Mouse Lymphoma Forward Mutation Assay (13)

Cell line:	L5178Y/TK$^{+/-}$ in the presence and absence of arochlor-induced rat liver S9
Concentration range:	100 to 500 μg/plate for the test material
Test method:	OECD Guidelines for Testing Chemicals (9)
Result:	the notified chemical was not mutagenic under the conditions of the assay; the positive controls gave the appropriate responses

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (14)

Species/strain:	mouse/Sprague-Dawley Harlan
Number and sex of animals:	5/sex/group
Doses:	1 250, 2 500 or 5 000 mg/kg of test material and vehicle control
Method of administration:	intraperitoneal
Test method:	OECD Guidelines for Testing Chemicals (9)
Result:	the notified chemical did not induce a significant increase in micronucleated polychromatic erythrocytes; not mutagenic; the positive controls gave the appropriate responses

9.4 Overall Assessment of Toxicological Data

Ultranox 641 has been shown to be of low acute oral and dermal toxicity in rats (LD_{50} > 5 000 mg/kg and > 2 000 mg/kg respectively). It caused slight skin and eye irritation in rabbit studies and was a moderate skin sensitiser in guinea pigs. A subacute oral study was performed in rats and an assessment was made of neurological effects using a functional observational test battery. There was no evidence of neurotoxic effects. Test related observations included changes in the clinical chemistry, haematological profile and metabolic adaptation in the liver at doses above 100 mg/kg/day in males and 300 mg/kg/day in females. No mutagenic activity was observed in *in vitro* and *in vivo* studies including the mouse micronucleus test.

On the basis of the data provided by the notifier, Ultranox 641 is classified as a skin sensitiser according to the Worksafe criteria (1).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

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

Test	*Species*	*Results*
acute toxicity	Zebra fish *Brachydanio rerio*	NOEC > 0.31 mg/L
acute toxicity	*Daphnia magna*	NOEC > 0.35 mg/L
Growth inhibition	Algae *Scenedesmus subspicatus*	NOEC > 0.22 mg/L
Respiration inhibition	Micro-organisms in aerobic activated sludge	NOEC > 100 mg/L

* NOEC - no observable effect concentration

In the above tests, supersaturated stock suspensions were prepared by stirring 100 mg/L of the notified chemical for 2 hours. These suspensions were filtered through a coarse filter paper and used without dilution. The measured concentrations of the notified chemical in the tests were well above the water solubility of the chemical. Thus, the test solution contained finely dispersed particles of the notified chemical. This is reflected in substantial decreases (up to 39%) of the concentrations of the notified chemical measured during the tests, as a result of the deposition of the particles of the chemical.

The ecotoxicity data for the notified chemical showed no toxic effects to fish, *Daphnia* and algae at concentrations well above the water solubility of the chemical. The activated sludge respiration inhibition test indicated that Ultranox 641 does not inhibit respiration of microorganisms at concentrations well above the water solubility of the chemical.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will be used as an antioxidant in polymers, which will be injection moulded or extruded into plastic articles. Once incorporated into the polymers the notified chemical is expected to remain within the polymer matrix. Hence, the majority of the notified chemical will share the fate of the plastic articles that will be disposed of to landfill or incinerated at the end of their useful lifetime. In landfill it is expected that the notified chemical will remain immobile.

Waste from the manufacture of plastic articles, polymers and masterbatches (<1 000 kg per annum) will be disposed of to landfill where it is expected that it will be immobile.

Hence, the overall environmental hazard of the chemical can be rated as low, given the low environmental exposure and lack of environmental toxicity up to the notified chemical's solubility in water.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical presents negligible risk to transport and storage workers under normal working conditions

Ultranox 641 will be used by laboratory staff during formulation and testing of polymer compounds. During these operations there is the potential for dermal exposure to occur. However, these tasks will be carried out infrequently and the amounts of notified chemical used in these procedures are very small. Therefore, the occupational health risk is considered to be minimal.

The potential for occupational exposure will be higher for those workers involved in polymer production. The procedures where exposure is most likely to occur include charging of feeder tanks, mixing of stock solutions and loading of feed hoppers. During these operations exposure via the dermal route is the most likely. The potential for inhalational exposure will be minimised by the low-dusting form of the notified chemical and by use of adequate ventilation. The notified chemical is a skin sensitiser and a potential skin and eye irritant. However, as the majority of the production processes will be carried out in a closed system, the health risk associated with the above procedures is considered to be low to moderate.

During masterbatch manufacture dermal exposure is likely to occur when workers are weighing and in batch operations. However, the notified chemical is expected to be used at low concentrations (< 2%) and much of the operations are carried out in closed systems therefore the health risk is considered to be low.

In the plastics industry process workers will only handle the notified chemical when it is encapsulated in the polymer and present at very low concentrations. The health risk of the notified chemical for these workers is considered to be minimal.

Based on the use pattern of the notified chemical, is considered that it will not pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Ultranox 641 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (15) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (16);
- Industrial clothing should conform to the specifications detailed in AS 2919 (17);
- Impermeable gloves or mittens should conform to AS 2161 (18);
- All occupational footwear should conform to AS/NZS 2210 (19);

- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly and put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.
- If ventilation and work practices are insufficient to reduce inhalational exposure to the Ultranox 641 to a safe level, as may occur during weighing and formulation then it is advisable for the appropriate respiratory device to be used. It should be selected and used in accordance to (AS/NZS) 1715 (20) and should comply with AS/NZS 1716 (21);

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (22).

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

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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14. Putman, D.L., Gudi, R. & Young, R.R. 1995, *Micronucleus Cytogenetic Assay in Mice*, Project no., G94BU49.122, Micrbial Associates, Inc, Maryland, USA.

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18. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves)*, Standards Association of Australia, Sydney.

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20. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1715-1994, Selection, Use and Maintenance of Respiratory Protective Devices*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

21. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

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

Attachment 1

The Draize Scale 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.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	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