File No: NA/661

June 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

LumiNova

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

LumiNova

1. APPLICANT

Way Out Evacuation System Pty Ltd of 103 Were Street BRIGHTON VICTORIA 3186 has submitted a standard notification statement in support of their application for an assessment certificate for LumiNova.

The notifier reports that the chemical has been notified and used in plastics and paints in European Union member countries, Switzerland, Japan and the USA.

Claims were made and accepted for the identity of the notified chemical to be exempt from publication in the Full Public Report and the Summary Report. The data items were: chemical name; CAS number; molecular and structural formulae; molecular weight; purity, exact import volume and sites at which the notified chemical will be used.

2. IDENTITY OF THE CHEMICAL

The notified chemical is a mixed aluminate of metals of high atomic weight.

Trade Names:	LumiNova LumiNova G-300 LumiNova G-500 LumiNova G-1000
Method of Detection and Determination:	the identity of the notified chemical was confirmed from X-ray diffraction data submitted by the notifier

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	light yellow powder
Melting Point:	thermally stable without melting up to 1 000°C
Density:	3630.3 kg/m^3
Vapour Pressure:	not measured as expected to be very low
Water Solubility:	300 mg/L at 20°C
Partition Co-efficient (n-octanol/water):	log P_{ow} < 0 at 20°C
Hydrolysis as a Function of pH:	test not conducted, see comments below
Adsorption/Desorption:	log Koc < 0.29 estimated, see comments below
Dissociation Constant:	test not conducted, see comments below
Surface Tension:	69.9 mN/m for 90% saturation solution
Flash Point:	not applicable as notified chemical is a solid
Flammability Limits:	not applicable (as notified chemical is a solid and thermally stable up to 1 000°C)
Autoignition Temperature:	not applicable (as notified chemical is a solid and thermally stable up to 1 000°C)
Explosive Properties:	not explosive
Reactivity/Stability:	not reactive
Particle Size Distribution:	range 0.881 – 221.7 μm, 3.51% (by volume) < 2.002 μm 0.49% (by volume) > 203.3 μm 96% (by volume) 2.002 – 203.3 μm, calculated mass median aerodynamic diameter = 40 μm calculated percentage less than 10 μm aerodynamic diameter is 9.5%

Comments on Physico-Chemical Properties

Tests were performed according to European Commission/OECD test guidelines (European Commission 1992), (OECD 1995-1996) at facilities complying with OECD Principles of Good Laboratory Practice. Test reports were provided (Flack,1995).

The notified chemical is an inorganic solid with a high melting point, and is expected to have a low vapour pressure.

The water solubility of the notified chemical was determined by stirring excess amounts of the test substance with water at 30°C for 1, 2 and 3 days in separate vessels. Each test was performed in duplicate. After the allotted time for dissolution, the mixtures were allowed to equilibrate at 20°C, and the aqueous phase was filtered through 0.2 μm membrane filters and then analysed for total dissolved material by gravimetric analysis. Dissolved constituent elements in the samples were also determined using atomic absorption spectroscopy and flame emission spectroscopy.

The results were equivocal and could not be used to accurately quantify the true "stoichiometric" water solubility of the pigment. They indicate that the water soluble material is more likely to be leached metal salt from the matrix rather than true dissolution of the aluminate.

It is to be noted that the anomalous solubility behaviour was also observed in the metal analyses performed as part of the ecotoxicity tests. The results were very variable, with no consistent pattern between nominal and measured concentrations.

Hydrolytic degradation of the notified chemical was not investigated since it is irrelevant for a solid inorganic compound of this nature, and would in any case be encompassed by data obtained during the water solubility study. However, the notifier indicated that the chemical is sensitive to moisture, and is degraded ("blackens") with exposure to water. Presumably this degradation is due to decomposition of the aluminate matrix, which possibly accounts for the anomalous and variable metal analysis results noted above.

An attempt to determine the n-octanol/water partition coefficient was made using the shake flask method, where an excess of the material (2.02 g) was stirred in a flask for several hours (overnight) with 1 L of n-octanol-saturated water at 20°C. This test prepared a saturated solution of the water soluble components of the material (see above), of which 40 mL was then shaken in a flask with 50 mL of water-saturated n-octanol for 15 minutes. This procedure was performed in duplicate, and the two phases were then separated by centrifugation and analysed for dissolved material by gravimetric analysis. This procedure was able to provide data only for the aqueous phase and indicated water soluble fractions between 1.4 and 1.7 g/L, which are significantly higher than the results from the dedicated water solubility study discussed above. Since no suitable analytical technique was available to determine the concentration of the material in the n-octanol, and it was apparent that the majority of the material partitioned into the aqueous phase, the value of log P_{ow} was taken as less than zero. Given the obvious variability in the water soluble fractions, and the predominantly ionic nature of the test substance, this estimate for log P_{ow} is accepted.

The value of log K_{oc} was estimated from log P_{ow} using the Kenaga and Goring correlation log K_{oc} = 0.55 log P_{ow} + 1.377 (cited in notifiers submission, although the detailed reference was

not provided). In any case the ionic nature of the notified chemical means that estimates of K_{oc} are irrelevant.

Taking log $P_{ow} < 0$ provides the estimate of log $K_{oc} < 1.38$, indicating that the material has little affinity for the organic component of soils, and that the dissolved ions would be very mobile in soil.

The notifier provided a test report on surface tension of water solutions of the material. The surface tension of a saturated water extract was diluted 10:9, producing a nominally 90% saturated solution. Comparison of the measured surface tension of 69.2 mN/m with that for distilled water (71.5 mN/m) shows that the material is not surface active. This result is in accord with the exclusively inorganic ionic nature of the chemical.

4. PURITY OF THE CHEMICAL

Degree of Purity:	Very high
Impurities:	strontium borate < 1% CAS# 12007-66-8 toxic properties unknown
Additives/Adjuvants:	none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia, but will be imported at less than 200 tonnes per annum. The notified chemical will arrive in 40 L or 30 kg steel drums lined with air-tight, water and humidity resistant reinforced plastic liners.

The notified chemical is presented in powder form for use as a phosphorescent pigment in specialised screen printing and textile inks and as a masterbatch (pellets containing the notified chemical) for use in a variety of plastic (polymer) resins, including polycarbonate, polyethylene, urethane, polyvinyl chloride and polystyrene. The inks and plastics incorporating the notified chemical will be used for preparation of safety signs and other materials associated with safety or hazard situations. The notified chemical may also be used for preparation of special luminous paints. It is anticipated that 60% of the notified chemical will be used in production of inks (and possibly paint), with the remainder used in extruded plastic products such as luminous emergency edge markers for stairs.

6. OCCUPATIONAL EXPOSURE

Number and Category of Worker

The following categories and number of workers may be exposed to the notified chemical during use.

Import and Distribution

Category of workers	***Number***	***Hours/Day***	***Days/Year***
Handling and storage	3	2	100

Paint/Ink and Plastic Resin Processing

Category of workers	***Number***	***Hours/Day***	***Days/Year***
handling	5	-	-
. opening of package	1	1	200
. blending with paint/plastic resin material	2	2	200
. painting/moulding	2	7	200
storage	1	Very low	-

Workplace Exposure

In the absence of measured exposure data, the notifier has provided predicted workplace dermal and inhalation exposure using the EASE (Estimation and Assessment of Substance Exposure) model[1] for formulation of plastic products, formulation and end use of paints and inks containing the notified chemical.

The exposure estimates derived from the model assume an open system, and the absence of engineering controls and personal protective equipment. The dermal and inhalation exposure assessment does not include any form of uptake (such as absorption through the skin in the case of dermal exposure).

Formulation - Plastic Products

The notified chemical is a component (30%) of polymer masterbatch pellets. The masterbatch pellets are removed from the original import package, weighed and transferred into a blending mixer. The masterbatch is diluted to 27% to 28% notified chemical by the addition of resin. Within an enclosed system this resin is extruded and moulded into finished plastic products. The notifier states that up to 2% of notified chemical may be lost during the moulding of pelletised resins into finished products and will be recovered by vacuuming.

Exposure to the notified chemical may occur during handling of the masterbatch pellets, weighing and transferance to the mixer. Once extruded the chemical is bound within the polymer matrix.

[1] The EASE model consists of criteria which categorise the types of exposure possible based upon physical properties of substances during processing, the use pattern and pattern of control.

The EASE estimate for dermal exposure (hands and forearms, approximately 2 000 cm^2) is:

Use pattern:	inclusion into matrix (chemical is physically incorporated into resin from which release into the environment is substantially curtailed).
Pattern of control:	direct handling (assumes worker handles the chemical in the absence of control measures and protective gear).
Dermal Contact Level:	intermittent (assumes 2 to 10 events per day involving exposure as part of a process).

The model predicts that, for workers with no protective gear, dermal exposure to the substance will be between 0.1 and 1.0 mg/cm^2/day.

Formulation - Paint/Ink
Exact details of the blending and bottling process were not provided by the notifier.

The notified chemical (in powder form) is removed from its original packaging, weighed and transferred to a blending vessel and mixed with other paint or ink ingredients and then bottled for subsequent distribution to end-users. Depending on the end use of the paint or ink, the notified chemical in the blend will vary from 28 to 50%.

Dermal exposure to the notified chemical may occur during handling of the dry powder, weighing and transferance to the mixer. Dermal exposure to the liquid paint or ink may occur during the filling process. Inhalation exposure may occur during handling of the dry powder.

The EASE estimate for dermal exposure (hands and forearms, approximately 2 000 cm^2) is:

Use pattern:	inclusion into matrix (chemical is physically incorporated into paint/ink matrix from which release into the environment is substantially curtailed).
Pattern of control:	direct handling (assumes worker handles the chemical in the absence of control measures and protective gear).
Dermal Contact Level:	intermittent (assumes 2 to 10 events per day involving exposure as part of a process).

The model predicts that, for workers with no protective gear, dermal exposure to the substance will be between 0.1 and 1.0 mg/cm^2/day.

The EASE estimate for inhalation exposure (to the dry powder) is:

Use pattern	dry manipulation (includes any manipulation of the dry material).
Pattern of control	local exhaust ventilation (LEV) absent (effective LEV removes the contaminant at point of origin or generation and therefore prevents contaminant from entering the air of the workroom where it might be subsequently inhaled).

The model predicts an inhalation exposure of 5 – 50 mg/m^3.

End Use - Paints and Inks
Details of paint and ink application techniques were not provided by the notifier, although it would be expected that manual application techniques and/or manual handling of painted articles predominates. The prepared paints and inks may contain 28 to 50% of the notified chemical. Dermal exposure may occur during use of the liquid paint or ink.

The EASE estimate for dermal exposure (hands and forearms, approximately 2 000 cm^2) is:

Use pattern:	inclusion into matrix (chemical is physically incorporated into resin from which release into the environment is substantially curtailed).
Pattern of control:	direct handling (assumes worker handles the chemical in the absence of control measures and protective gear).
Dermal Contact Level:	intermittent (assumes 2 to 10 events per day involving exposure as part of a process).

The model predicts that for workers with no protective gear, dermal exposure to the substance will be between 0.1 and 1.0 mg/cm^2/day.

End Use - Plastic Products
The notified chemical in finished plastic product is bound within a plastic matrix. Therefore, the potential for dermal contact to, and absorption of, the notified chemical is negligible.

Waste Collection
It is anticipated that the plastic liners of empty drums will retain less than 0.01% of their original content. The drums are not washed out and are disposed of by licensed industrial waste collection contractors. Dust and dermal exposure to these workers is expected to be negligible as long as they do not directly handle the plastic liners.

Waterside, Transport and Storage
The total import volume will be transported by road in enclosed trucks to a storage facility. Waterside, transport and warehouse workers, should not be exposed to the notified chemical during storage and distribution, except in the event of a spill.

Prevention of Worker Exposure

The notifier states that the notified chemical will be blended into paints and inks in specific mixing areas under local exhaust ventilation to capture airborne particles.

Sites where the notified chemical is used will have a precipitation/filtration pool or factory water unit to trap any waste material present in aqueous waste water streams. Airborne and floor dusts are collected by conventional methods used for the control of waste pigments, additives and other chemical substances in the workplace. Due to the high specific gravity of the notified chemical, any material that enters the air during the blending process will not enter the factory ventilation systems but will be trapped by filters.

Workers are required to wear goggles, rubber gloves, gas and dust filter masks and overalls during formulation of plastic products and paints and inks. Industrial painters and printers are also likely to wear personal protective equipment, for example, overalls.

Worker Education and Training

The notifier states that the notified chemical will only be used by trained employees. Workers will receive training (2 hour course bi-annually) on handling precautions using a manual and education (2 hour course bi-annually) on chemical properties, prevention of hazards against health, environmental risk and prevention and process precautions. Material Safety Data Sheets (MSDS) are available to all staff and users at all times

7. PUBLIC EXPOSURE

The notified chemical is not manufactured locally but imported in containers as described in Section 5. Transport of the notified chemical is by road. In the event of an accidental spill, containment of the notified chemical is by the methods prescribed in the MSDS. Subsequent disposal of spilt material will be to landfill in accordance with state or territory regulations.

The notified chemical will be supplied to specialist paint users and industrial blenders only. The notified chemical will only be handled by trained employees during mixing and painting processes and public exposure to the powder is expected to be negligible.

There should be negligible exposure of the notified chemical to customers using the final articles due to the nature of the finished products. When used in plastic resin, the notified chemical is contained within the plastic matrix. Exposure from painted surfaces (for example, road and safety signs) will also be very low as the surface of the sign will be laminated or otherwise protected for weather proofing purposes, thus minimising the potential for environmental exposure. In addition, painted surfaces will generally be inaccessible to the public.

During the lifetime of products containing the notified chemical it is estimated that less than 1% of the substance initially present in plastic resins will leach. Losses due to leaching from paints are estimated to be less than 10%.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier indicated that some release of the new pigment was possible during manufacture of plastic articles, screen printing inks and paints. During manufacture of plastic articles (one batch per day), and assuming that a typical batch of 1 000 kg of resin may contain 28% of LumiNova, and that 0.2% of the batch may be wasted and lost to receiving waters, this equates to a maximum daily release of 560 grams of pigment. Assuming that this release is to a sewer system serving a population of 10 000 (ie assumed daily sewage flow of 2 000 000 L), and that following passage through the sewage treatment plant (where no removal takes place due to the high water solubility), a further dilution factor of 10 takes place, the Predicted Environmental Concentration (PEC) of the pigment in receiving waters is estimated as 0.028 mg/L.

Similarly, the notifier estimates that during printing ink and/or paint manufacture release of the pigment would result in a PEC of 0.0018 mg/L, while a further typical release during paint application would result in an additional 0.002 mg/L. Taking these together, the estimated PEC due to manufacturing and application activities is 0.032 mg/L. However, as pointed out in the notification statement, much of the released pigment would be encapsulated within the plastic matrix, and would not be immediately available for dispersal into the wider water compartment. Consequently, the true PEC would be much lower than the estimated value.

The notifier indicates that empty drums of the notified chemical would contain less than 5 grams of residual pigment. The drums are disposed of by licensed waste collectors, and would probably be placed into landfill. Fugitive pigment resulting from the production of plastic masterbatches will be collected using vacuum techniques and would also be placed into landfill. Similarly residues from mixing vessels and application equipment used in preparing and applying the screen printing inks is expected to be collected by the responsible printing personnel, and disposed of to landfill.

Fate

At the end of their useful lives, the textile and plastic articles containing the new chemical would be incinerated or placed into landfill. This mode of disposal would also apply to residuals and wastes from manufacturing processes involving the pigment. As indicated in the MSDS, deposition into landfill is the preferred method for disposal, but even after incineration the inorganic pigment would remain with the ash and most likely be placed into landfill. Consequently, when considering the overall fate of the new chemical in the environment, it is sufficient to consider only the fate after having been placed into landfill.

The plastics and textiles articles would be slowly degraded in a landfill through abiotic and biological processes, “liberating” the associated inorganic pigment. The pigment is a solid crystalline material, but appears to be appreciably soluble in water (see discussion of physico-chemical properties), and consequently could be expected to slowly leach from the landfill sites. Due to the low value for K_{oc} it is not likely to associate with sediments or soils, and if released in landfill leachate or in other ways, the chemical (or more likely its metallic components) is expected to remain in the water compartment. However, since it is an inorganic solid with moderate to high water solubility and low log P_{ow}, the notified chemical is unlikely to bioaccumulate. The compound will not biodegrade and is expected to persist in the environment, although the distribution of the elemental components would be very diffuse. It is possible that the constituent elements may eventually become associated with insoluble minerals in the aquatic sediments, although this would depend on local environmental factors in the water compartment such as pH and ambient levels of sulphate, and bicarbonate.

9. EVALUATION OF TOXICOLOGICAL DATA

Tests were performed according to OECD test guidelines (OECD 1995-1996) at facilities complying with OECD Principles of Good Laboratory Practice.

9.1 Acute Toxicity

Summary of the acute toxicity of LumiNova

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	> 2 000 mg/kg	(McRae, 1995)
acute dermal toxicity	rat	> 2 000 mg/kg	(McRae, 1995)
skin irritation	rabbit	non irritant	(Parcell, 1995)
eye irritation	rabbit	slight irritant	(Parcell, 1995)
skin sensitisation	guinea pig	non sensitising	(Allan, 1995)

9.1.1 Oral Toxicity (McRae, 1995)

Species/strain:	rat/ Sprague Dawley (CD)
Number/sex of animals:	5/sex per group
Observation period:	15 days
Method of administration:	a single dose of 2 000 mg/kg (20% w/v solution in corn oil) administered by gavage
Test method:	OECD TG 401 – Limit Test
Clinical observations:	pilo-erection was observed in all animals through to Day 2
Mortality:	none
Morphological findings:	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 (McRae, 1995)

Species/strain:	rat/ Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	a single dose of 2 000 mg/kg (166.67% w/v in corn oil) applied to an intact skin site and covered with semi-occlusive dressing; after 24 hours the dressing and residual test material were removed
Clinical observations:	bodyweight fluctuations in the occasional animal
Test method:	OECD TG 402
Mortality:	none
Morphological findings:	none
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of very low dermal toxicity in rats

9.1.3 Inhalation Toxicity

An acute inhalation toxicity test has not been conducted for the notified chemical and claims were made and accepted for variation of schedule requirements for this toxicological end point. To support their claim the notifier states that the median particle size of the notified chemical is 40 μm in diameter, with less than 10% with a diameter of 10 μm. This coupled with the high specific gravity and negligible vapour pressure of the substance, limits exposure via the inhalation route. The notifier also states that acute dermal and oral studies indicate the notified chemical is unlikely to be harmful.

9.1.4 Skin Irritation (Parcell, 1995)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 females
Observation period:	4 days
Method of administration:	0.5 g of the test substance was applied to intact skin site; the site was covered with semi occlusive dressing; after 4 hours the dressing and residual test material were removed
Test method:	OECD TG 404

Comment: no dermal reactions were observed one, 24, 48 or 72 hours after exposure

Result: the notified chemical was not irritating to the skin of rabbits

9.1.5 Eye Irritation (Parcell, 1995)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 2 males; 1 female (pilot animal)

Observation period: 7 days

Method of administration: 0.1 mL (100 mg) of the test substance was instilled in the conjunctival sac of one eye of each rabbit whilst the contralateral eye of each rabbit served as the control

Test method: OECD TG 405

Draize scores of nonirrigated eyes:

		Time after instillation											
Animal	*1 hour*		***1 day***		***2 days***		***3 days***		***4 days***		***7 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
1F	[1]D	0	0	0	0	0	0	0	0	0	0	0
2	D	0	0	0	0	0	0	0	0	0	0	0
3	D	0	0	0	0	0	0	0	0	0	0	0
Iris												
1F		0		0		0		0		0		0
2		0		0		0		0		0		0
3		0		0		0		0		0		0
Conjunctiva	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***
1F	2	1	1	0	0	0	0	0	0	0	0	0
2	1	1	1	0	0	0	0	0	0	0	0	0
3	1	1	1	0	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis. F-female rabbit. D – dulling.

Comment:	all animals exhibited dulling of the cornea one hour post exposure and transient well-defined conjunctival irritation; all eyes were normal at the end of day 2
Result:	the notified chemical was a slight irritant to the eyes of rabbits

9.1.6 Skin Sensitisation (Allan, 1995)

Species/strain:	guinea pig/Dunkin Hartley White
Number of animals:	10 males (test group), 5 males (control group)
Induction procedure:	test animals: Day 1 - three pairs of intradermal injections (0.1 mL) into the dorsal skin of the scapular region: - Freund's complete adjuvant (FCA) 1:1 in water for irrigation - the test substance, diluted to 7.5% w/v in Alembicol D - the test substance at 7.5% w/v in a 50:50 mixture of FCA and Alembicol D. Day 6 - the same interscapular area was pre-treated with 0.2 mL of 10% w/w sodium lauryl sulphate in petrolatum Day 7 - filter paper saturated with 0.4 mL the test substance, 70% w/v in Alembicol D was applied to the treated area and held under occlusive dressing for 48 hours during the induction phase the control animals were treated similarly to the test animals omitting the notified chemical from the intradermal injections and topical applications
Challenge procedure:	test and control animals two weeks after topical induction, the posterior left flank of each animal was treated with test substance, 70% w/v in Alembicol D under occlusive dressing for 24 hours; the anterior left flank was treated with the test substance, 35% w/v in Alembicol D
Challenge outcome:	none of the animals exhibited evidence of skin sensitisation
Test method:	Magnusson and Kligman Maximisation Test OECD TG 406

Result:	the notified chemical was not sensitising to the skin of guinea pigs

9.2 28-Day Repeated Dose Oral Toxicity (Yamasaki, 1995)

Species/strain:	rat/Crj:CD(SD)
Number/sex of animals:	6/sex/group
Method of administration:	gavage; vehicle was olive oil
Dose/Study duration:	test substance administered daily for a total of 28 consecutive days: 0 mg/kg/day (control) 0 mg/kg/day (control recovery) 10 mg/kg/day (low dose) 40 mg/kg/day (intermediate dose I) 200 mg/kg/day (intermediate dose II) 1 000 mg/kg/day (high dose) 1 000 mg/kg/day (high dose recovery) treatment groups were sacrificed at the end of the 28 day treatment period; the recovery animals were sacrificed after a 2 week recovery period
Mortality:	one male from the 200 mg/kg/day dose group on day 13; stated by authors to be due to error in administration
Clinical observations:	salivation after dosing was noted in treated animals, 13 animals receiving 1 000 mg/kg/day, 5 animals receiving 200 mg/kg/day, 4 animals receiving 40 mg/kg/day, 2 animals receiving 10 mg/kg/day and one animal in the vehicle control group
Haematology:	treatment phase: no abnormalities were detected at the end of the treatment phase: decreased prothrombin times were recorded in high dose males; decreased segmented neutrophils and increased lymphocyte counts were recorded in high dose females a the end of the recovery phase;

Clinical chemistry:	treatment phase: no abnormalities were detected at the end of treatment; recovery phase: at the end of the recovery period increased albumin, albumin/globulin ratio and total bilirubin and decreased creatinine levels were recorded in high dose males; increased blood urea nitrogen was detected in high dose females
Urinalysis:	no abnormalities were detected
Macroscopic examination:	treatment phase: a blackish region of the mucosa of the glandular stomach was noted in a 200 mg dose male and a control group male; blackish mucosa of the glandular stomach was observed in one high dose female and whiteish patches in the liver in one low dose female; recovery phase: no significant treatment related findings
Histopathology:	treatment phase: necrosis of the glandular stomach was noted in one intermediate dose II male; necrosis of hepatocytes were noted in one low dose female; all other findings were no different to those found in control animals; recovery phase: no abnormalities detected in treated animals
Organ weights:	treatment phase: a significant increase in absolute adrenal gland weight in high dose males; recovery phase: a significant increase in relative spleen weight in high dose females
Test method:	OECD TG 407
Comment:	the notified chemical did not exhibit any significant organ toxicity in rats; changes in haematology and clinical chemistry parameters observed at the end of the recovery period in high dose animals were considered to be accidental as they were not observed at the end of the treatment period; increased spleen weights in high dose females at the end of recovery were considered accidental as there was no change in organ weight and

	histopathological examinations at the end of the treatment period; increased absolute adrenal weights in high dose males were suspected as being related to treatment, however, there were no histopathological findings associated with the weight increase, the cause of death of the one animal during the treatment phase was attributed to dose administration error
Result:	the NOEL was established at 200 mg/kg/day, based upon increased absolute adrenal gland weights in males of the 1 000 mg/kg/day dose group

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Jones, 1995)

Strains:	*Salmonella typhimurium* TA 1537, TA 1535, TA 100 and TA 98 and *Escherichia coli* WP2 (*uvrA*)
Metabolic activation system:	liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Concentration range:	312.5, 625, 1 250, 2 500 and 5 000 µg/plate; each concentration was tested in triplicate, with or without metabolic activation, in two independent experiments; appropriate strain specific positive control reference substances were used
Test method:	OECD TG 472
Comment:	there were no significant increases in revertant colony numbers at any dose level, with or without metabolic activation; concurrent positive controls used in the test induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be satisfactory
Result:	the notified chemical is not considered to be mutagenic in the bacterial strains tested

9.3.2 Chromosomal Aberration Assay in Chinese Hamster Lung Fibroblasts (Ogura, 1995)

Cells:	Chinese Hamster Lung Fibroblasts
Metabolic activation system:	liver fraction (S9 mix) from rats pretreated with phenobarbital and 5,6-benzofulavone
Dosing schedule:	two independent experiments as follows <u>without metabolic activation:</u> 1 250, 2 500 and 5 000 µg/mL; treatment time = 24 hours or 48 hours; positive control: 0.05µg/mL mitomycin C; <u>with metabolic activation:</u> 1 250, 2 500 and 5 000 µg/mL, treatment time: 6 hours, recovery time: 18 or 42 hours positive control: 10µg/mL cyclophosphamide;
Test method:	OECD TG 473
Comment:	precipitation was observed at all test doses; the mitotic index for each maximum concentration was less than 50% in the groups treated, in the absence of metabolic activation and in the 42 hour recovery group, in the presence of metabolic activation and greater than 50% in the 18 hour recovery group in the presence of metabolic activation; the test substance did not cause any significant increases in the proportion of aberrant cells, at any dose level, or treatment time in the presence or absence of metabolic activation; positive controls used in the test caused marked increases in the proportion of aberrant cells and the activity of the S9 fraction was found to be satisfactory
Result:	the notified chemical was not considered to be clastogenic under the conditions of this chromosomal aberration test

9.4 Overall Assessment of Toxicological Data

The notified chemical has very low acute oral toxicity (LD_{50} > 2 000 mg/kg) and low dermal toxicity (LD_{50} > 2 000 mg/kg) in rats. Acute inhalation studies have not been conducted for the notified chemical and claims were made and accepted for variation of schedule requirements for this toxicological end point, on the basis of the concentration of respirable particles, high specific gravity and negligible vapour pressure of the substance. In rabbits, the notified chemical was not a skin irritant but was slightly irritating to eyes. The notified chemical was not sensitising to guinea pig skin.

In a 28 day repeat oral dose study, the notified chemical did not exhibit any significant organ toxicity in rats; changes in haematology and clinical chemistry parameters noted at the end of the recovery period were considered co-incidental as they were observed only at the end of the treatment period. Increased spleen weights in high dose females at the end of recovery were also considered accidental as there was no changes in observed organ weight or histopathology at the end of the treatment period. Increased absolute adrenal weights in high dose males were suspected as being related to treatment, however, there were no histopathological findings associated with the weight increase. The NOEL was established at 200 mg/kg/day, based upon increased absolute adrenal gland weights in males of the 1 000 mg/kg/day dose group.

The notified chemical revealed no mutagenic activity in a bacterial test system or *in vitro* chromosome aberration test.

Based on the data submitted the notified chemical would not be a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided the following ecotoxicity data in support of their application. The ecotoxicity tests were performed in accordance with OECD Test Guidelines (OECD 1995-1996).

Test	*Species*	*Results (Nominal)* mg/L	*References*
Acute Toxicity (OECD TG 203)	*Oncorhynchus mykiss* (Rainbow trout)	LC_{50}(96 h) = 6.8 NOEC (96 h) = 1.8	(Bell, 1995)
Acute Immobilisation (OECD TG 202 Part 1)	*Daphnia magna*	EC_{50}(48 h) = 13 NOEC(48 h) = 4.6	(Bell, 1995)
Inhibition of Algal Growth (OECD TG 201)	*Selanastrum capricornatum*	E_bC_{50}(72 h) =19 NOEC(72 h) = 4.6 ErC_{50}(0-72 h) = 29	(Bell, 1995)
Inhibition of Bacterial Respiration (OECD TG 209)	Activated Sludge Bacteria	EC_{50} (3 h) > 100	(Kelly, 1996)

The tests on rainbow trout were performed using solutions of the test material made up in dechlorinated water. The tests were conducted over a 96 hour period at a controlled temperature of 16±1 ^{o}C with supplementary aeration, and the test media was replaced daily in a batchwise manner. Five solutions of the chemical with nominal concentrations of 4.6, 10, 22, 46 and 100 mg/L were tested, together with one control. The measured results were extremely variable, with measured concentrations of the notified chemical between 10 and 84% of the nominal concentrations. There appeared to be no pattern to the variation in determined concentrations, which is similar to the anomalous findings in the water solubility study. However, it was noted during the analytical work that the apparent solubility of the notified chemical appeared dependent on the amount of starting material, and this is possibly connected with the hydrolytic degradation mentioned earlier in connection with the water solubility and hydrolytic degradation (see section 3 Physico - Chemical Properties).

Seven fish were tested at each concentration, and during these tests the pH of the test solutions was always between 7.9 and 8.1, dissolved oxygen levels were always between 8.3 and 8.9 mg/L and mean water hardness was 137 mg/L as $CaCO_3$. The test results indicate that the notified chemical is moderately toxic to rainbow trout with a nominal 96 hour LC_{50} of 6.8 mg/L determined using the method of Thompson and Weil (Thompson et al 1952). The only sublethal effect noted in the test report was loss of equilibrium. The responses listed in the raw data were such that Probit analysis was not possible, but it is agreed that the 96-hour LC_{50} would lie between 4.6 and 10.0 mg/L.

The acute immobilisation tests on daphnia were performed using solutions of the test material made up in dechlorinated water. A stock solution of the test material was serially diluted and

used in a static non-renewal system over a 48-hour period at a controlled temperature of 22°C. Five solutions of the chemical with nominal concentrations of 4.6, 10, 22, 46 and 100 mg/L were tested, together with one control.

Ten daphnia were tested at each concentration, with each test performed in duplicate. During these tests the pH of the test solutions was always between 7.5 and 8.4, while dissolved oxygen levels (measured for the control only) were always between 7.9 and 8.4 mg/L. The criterion for deciding on immobilisation was if the animals were unable to swim after gentle agitation of the test vessel. The results indicate that the notified chemical is slightly toxic to *Daphnia magna* with a nominal 48-hour EC_{50} of 13 mg/L determined using the method of Thompson and Weil. The responses listed in the raw data were such that Probit analysis was not possible, but it is agreed that the 96-hour LC_{50} would lie between 10.0 and 22.0 mg/L. Again, although attempts were made to measure the concentration of the notified chemical in the test water, this was not possible because of the large variability in the results.

A chronic study on daphnia reproduction was not performed.

A test on the inhibition of algal growth was conducted on *Selanastrum capricornutum* over a 72 hour incubation period at 24°C at pH 8.0-8.1 with nominal concentrations of the test substance in dechlorinated water of 4.6, 10, 22, 46 and 100 mg/L, together with a control containing no chemical. As with the other ecotoxicology tests, there was significant variation between the nominal and measured concentrations of the test substance. The nominal result of EC_{50} = 19 mg/L indicates that the notified chemical is slightly toxic to this species of green algae.

The notified chemical was at most slightly toxic to sewage sludge bacteria, and in a parallel reference test using 3,5-dichlorophenol, the 3-hour EC_{50} was determined as 10.0 mg/L.

These ecotoxicity results indicate that the new pigment is slightly to moderately toxic to the aquatic test species. It is likely that the toxicity is associated with the release of aluminium as opposed to other metals, since aluminium precipitates as an amorphous gel of hydrated hydroxides in the pH region 7.4-8.5 where the tests were conducted. This material may disrupt oxygen and gas transfer in aquatic organisms by coating gills and other organs.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical is appreciably water soluble, but when bound into polymer matrices in plastic articles or with binders on the surface of screen printed signs, little release is likely because of the low contact between water and the hydrophobic plastic encapsulating the pigment. The notifier indicates that when used as a pigment in screen printed signs, it is important that the pigment be protected from exposure to water by regular application of clear coat protective lacquers. However, although the notifier estimates that only 1% of the pigment would be lost through leaching during the service life of the various signs and plastic articles containing the notified chemical, some leaching and loss of the pigment seems inevitable due to factors such as irregular or incomplete maintenance of the signs and wear and tear of plastic stairway markers etc. This would probably result in irreparable damage (see Comments on Physico - Chemical Properties Section 3) leading to replacement of the affected sign(s) or other articles.

Eventually all the painted signs and plastic articles will be degraded, for example, through incineration or slow degradation and decomposition in landfill, and the integrity of the polymer matrices would be breached allowing for contact of the notified chemical with water and subsequent leaching of the aluminium and other metals. Ultimately all the notified chemical would be released into the environment, but since the hazard and safety signs are likely to be used throughout Australia, release would be widespread and diffuse. Since it is anticipated that up to 100 tonnes of the pigment may be imported each year, this ultimately equates to an annual release of up to 100 tonnes per year. All released metals will be mobile in soils and consequently all the material will ultimately be released to the water compartment.

Some release is likely during manufacture and application of screen printing inks and plastic articles and paint containing the pigment. However, as noted above this estimated to lead to a typical Predicted Environmental Concentration of around 0.03 mg/L, which is three orders of magnitude below toxic levels. Further, much of this released pigment will be associated with plastic in a solid matrix, and will not be immediately released into the wider environment.

The notified chemical is slightly to moderately toxic to the aquatic life forms against which it has been tested, and all is likely to be released to the water compartment. This toxicity is probably associated with precipitation of gelatinous aluminium hydroxides rather than the other metals. However, except in the cases of release during manufacturing processes, the primary release of the pigment will be associated with the slow degradation of plastic and textile articles into which the pigment is incorporated. This release will be widespread and very diffuse, and unlikely to lead to toxic concentrations of the chemical.

When used as indicated in the notification, the notified chemical is unlikely to present a hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notifier reports that the notified chemical has been used as a phosphorescent pigment in plastics and paints in European Union member countries, Switzerland, Japan and the USA for five years with no reported health implications associated with its use.

The notified chemical had very low acute oral toxicity (LD_{50}> 2 000 mg/kg) and low dermal toxicity (LD_{50} > 2 000 mg/kg) in rats. The notified chemical was a slight eye irritant but was not a skin irritant in the rabbit, and was not sensitising to guinea pig skin. A 28 day oral repeat dose study in rats revealed no evidence of systemic toxicity at doses of 200 mg/kg/day; at 1 000 mg/kg/day increased absolute adrenal weights in males were observed but these were not accompanied by histopathological findings. The NOEL was established at 200 mg/kg/day. Bacterial mutagenicity and an *in vitro* cytogenetic study were negative. Acute inhalation studies were not conducted with the notified chemical. The calculated mass median aerodynamic diameter is 40 μm and the percentage of respirable particles (<10 μm) was 9.5% by volume. Therefore, potential for inhalation of the notified chemical in powder form exists.

Based on the data submitted the notified chemical would not be classified as a hazardous substance under NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999).

Occupational Health an Safety

Formulation, Blending and End Use
In the absence of measured exposure data, the notifier has provided predicted workplace dermal and inhalation (dust) exposure using the EASE (Estimation and Assessment of Substance Exposure) model. The parameters used in the model assume an open system, and the absence of engineering controls and personal protective equipment. NICNAS concurs with the assumptions and the parameters selected for input into the EASE computer model.

During formulation of plastic products exposure to the notified chemical is most likely to occur during handling of the masterbatch. The model predicts dermal exposure of the arms and forearms will be between 0.1 and 1.0 mg/cm^2/day, which is considered moderate. Inhalation exposure will be negligible.

Assuming 10% dermal absorption, the body burden following dermal exposure to the masterbatch is (calculated by the product of the skin area of both hands and forearms (2 000 cm^2) and the value of 0.1 to 1.0 mg/cm^2/day of substance deposited on the skin, divided by the average bodyweight of a worker, ie 70 kg) in the range of 0.29 to 2.86 mg/kg/day.

During blending of the notified chemical into paints and inks, dermal and inhalation exposure is most likely to occur as a result of dry powder charging of mixing vessels. During blending/bottling procedures exposure will be limited to skin contact. For these activities the model predicts moderate (0.1 to 1.0 mg/cm^2/day) dermal exposure and inhalation exposure is predicted at 5 – 50 mg/m^3.

Assuming that $10m^3$ air is inhaled per day, an average worker weight of 70 kg and 100% adsorption, the body burden resulting from inhalation exposure in the range of 5 to 10 mg/m^3 would be 5 (or 10) x 10/70 = 0.71 to 1.42 mg/kg/day. A range of 5 to 10 mg/m^3 is chosen instead of the range 5 to 50 mg/m^3 predicted in the EASE model because the blending process would be an intermittent procedure and actual exposures would be at the low end of the predicted ranges. The use of personal protective equipment will further control exposure. The upper value of 10 mg/m^3 is also chosen as it represents the NOHSC 8-hour TWA exposure standard for aluminium oxide (measured as inspirable dust).

Assuming 10% dermal absorption, the body burden following dermal exposure during blending of the powder into paints and inks is (calculated by the product of the skin area of both hands and forearms (2 000 cm^2) and the value of 0.1 to 1.0 mg/cm^2/day of substance deposited on the skin, divided by the average bodyweight of a worker, ie 70 kg) in the range of 0.29 to 2.86 mg/kg/day.

The body burden from combined dermal and inhalation exposure is in the range of 6.7 to 13.4 mg/kg/day.

During the end use of prepared paints and inks, dermal exposure is calculated between 0.1 and 1.0 mg/cm^2/day, which is considered moderate. Inhalation exposure will be negligible.

Assuming 10% dermal absorption, the body burden following dermal exposure to prepared inks and paints is (calculated by the product of the skin area of both hands and forearms (2 000 cm^2) and the value of 0.1 to 1.0 mg/cm^2/day of substance deposited on the skin, divided by the average bodyweight of a worker, ie 70 kg) in the range of 0.29 to 2.86 mg/kg/day.

The notified chemical has low acute toxicity and therefore the risk of adverse effects following acute exposure to the notified chemical is considered low. Slight eye irritation immediately following exposure may occur, however, the wearing of eye protection should minimise this risk.

To characterise the risk associated repeated or prolonged exposure to the notified chemical, the margin of exposure (MOE) can be calculated by comparing the EASE exposure estimate with the NOEL of 200 mg/kg/day.

The Table below presents exposure estimates and MOE for dermal, inhalation and combined exposure.

PROCESS	EXPOSURE ESTIMATE (mg/kg/day)			MOE
	Dermal	Inhalation	Dermal & Inhalation	
Plastic Products:				
. formulation & moulding,	0.29 – 2.86	negligible	0.29 – 2.86	70 to very high
. end use	negligible	negligible	negligible	very high
Paints & Inks:				
. formulation	0.29 – 2.86	0.71 - 1.42	1 to 4.28	47 to 200
. end use	0.29 – 2.86	negligible	0.29 – 2.86	70 to very high

In summary, the calculated MOE predict low level of concern, in the absence of engineering controls and personal protective equipment.

However, the formulation process is enclosed and the notifier states that local exhaust ventilation will be positioned to capture airborne particles to control inhalation exposure to the notified chemical. In addition, the notified chemical and formulations containing the chemical will be handled and used by skilled, trained workers wearing suitable personal protective equipment, that is, dust masks, goggles, rubber gloves and overalls. These control measures are stated by the notifier to be standard practice. There is, therefore, little cause for concern with respect to systemic effects following repeated exposure during formulation and end use. The risk associated with the proposed use of the notified chemical will be low as long as these engineering and personal protection controls are in place.

As indicated by the MOE and as part of good hygiene practices, dust levels in the workplace should be controlled to well below the NOHSC exposure standard for 'Aluminium oxide, 10 mg/m^3 TWA (measured as inspirable fraction)'(NOHSCa 1995). Since the notified chemical contains respirable particles, the ACGIH respirable particulate threshold limit value (TLV) of 3 mg/m^3 can be used as guidance for the control of respirable dust in the workplace (ACGIH 1998). Employers are responsible for ensuring the exposure standard is not exceeded.

Biological monitoring of a constituent element of the notified chemical is proposed by the notifier for workers handling the notified chemical. It is recommended that the authorised medical practitioner responsible for health surveillance in the workplace give due consideration to the *Guidelines for Health Surveillance – Introduction* (NOHSCb 1995) before implementation of a health surveillance program for this chemical.

Transport, Storage and Disposal
During the importation and transportation of the notified chemical, there is unlikely to be any worker exposure, except in the event of a spill. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier. Exposure to the notified chemical from disposal of original import containers is expected to be negligible unless workers handle the liners of empty drums which are estimated to retain less than 0.01% of chemical.

Public Health

Based on the very low exposure of the public to the notified chemical and its physicochemical and toxicological properties it is considered that the notified chemical will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

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

- As a precautionary note in the event of a major spill either during transport or formulation, it is recommended that MSDS and label for the notified chemical carry the safety phrase – avoid breathing dust.

- Avoid generation and breathing of dust when handling the notified chemical in powder form;

- Provide local exhaust ventilation when handling the notified chemical in powder form(Standards Australia 1994);

- Dust levels in the workplace should be controlled to below the NOHSC exposure standard for 'Aluminium oxide, 10 mg/m^3 TWA (measured as inspirable fraction)'(NOHSCa 1995). Since the notified chemical contains respirable particles, the ACGIH respirable particulate threshold limit value (TLV) of 3 mg/m^3 can be used as guidance for the control of respirable dust in the workplace (ACGIH 1998). Employers are responsible for ensuring the exposure standard is not exceeded;

- The authorised medical practitioner responsible for health surveillance in the workplace give due consideration to the *Guidelines for Health Surveillance – Introduction* (NOHSCb 1995) before implementation of a health surveillance program for the notified chemical.

- Respiratory protection should conform to AS 1715 (Standards Australia/Standards New Zealand 1994), and AS 1716 (Standards Australia/Standards New Zealand 1994);

- Safety goggles should be selected and fitted in accordance with AS 1336 (Standards Australia 1994) to comply with 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 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;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

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, 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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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