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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Phosphoric Trichloride, Reaction Products with Bisphenol A and Phenol

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Director
Chemicals Notification and Assessment

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Phosphoric Trichloride, Reaction Products with Bisphenol A and Phenol

1. APPLICANT

Plastral Fidene Pty Ltd of 11B Lachlan St WATERLOO NSW 2017 (ACN 000 144 132) has submitted a standard notification statement in support of their application for an assessment certificate for "Phosphoric trichloride, reaction products with bisphenol A and phenol".

2. IDENTITY OF THE CHEMICAL

The molecular and structural formulae, molecular weight, spectral data, and purity have been exempted from publication in the Full Public Report and the Summary Report.

Chemical Name:	Phosphoric trichloride, reaction products with bisphenol A and phenol
Chemical Abstracts Service (CAS) Registry No.:	181028-79-5
Other Names:	None
Marketing Name:	NcendX P-30

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	A viscous slightly cloudy liquid
Boiling Point:	>240-250°C
Specific Gravity:	1.248-1.272 at 25°C
Relative Density:	1.2576 at 20°C
Vapour Pressure:	3.1×10^{-19}kPa at 25°C
Water Solubility:	$<2 \times 10^{-5}$g/L at pH 4.0, 7.0 and 9.0 (flask method)
Partition Co-efficient (n-octanol/water):	Log P_{OW} = 4.0-5.2 (HPLC method)

Hydrolysis as a Function of pH:	See comments below.
Adsorption/Desorption:	Log K_{OC} = 6.0-18.2
Dissociation Constant:	Not determined
Particle Size:	The notified chemical is a liquid.
Flash Point:	>360°C (closed cup method)
Flammability Limits:	Not flammable
Autoignition Temperature:	625°C
Explosive Properties:	None expected
Reactivity/Stability:	Stable

3.1 Comments on Physico-Chemical Properties

Boiling point, water solubility and partition coefficient were determined using accepted OECD test methods (Lightbody, 1999).

The boiling point was determined by Lightbody (1999) using the Siwoloboff Method where a capillary tube with a fused end is placed in the sample tube with enough of the sample substance to submerge the fused part. The apparatus was heated until bubbles emerged rapidly from the capillary. The boiling point was taken as the temperature at which, on momentary cooling, the string of bubbles stops and fluid rises in the capillary. No boiling occurred below 250ºC in the first test and 240ºC in the second test.

The specific gravity was determined by Cobb & Featherstone (1999) using an Anton Paar DMA 48 Density Meter and a Cannon N.8 certified viscosity standard.

The relative density was determined by Lightbody (2000) using the pycnometer method. The test was carried out in triplicate with results ranging from 1.2533 to 1.2630.

The vapour pressure was determined by Tremain (2000) using a balance system where the vapour pressure was determined at a number of temperatures using a mass difference technique. The data was extrapolated to provide a value for 25 ºC.

The water solubility was determined by Lightbody (1999) in triplicate using the flask method. Approximately 100 mg of the test material was weighed into three separate flasks, and 20 mL of aqueous media (Milli-Ro water at pH 4, pH 7 and pH 9) was added. The flasks/vials were shaken in an orbital shaker at 30ºC and 200 rpm. Samples were removed at 24, 48 and 72 hours using three replicates for each period. Following agitation the sample aliquots were allowed to stand for at least 24 hours at 20 ºC, and the resulting solutions were centrifuged, filtered and analysed for the dissolved material using High Performance Liquid Chromatography (HPLC). The water solubility at 20ºC was determined to be $<2 \times 10^{-5}$g/L.

The rate of hydrolysis of the compound was investigated using the screening test of OECD TG 111 (Lightbody, 2000) but the low water solubility of the compound (and therefore low levels of material used) proved insufficient for the method to detect a 10% change in the concentration of the test material.

The n-octanol/water partition coefficient was determined by Lightbody (1999) using the HPLC method with UV detection. The retention time of the test compound was compared with those for nine reference compounds with known values for Pow. The reference compounds included thiourea, bromobenzene, acetanilide, 4-chlorophenol. The first test run, using methanol/water as the mobile phase, gave small peaks equivalent to a partition co-efficient of 4.0 (due to the monomer) and 5.2 (due to the dimer). The second test run, using acetonitrile/water as the mobile phase, gave small peaks equivalent to 4.1 and 4.7, confirming that the partition co-efficient is between the range of 4.0-5.2.

The value for Log Koc, which is a measure of the compound's ability to bind to the organic component of soils and sediments was estimated by Lightbody (1999) using the partition co-efficient in the following equation: Log Koc = 0.81 X Log Kow + 0.10. The high value for the calculated Log Koc indicates that the chemical will bind strongly to the organic component of soils and sediments.

Due to the low water solubility of the new compound determination of dissociation constant is not possible. It contains no acidic or basic groups, so dissociation constant data are not considered necessary.

4. PURITY OF THE CHEMICAL

Degree of Purity: >90%

Hazardous Impurities:

Chemical name:	Triphenyl phosphate
Synonyms:	Phosphoric acid, triphenyl ester
CAS No.:	115-86-6
Weight percentage:	0.5-5.0
Toxic properties:	Cholinesterase inhibitor; Moderately toxic by ingestion; Toxic by inhalation (HSDB); NOHSC Exposure Standard 3 mg/m^3 TWA (NOHSC, 1995).
Chemical name:	Phenol
Synonyms:	Carbolic acid
CAS No.:	108-95-2
Weight percentage:	< 0.05%
Toxic properties:	Toxic in contact with skin and if swallowed; Causes burns; Irritating to eyes and skin (NOHSC, 1999b); NOHSC Exposure Standard 1 ppm TWA 'skin

notation' (NOHSC, 1995).

Additives/Adjuvants: None.

5. USE, VOLUME AND FORMULATION

The notified chemical, NcendX P-30, is to be incorporated as a halogen-free flame retardant for polycarbonate/acrylonitrile-butadiene-styrene blend (PC/ABS) and polystyrene/ polyphenylene oxide blend (PS/PPO) resin systems. The PC/ABS and PS/PPO resin systems are used to make electronic enclosures, such as monitors, televisions and computers. The concentration of the notified chemical in the compounded products is expected to be in the 10-20% range.

In the first year, most of NcendX P-30 will arrive in Australia as a component in compounded plastic articles. Later on, uncompounded chemical will be shipped as a liquid (≥95%) in 250 L steel drums or 20 000 L isotanks. Long-term expectations are that most of the notified chemical will continue to enter Australia as a component in compounded plastic articles. The annual import volume of the notified chemical is as follows:

Year	1	2	3	4	5
Volume (tonne)	10	20	50	50	50

6. OCCUPATIONAL EXPOSURE

Transport, storage and laboratory staff
There will be 10-50 personnel including wharf handlers and 10 store personnel/laboratory staff involved in the transport, storage and analysis of the notified chemical.

The concentration of NcendX P-30 will be 95% minimum when it is shipped uncompounded. Transportation personnel will receive the containers and transport them between the receiving port and receiving store. Stores personnel will receive and store the shipping containers. Transport workers will then move the containers to the production sites.

These workers could be exposed to the notified chemical only in the case of an accident where the packaging is breached.

Production process
The notifier estimated that there would be 20 production process operators involved in formulating the uncompounded notified chemical.

Production process operators will measure the notified chemical, transfer it to a holding tank by direct pour or pressure/vacuum line transfer, control mechanical mixing and dispense the mixture into moulds. In this operation, NcendX P-30 and compounding agent are pumped direct from containers or holding tanks to a mixing head/dispenser and injected directly into moulds, which can be single or multiple moulds, in static or moveable carousels. The compounded product is removed from moulds either manually or is automatically ejected. The concentration of NcendX P-30 in the compounded products is expected to be 10-20%.

These workers also undertake occasional cleaning of tanks and drums. In the production process, dermal contact is considered to be the main route for occupational exposure.

Production processes including the delivery, mixing and dispensing processes used in casting operations are automated and contained. Local ventilation will be used to maintain low levels of fugitive emission from the sources in the compounding process. Dust containing the notified chemical is not anticipated but if present at above the NOHSC inspirable dusts level (10 mg/m^3), a particulate respirator with full head covering and eye protection will be used. Other personal protective equipment the notifier proposed includes eye protection, chemical impermeable gloves and work clothing.

End use
After compounding into plastic, NcendX P-30 will be encapsulated and physically contained within the material. No cutting, sawing or machining of the plastic articles that contain NcendX P-30 is expected. Thus, no exposure is anticipated after compounding.

7. PUBLIC EXPOSURE

The notified chemical is not available for sale to the general public but will be used as a flame retardant ingredient in compounded plastic products that may be available to the public. The potential for public exposure to the notified chemical during transport, reformulation or disposal is assessed as negligible. Plastic products containing the notified chemical will be used as housings for items such as televisions, computers and monitors and the notifier has stated the notified chemical and any impurities will be physically contained within the plastic matrix. Therefore there is little potential for exposure.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Very little release of the chemical is anticipated during use of the formulated granules in the preparation of the moulded plastic products.

When the liquid form of the chemical is used for formulating polymer granules in Australia, residues left in the 200 L drums will be washed out with an appropriate solvent and collected by an approved waste contractor for disposal. It is anticipated that 0.5 kg will remain in each drum after 'emptying' which will result in a release of up to 100 kg/annum. The empty drums will be scrapped for metal recovery or re-used after cleaning. When the liquid material is transported in isotanks, no release to the environment from residues is expected, as the tanks will be returned to the USA for cleaning and re-use.

The notifier indicates that some of the NcendX P-30 will be released in a liquid form from equipment cleaning. This waste will be collected and sent for processing at an appropriate waste treatment plant, burnt off or subjected to biological treatment. There is also potential for some release of the polymer containing the new chemical from pipes and ducts in the extrusion equipment during routine maintenance of equipment. However, most of this is expected to be in an inert solid state with the new substance bound within the polymer matrix. It is expected to be placed into landfill for disposal. The notifier has estimated that

approximately 1% of the new substance will be lost as waste during production, which equates to up to 500 kg/annum at maximum import volume.

Initially polymer formulations containing the new chemical are to be used in the manufacture of moulded casings with wide distribution throughout the community. Long term release of the chemical as result of discarding old consumer products or electrical equipment would be very diffuse.

Some release of the chemical is possible as a result of "blooming" from the manufactured articles during day to day use. This process is the slow diffusion of the chemical from the interior of the plastic article to the surface. It may be removed through cleaning processes and released in waste water, presumably mainly to sewer. However, the notifier indicated that the blooming of the new compound from the plastic articles is unlikely due to the low vapour pressure and low water solubility and high molecular weight of the substance.

While recycling of the plastic in discarded articles is theoretically possible, this is not anticipated to take place on a large scale. Consequently, the majority of the imported chemical will be discarded with old plastic articles at the end of their useful lives, and these are likely to be either incinerated or be placed into landfill.

8.2 Fate

A test for ready biodegradability conducted according to the Modified Sturm Test (OECD TG 301) indicated that the chemical only very slowly degraded under the conditions of the test (Armstrong & White, 1999). Measurements after 28 days incubation of the test substance with sewage sludge indicated a maximum of 2% degradation. The reference compound used during this test was sodium benzoate, and 68.7% biodegradability was achieved by day 7 and a cumulative total of 84.9% was achieved by test termination. The result of this test indicates that the new chemical is not readily biodegradable.

Little of the new chemical is likely to be released during the manufacturing process, and most of this that is released is likely to be placed into landfill. The notifier indicates that this is the preferred method for disposal. However, if in the future some of the waste is in liquid form, it will be subject to treatment before release to the environment. The eventual fate of the majority of the imported chemical will be strongly linked to that of discarded plastic articles, and these are likely to be either placed into landfill or be incinerated.

Material disposed of into landfill will be incorporated in a solid polymer matrix (ie the plastic article) where it will be immobilised. However, the polymer matrix will be slowly degraded through the biological and abiotic processes operative in landfills, and release the notified chemical. Blooming of the polymer on broken pieces of plastic would contribute to this mode of release.

The compound has a large estimated value for Koc (Log Koc 6.0-18.2) indicating strong affinity for the organic component of soils and sediments, and low mobility in these media. The chemical is not readily biodegradable, but when bound to, or otherwise associated with soils and sediments it could be expected to be slowly degraded through the agency of biological and abiotic processes operative within landfills.

Complete combustion of the chemical in the presence of excess oxygen would be expected to destroy the material with production of water vapour and oxides of carbon. Some solid phosphate salts would also be formed, and these would become incorporated with the waste incinerator ash.

The high value for Log Pow (4.0-5.2), relatively low molecular weight (692.7-1425.4) and low water solubility (<2 X 10^{-5}g/L) indicate large potential for bioaccumulation (Connell, 1990). However, since the compound is expected to slowly biodegrade, and is in any case unlikely to enter the water compartment in significant volumes, the potential for bioaccumulation is expected to be low.

9. EVALUATION OF TOXICOLOGICAL DATA

Tests were performed according to EEC/OECD guidelines at facilities complying with OECD Principles of Good Laboratory Practice. All toxicity studies were conducted on the notified chemical, NcendX P-30.

9.1 Acute Toxicity

Summary of the acute toxicity of NcendX P-30

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50}>2 000 mg/kg	Donald & Edgar, 1999
acute dermal toxicity	rat	LD_{50}>2 000 mg/kg	Edgar, 1999a
skin irritation	rabbit	Slightly irritating	Edgar, 1999b
eye irritation	rabbit	Slightly irritating	Edgar, 1999c
skin sensitisation	guinea pig	Non-sensitising	Edgar, 1999d

9.1.1 Oral Toxicity (Donald & Edgar, 1999)

Species/strain:	Rat/Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	2 000 mg/kg, administered by oral (gavage)
Test method:	OECD TG 401; limit test
Mortality:	No deaths were recorded.
Clinical observations:	No clinical signs of toxicity were noted.
Morphological findings:	No abnormalities were noted at necropsy.

Comment:	None.
LD_{50}:	>2 000 mg/kg
Result:	The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Edgar, 1999a)

Species/strain:	Rat/Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	A dermal dose of 2 000 mg/kg was applied under an occlusive dressing for 24 hours.
Test method:	OECD TG 402, limit test
Mortality:	No deaths were recorded.
Clinical observations:	Red discharge from the nose was observed on Day 1.
Morphological findings:	No abnormalities were noted at necropsy.
Comment:	None,
LD_{50}:	> 2 000 mg/kg
Result:	The notified chemical was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity

An inhalation toxicity study was not provided.

9.1.4 Skin Irritation (Edgar, 1999b)

Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	3 females.
Observation period:	7 days
Method of administration:	A volume of 0.5 mL was applied under a semi-occlusive dressing for 4 hours.
Test method:	OECD TG 404

Draize scores:

Animal #	*Time after treatment*				
	1 h	*24 h*	*48 h*	*72 h*	*Day 7*
Erythema					
1	[a]0	0	1	1	0
2	0	0	0	0	0
3	1	1	1	1	0
Oedema					
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0

[a] see Attachment 1 for Draize scales

Comment: Very slight erythema was observed up to 3 days after patch removal in 2 animals.

Result: The notified chemical was slightly irritating to the skin of rabbits.

9.1.5 Eye Irritation (Edgar, 1999c)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 3 females

Observation period: 6 days

Method of administration: A volume of 0.1 mL was instilled into the conjunctival sac of one eye.

Test method: OECD TG 405

Draize scores:

	Time after instillation														
Animal	***1 h***			***24 h***			***48 h***			***72 h***			***Day 5***		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	0	1	0	0	1	0	0	1	0	0	1	0	0	0
2	1	0	1	0	0	1	0	0	1	0	0	1	0	0	0
3	1	0	1	0	0	1	0	0	1	0	0	1	0	0	1

[1] see Attachment 1 for Draize scales

r = redness c = chemosis d = discharge

Draize scores for cornea (opacity and area) and iris were zero during the study. The Draize scores for conjunctiva of animal number 3 became zero on Day 6.

Comment: Slight conjunctival redness was observed in all animals 1 hour after treatment. Slight discharge was also observed in all animals up to either 72 hours after treatment or day 5 of the study.

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

9.1.6 Skin Sensitisation (Edgar, 1999d)

Species/strain: Guinea pig/Dunkin Hartley.

Number of animals: Test group: 20;
Control group: 10.

Induction procedure:

test group: Intradermal Induction:

day 1 Three pairs of intradermal injections (0.1 mL) across the scapular region of the animals (vehicle: maize oil):

- Freund's complete adjuvant (FCA) 1:1 in water;
- 30% notified chemical in vehicle;
- 30% notified chemical in a 1:1 mixture of FCA and water.

Topical Induction:

day 7 A 48-hour occluded application of the notified chemical (50% in vehicle) to the test area.

control group: Treated similarly to the test animals using vehicle instead of the notified chemical in the intradermal injections and topical application.

Challenge procedure:

day 21 Test and Control animals:
Occluded applications of a patch of 100% notified chemical on the upper left flank and a patch of the vehicle on right flank of each animal for 24 hours.

Test method: OECD TG 406

Challenge outcome:

Challenge concentration	*Test animals*		*Control animals*	
	*24 hours**	*48 hours**	*24 hours*	*48 hours*
Vehicle	**0/19	0/19	0/10	0/10
100%	0/19	0/19	0/10	0/10

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

Comment: One animal in the test group was found dead prior to intradermal induction.

Result: The notified chemical was non-sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity (Rusty & Rush, 2000)

Species/strain: Rat/Sprague Dawley Crl:CD

Number/sex of animals: 5/sex/group; 3 test groups, 1 control group, 2 recovery groups (high dose and control)

Method of administration: Oral (gavage)

Dose/Study duration: Control group: 0 mg/kg/day;
Low dose group: 250 mg/kg/day;
Mid dose group: 500 mg/kg/day;
High dose group: 1 000 mg/kg/day;
Vehicle: polyethylene glycol 400 (PEG 400).

Animals were treated for 28 consecutive days followed by a 14 day treatment free (recovery) period for the recovery groups.

Test method: OECD TG 407

Clinical observations:
There were no deaths during the study period.

There were no significant differences in bodyweight gain, food consumption, and clinical signs among the groups during the treatment or recovery phases of the study.

Weekly neurotoxicological examination of the animals during the treatment phase did not show any notable abnormalities. The high-dose males at the end of the recovery phase had some statistically significant increases in arousal, motor activity and rearing. These were not considered to be of toxicological significance, because they were noted 2 weeks following cessation of treatment and were found in relation to the lower than usual responses in mean arousal and motor activity in control animals.

Clinical chemistry/Haematology
There were no toxicological significant differences in clinical chemistry or haematology parameters evaluated. Changes were noted in thromboplastin time, platelet count, and cholesterol in some groups, but there was a lack of a clear dose-response relationship and these results were within or near the historic control ranges in the test laboratory.

Pathology:
There were no toxicological significant differences in organ weights among the groups during the treatment or recovery phases of the study. The statistically significant increase in relative adrenal gland weights in mid-dose females was not considered to be treatment-related, because there was no dose-response relationship and the absolute weights were unaffected.

There were no significant differences in gross necropsy observations among the groups during the treatment or recovery phases.

There were no treatment related microscopic lesions among the control and the high-dose groups examined in the study.

Comment:
Oral administration of the notified chemical to rats for a period of 28 consecutive days at dose levels up to 1 000 mg/kg/day produced no treatment-related changes in the parameters measured.

Result:
The notified chemical was considered to have a No Observed Effect Level (NOEL) of 1 000 mg/kg/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Cattanach, 1999)

Strains:	*Salmonella typhimurium* TA1535, TA1537, TA98 and TA100, and *Escherichia coli* WP2*uvr*A
Metabolic activation:	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.
Concentration range:	First test: 0, 156.25, 312.5, 625, 1250, 2 500 and 5 000 μg/plate. Second test: 0, 15.6, 31.25, 62.5, 125, 250 and 500 μg/plate. DMSO was used as the vehicle. Triplicate plates were prepared for each bacterial strain and dose level, in both the presence and the absence of S9-mix.

Positive controls:
When with S9 mix
2-aminoanthracene for all strains.

When without S9 mix
2-nitrofluorene (2-NF) for TA98;
Methyl methanesulphonate (MMS) for TA100;
9-aminoacridine (9-AA) for TA1537; and
N-ethyl-N-nitro-N-nitrosoguanidinne (ENNG) for TA1535 and WP2*uvr*A.

Test method: Similar to OECD TG 471 & 472

Comment: Precipitation was observed at 312.5 µg/plate and above. There was no toxicity to the bacteria under the test conditions.

Under the conditions of the study, the notified chemical caused no substantial increases in revertant colony numbers over control counts at any concentration in either the presence or absence of the rat liver microsomal enzymes.

All positive and negative controls responded appropriately.

Result: The notified chemical was considered to be non-mutagenic under the conditions of the assay.

9.3.2 Chromosome aberration test in CHO cells *in vitro* (Murie, 2000)

Cells: Chinese hamster ovary (CHO) cells

Metabolic activation: Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.

Experimental design: Two independent experiments were conducted in duplicate. DMSO was used as the vehicle. The experimental design and concentrations tested are tabulated below:

Metabolic Activation	***Experiment No***	***Test substance concentration (µg/mL)***	***Controls***
-S9	1	22 hour treatment: 0, 20, 39, 78, 156, 313, 625, 1 250, 2 500 and 5 000.	Positive: MMS. Negative: DMSO.
	2	22 hour treatment (24 hour harvest): 0, 39, 78, 156, 313, 625 and 1 250. 46 hour treatment (48 hour harvest): 0, 39, 78, 156, 313, 625 and 1 250.	Positive: MMS. Negative: DMSO.

+S9	1	6 hours treatment: 0, 20, 39, 78, 156, 313, 625, 1 250, 2 500 and 5 000.	Positive: CPH. Negative: DMSO.
	2	6 hours treatment (24 hour harvest): 0, 39, 78, 625, 1 250 and 2 500. 6 hours treatment (48 hour harvest): 0, 39, 78, 625, 1 250 and 2 500.	Positive: CPH. Negative: DMSO.

- cultures selected for metaphase analysis
DMSO: Dimethyl sulphoxide
CPH: cyclophosphamide

Test method: OECD TG 473

Comment: Precipitation increased gradually from 78 µg/mL. Cytotoxicity was observed at 156 and 625 µg/mL and above with and without S9 mix, respectively in the first test, and at 625 and 156 µg/mL and above with and without S9 mix, respectively in the second test.

The test substance did not induce any significant or dose-related increases in the frequency of cells with aberrations in either experiment.

All positive and negative controls responded appropriately.

Result: The notified chemical was considered to be non-clastogenic under the conditions of the study.

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Watson & Innes, 2000)

Species/strain: Mice/CD-1

Number and sex of animals: Test group: 10/sex,
Vehicle control group: 5/sex,
Positive control group: 5 males.

Doses: Dosing: 2 000 mg/kg at 0 and 24 hours.
Sampling: 48 hours.

Vehicle: maize oil.
Positive control: CPH.

Method of administration: Oral (gavage).

Test method: OECD TG 474

Comment:	No animal deaths occurred and no adverse effects were observed following treatment. No significant increase in micronucleated polychromatic erythrocytes compared to the controls. Both positive and negative controls responded appropriately.
Result:	The notified chemical was non clastogenic in bone marrow cells of the mouse *in vivo*, under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity (LD_{50} >2 000 mg/kg) and low acute dermal toxicity (LD_{50} >2 000 mg/kg) in the rat. An inhalation study was not provided. It was slightly irritating to rabbit skin and eye and non-sensitising to guinea pig skin.

The notified chemical contains triphenyl phosphate as an impurity at concentrations up to 2.3%. Triphenyl phosphate is a cholinesterase inhibitor with signs of toxicity likely to be similar to other cholinesterase inhibitors and to include delayed peripheral neuritis leading to flaccid paralysis.

In a repeat dose study, rats were given NcendX P-30 by oral gavage at doses of 0, 250, 500 and 1000 mg/kg bw/day for 28 days followed by a 14 day recovery period. There were no treatment-related changes in any of the measured parameters. Males at 1 000 mg/kg/day had statistically significant increases in arousal, rearing and motor activity 2 weeks after treatment had ceased. Since only 0 and 1 000 mg/kg/day groups were assessed at day 40, it was not possible to determine whether there was a dose-response relationship. However, no similar changes occurred during treatment, no similar increases were observed in females and there were no gross morphological or microscopic changes indicative of neurotoxic damage. Therefore, the changes observed in males were considered unlikely to be toxicologically significant. The results of the study allowed an NOEL of 1 000 mg/kg/day (highest dose tested) to be established.

In genotoxicity studies, the notified chemical was not mutagenic in bacteria, nor did it induce an increased incidence of chromosomal aberrations in Chinese hamster ovary cells *in vitro*. The notified chemical was non-clastogenic in an *in vivo* micronucleus assay in mice.

Based on the available data, the notified chemical has a toxicology profile that does not require classification as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided the following ecotoxicity data, which were performed in accordance with OECD Test Guidelines.

Test	*Species*	*Results (Nominal)*
Acute Toxicity [OECD 203]	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}(96 h) > 0.025 mg/L NOEC = 0.025 mg/L
Acute Immobilisation [OECD 202]	*Daphnia magna*	EC_{50}(48 h) > 0.034 mg/L NOEC = 0.034 mg/L
Reproduction Test [OECD 211]	*Daphnia magna*	EC_{50}(21 days) > 0.02 mg/L NOEC = 0.02 mg/L
Inhibition of Algal Growth [OECD 201]	*Selanastrum subspicatus*	EbC_{50} (72 h) > 0.02mg/L NOEC = 0.02 mg/L
Inhibition of Bacterial Respiration [OECD 209]	Activated sludge bacteria	Not inhibitory (See notes below)

Fish

The acute test on rainbow trout (Knight, 2000a) was a Semi-static Limit Test (replacement of test solutions at 24 h intervals) performed over 96 hours using a solution of the test substance made up at a nominal concentration of 2 mg/L in reconstituted fresh water prepared according to a modified OECD method. The test was performed using ten fish in the test vessel. A solvent control and a non-solvent control were run in parallel, also using ten fish. During the tests the temperature was between 14.1-14.9ºC, while the pH was always between 7.1 and 7.4 and dissolved oxygen at or above 88% air saturation.

It is to be noted that the nominal concentration of 2.0 mg/L for the test chemical was greater than the measured water solubility (<0.02 mg/L), and in order to attain this nominal concentration, a co-solvent (acetone) was used. Firstly a stock solution was prepared by dissolving 100 mg of the new substance in 5 mL of acetone. A 2 mL aliquot was added to the test vessels in order to produce the indicated nominal concentrations. However, analysis of samples of the test solutions taken at 0 and 24 hours indicated concentrations of 0.041 mg/L and 0.015 mg/L, respectively. Therefore the mean measured concentration of NcendX P-30 over the 24 h replacement period was taken to be 0.025 mg/L. It is likely that there was undissolved precipitate present in the test tanks, as the nominal concentration of the test substance was two orders of magnitude higher than the measured concentration of the substance.

All test specimens survived over the 96 hour test period. Further, no physical or behavioural anomalies were observed during the test period, and it was concluded that the new chemical is non toxic to rainbow trout up to the limits of its water solubility.

Daphnia (Acute Immobilisation)

The tests on *Daphnia magna* (Knight, 2000b) were conducted over a 48 hour period, using a static limit test methodology (no replacement of test solution). As with the fish test, the test solution was prepared using acetone. Four replicate tests were conducted using ten daphnia in each test vessel, together with four solvent controls and four non-solvent controls, also using ten test animals. During the tests the temperature was between 19.9-20.8ºC, while the pH was always between 8.3-8.4 and dissolved oxygen at or above 82% of air saturation. Analysis of samples of the water for the new compound at 0 and 48 hours found concentrations of

0.077 and 0.015 mg/L, respectively, which equates to a mean measured concentration of 0.034 mg/L (when centrifuged) of NcendX P-30.

No immobilisation or other aberrant behaviour of any of the test daphnia was observed during the course of the test. These results indicate that the new chemical is not toxic to this species up to the limits of its water solubility.

Daphnia (Reproduction)

The tests on *Daphnia magna* (Knight, 2000c) were conducted over a 21 day period, using a semi-static limit test methodology (test solutions renewed at either 48 h or 72 h intervals). As with the fish and daphnia test, the test solution was prepared using acetone. Ten replicate tests at the following nominal concentrations (0.0125, 0.025, 0.05, 0.1 and 0.2 mg/L) were conducted using one daphnia of between 6 and 24 h old added to each tank at test initiation. Ten solvent controls and ten non-solvent controls were run, also using one test parent. During the tests the temperature was between 20.0-21.0ºC, while the pH was always between 8.2-8.6 and dissolved oxygen at or above 88% of air saturation. Analysis of samples of the water for the new compound at 0, 2, 9, 11, 19 and 21 days found the mean concentrations of the test solutions were <0.006, 0.010, 0.015, 0.021 and 0.022 mg/L, respectively.

The EC50 could not be calculated for number of neonates per reproducing adult as the percentage reduction values did not span 50% of the control. The EC50 was therefore concluded to be greater than the maximum achievable solubility of NcendX P-30 in the test (0.022 mg/L). The NOEC for daphnia reproduction was determined to be 0.021 mg/L at days 14 and 21. These results indicate that the new chemical has no effect on daphnia survival and reproduction up to the limits of its water solubility.

Algae

A limit test on the inhibition of algal growth (Knight, 2000d.) was also conducted on *Selanastrum subspicatus* over a 72 hour incubation period at 24-25ºC with nominal concentration of the test material of 2.0 mg/L. The test material was introduced to the solutions in the manner indicated above for fish and daphnia. Six replicate tests were conducted in 250 mL Erlenmeyer flasks, together with six solvent and six non-solvent control flasks. Each flask contained 50 mL of the test medium, and the flasks were ultrasonicated for 2-3 min to aid solubility. The pH of the test solutions remained between 8.0 and 8.5 for the duration of the test. The growth of algal biomass was determined over the test period by removing aliquots which were centrifuged and the algal cell concentration measured using a Compound Light Microscope and Neubauer Counting Chambers. The average specific growth rate was measured for each replicate flask during the experimental period using daily cell counts. Growth curves were calculated for each test concentration and the area under each curve determined. There was no apparent difference between growth rates and areas under growth curves for test and solvent controls. Consequently it was concluded that the new compound is not inhibitory to growth of algae up to the limits of its water solubility.

Analysis of the solutions for the test compound at 0 and 72 hours to confirm the concentration of the test material gave results of 0.035 and 0.011 mg/L, respectively, with a mean concentration of 0.02 mg/L.

Sewage Bacteria

A test on the inhibition of bacterial respiration was also conducted (Armstrong, 2000). The test substance was suspended in de-ionised water at nominal loadings of 10, 31.6, 100, 316

and 1,000 mg/L using a 3-6 minute sonication to assist dispersion (there was undissolved test material visible in the 1000 mg/L flask). The test flasks were prepared by adding synthetic sewage feed to the sewage sludge bacteria then introducing the de-ionised water with the test dispersions. Following a 3 hour aeration, the contents of the flasks were poured into darkened 300 mL BOD bottles fitted with oxygen sensing electrodes. The rate of oxygen consumption was measured for the dispersions, and compared with that in a control vessels. None of the tests indicated any significant inhibition of bacterial respiration compared with the controls, and it was concluded that the new chemical was not toxic to sewage bacteria up to the limits of its water solubility.

In contrast to tests with the new chemical, a reference test conducted with 3,5-dichlorophenol the EC50 was calculated to be 8.2-11.9 mg/L, meeting the criteria for a valid test.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is not expected to be high when it is used for the manufacture of plastic cases for electronic equipment as indicated in the notification statement.

Very little chemical is expected to be released during manufacturing processes. It is estimated at around 1% of import quantities, or a maximum of 500 kg per year. However, some slow release of the chemical may occur as a result everyday use and cleaning of polymer articles, which is likely to enter the sewer system with discarded cleaning water. In the sewer the chemical will become strongly associated with sediments.

Plastic articles containing the new chemical such as computer cases, monitors and televisions are unlikely to be recycled. At the end of their useful lives, they will most likely be discarded to landfill or incinerated.

Notified chemical in landfill is likely to be slowly released as a consequence of the slow degradation of the polymer matrix in which it is encapsulated. It is expected to become associated with the organic component of soils and sediments. The chemical is not readily biodegradable, and the available data indicates that it is only very slowly degraded by sewage bacteria. However, once released and adsorbed to soils and sediments in a landfill, it is expected to be slowly degraded through the biological and abiotic processes operative in these situations.

Very little of the compound is expected to enter the water compartment, so exposure to aquatic organisms is expected to be low. The notified chemical is not toxic to those aquatic species against which it has been tested up to the limits of its water solubility, and so any release to the water compartment would entail a low environmental hazard. The notified chemical is not readily biodegradable and the high value for Log Pow, moderate molecular weight (around 692-1425) and low water solubility indicate high potential for bioaccumulation. However, any potential for bioaccumulation will be mitigated by the expected low exposure to the water compartment.

It is of interest to note that unlike many currently used fire/flame retardant compounds the new chemical does not contain halogens like chlorine and bromine. In this respect, use of the new material offers environmental advantages over halogenated compounds, since its

incineration will not entail risk of production of halogenated dioxins and furans. This aspect of halogenated flame retardants has raised some wide environmental concerns due to the environmental persistence of the compounds themselves, and their potential for dioxin production in fires.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical was of very low acute oral toxicity and low acute dermal toxicity in rats. It was slightly irritating to rabbit skin and eye and non-sensitising to guinea pig skin. In a 28-day repeat dose oral toxicity study in rats, a NOAEL of 1 000 mg/kg/day, the highest dose tested, was established. The notified chemical was not mutagenic in bacteria, and not clastogenic in a CHO cell chromosomal aberration assay or in a mouse micronucleus assay.

Based on the available studies, the notified chemical is not considered to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a).

Occupational Health and Safety
Exposure to the notified chemical is not expected during transport or storage as long as the packaging remains intact. The risk of adverse health effects for transport and storage workers is considered to be low.

In the event that the chemical is not introduced in compounded plastic articles, but as a liquid for processing into formulated resin articles, dermal exposure may occur when opening drums, connecting and disconnecting suction pumps during transfer operations. The blending and extrusion processes are described as enclosed and automated, therefore further exposure would be limited. The preparation of the moulded and extruded finished articles from resin is performed in purpose built facilities fitted with vacuum extraction equipment, to minimise release of fugitive particulate material. Workers handling the notified chemical will wear protective equipment including chemical impermeable gloves, safety glasses and overalls.

Occupational exposure to the notified chemical cannot occur after the articles are made since the notified chemical is encapsulated within the finished plastic articles. In this form, the notified chemical is not bioavailable, hence health risk to workers is expected to be negligible.

Public Health
The notified chemical is not available for sale to the general public but will be used as a flame retardant ingredient in compounded plastic components of computers, computer monitors and televisions that may be publicly available. The risk to public health from the notified chemical is likely to be low because the notified chemical is physically contained within the plastic matrix and is unlikely to be bioavailable.

13. RECOMMENDATIONS

To minimise occupational exposure to "Phosphoric trichloride, reaction products with bisphenol A and phenol" the following guidelines and precautions should be observed:

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

- 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 containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

14. MATERIAL SAFETY DATA SHEET

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

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

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

CORNEA

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

CONJUNCTIVAE

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

IRIS

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

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