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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

# Cerium Sulphide

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Director
Chemicals Notification and Assessment

# FULL PUBLIC REPORT

## Cerium Sulphide

## 1. APPLICANT

Rhone-Poulenc Chemicals Pty Ltd of 100 York Street SOUTH MELBOURNE VICTORIA 3205 has submitted a standard notification statement in support of their application for an assessment certificate for cerium sulphide.

## 2. IDENTITY OF THE CHEMICAL

| | |
|---|---|
| **Chemical Name:** | cerium sulphide |
| **Chemical Abstracts Service (CAS) Registry No.:** | 12014-93-6 |
| **Other Names:** | dicerium trisulphide |
| **Trade Name:** | cerium sulphide (red) |
| **Marketing Name(s):** | Neolor |
| **Molecular Formula:** | $Ce_2S_3$ |
| **Molecular Weight:** | 376 |
| **Method of Detection and Determination:** | ultra violet/visible (UV/Vis) spectroscopy and X-ray diffraction method use to determine Cerium sulphide; Cerium quantified by gravimetry and plasma emission spectroscopy and sulphur quantified by LECO technique. |

## 3. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| **Appearance at 20°C and 101.3 kPa:** | red pellets (manufactured as approximately 1 mm particle; described as "potentially dusty") |
| **Melting Point:** | 2450°C (under nitrogen) |
| **Specific Gravity:** | $D_4^{20}$ = 4.4562 at 20°C |
| **Vapour Pressure:** | not determined (see comments below) |
| **Water Solubility:** | not determined (see comments below) |
| **Partition Co-efficient (n-octanol/water):** | not determined (see comments below) |
| **Hydrolysis as a Function of pH:** | not determined (see comments below) |
| **Adsorption/Desorption:** | not determined (see comments below) |
| **Dissociation Constant:** | not determined (see comments below) |
| **Flash Point:** | not applicable ( notified chemical is a solid) |
| **Flammability Limits:** | not flammable |
| **Autoignition Temperature:** | 335ºC |
| **Explosive Properties:** | notified chemical is not explosive |
| **Reactivity/Stability:** | notified chemical is considered to be stable |
| **Particle Size:** | the notified chemical is manufactured as 1 mm pellets; imported as a fine powder less than 2 μm diameter.(all toxicological tests were performed using the powdered form of the notified chemical) |

**Comments on Physico-Chemical Properties**

The water solubility of the notified chemical has not been determined. Lanthanide chalcogenides are hydrolysed in the presence of water (1). The notifier indicates that the notified chemical rapidly reacts with water according to equation one rather than dissolving in it.

$$Ce_2S_{3\,(s)} + 4\,H_2O_{(l)} + 2\,CO_{2\,(dissolved)} \longrightarrow 2\,CeOHCO_{3\,(s)} + H_2S_{(g)} \quad (1)$$

The ecotoxicity studies determined the concentration of cerium and sulphur in the test solution after equilibrating aliquots of the notified chemical with the test media for 168 hours. The elemental analysis showed only µg/L concentrations of cerium and sulphur, indicating only a small fraction of the elemental constituents of the chemical are dissolved in the aqueous phase.

The rapid hydrolysis of the notified chemical in aqueous solution precludes the determination of the octanol water coefficient, the adsorption/desorption behaviour and dissociation constant for the notified chemical.

## 4. PURITY OF THE CHEMICAL

| **Degree of Purity:** | *lower limit %* | *upper limit %* |
|---|---|---|
| **Cerium** | 68.5 | 76.5 |
| **Sulphur** | 19.0 | 27.0 |

**Hazardous Impurities:**

| | |
|---|---|
| *Chemical name:* | lithium |
| *CAS No.:* | 7439-93-2 |
| *Weight percentage:* | ≤ 0.5 |
| *Toxic or hazardous properties:* | a very dangerous fire hazard* when exposed to heat or flame; corrosive (R34) (2)<br>*the notifier claims the lithium is in combination with sulphur and has no dangerous properties concerning fire hazard |

**Additives/Adjuvants:** none

## 5. USE, VOLUME AND FORMULATION

The notified chemical will be manufactured as pellets in France. It will be imported as a fine powder (< 2 μm) as a component of the range of Neolor products at a concentration greater than 80%. Neolor will be used as a colourant for plastic in the polymer industry. In Australia, Neolor will be reformulated (master batch process) into plastic colour concentrates and compounds, which will be used mainly in the manufacture of bottle crates and tools. The final concentration of cerium sulphide in the plastic is approximately 0.5% or 1.0% (w/w), depending on the degree of brightness required.

A master batch is a solid mixture of one or more compounds in a suitable carrier resin polymer. The concentration of the notified chemical in master batches is expected to be up to 65%. The process for formulating a master batch consists of weighing and blending of the chemical, polymer and other compounding ingredients. The blending is carried out in closed/sealed mixers. This preblending process is followed by a melting and extrusion process that completely dissolves and encapsulates the notified chemical into the polymer.

During 1997, Rhone-Poulenc imported 1 tonne of the notified chemical into Australia under section 21 of the Act (commercial evaluation category). The notified chemical is currently in use at two sites in Australia.

It is estimated that 2 tonnes of the notified chemical will be imported during 1998 increasing to 10 tonnes by the end of 2001.

## 6. OCCUPATIONAL EXPOSURE

The notified chemical is imported in 25 kg fibre drums with plastic liners. The total imported volume will be transported by road to up to ten industrial establishments in the Melbourne metropolitan area to be formulated into master batches. There is not expected to be any exposure to the notified chemical during storage and distribution, except in the event of a spill.

*Reformulation*
The notified chemical is currently in use at two sites. At one site, about 3 plant operators are involved in the production process for less than one hour, 3 to 4 times a week. At the second site about 9 plant operators are involved in the production process.

At each industrial establishment the drum containing Neolor (containing the notified chemical) is opened and the substance (< 2 μm particles) is manually weighed and transferred to the mixer with other pigments, additives and resin. Blending is carried out within an enclosed system. The blended product containing the notified chemical is then transferred within the closed system to an extruder, which is maintained at a temperature range of 150 to 300ºC to produce a master batch consisting of coloured plastic pellets. Information on the size or stability of the pellets was not provided. The concentration of the notified chemical in the master batch is expected to be up to 65%. During the latter process the notified chemical completely dissolves and is incorporated within the resin material. Following batch

production the vessels are cleaned. The primary source of exposure to the notified chemical during master batching will be when weighing and charging the blending vessel. Dermal and ocular exposure may occur during these processes. Similar exposure is also anticipated during cleaning of mixer vessels. Local exhaust ventilation will be in place over the weighing and mixing area to capture any airborne dust particles.

*End use*
Master batches containing the notified chemical will be transported to plastic part manufacturers in 25 kg packages and would use either injection moulding or plastic extrusion method to incorporate the master batch in the subsequent manufacture of plastic articles. The notifier has not provided any details of the processes involved. The notified chemical will be present at less than 1% in the finished plastic product and very limited exposure is expected during end use, as it is now compounded into the plastic product.

## 7. PUBLIC EXPOSURE

The notified chemical is for industrial use only. The potential for public exposure to the notified chemical during transport and industrial use or from disposal is assessed as negligible. Although the public will make contact with plastic goods containing the notified chemical (approximately 0.5 – 1%), exposure will be negligible since the notified chemical (at a low concentration) will be incorporated into the plastic resins, will not migrate outside the resin matrix and hence will not be bioavailable.

## 8. ENVIRONMENTAL EXPOSURE

### Release

Under normal conditions release of the notified chemical is not expected during storage and transportation. The Material Safety Data Sheet (MSDS) contains adequate instructions for handling a spill should one occur.

A trace amount (less than 4 kg per annum) of the chemical will remain in the packaging in which the chemical is imported. The package containing trace amounts of the notified chemical will be disposed of to landfill.

Waste from master batch formulation, consisting of dirty spilt material or purging material, is estimated to be less than 50 kg (0.5%) per annum. This material will be disposed of to landfill sites in Melbourne.

The manufacture of plastic articles by injection moulding or plastic extrusion is not expected to result in the release of significant amounts of the chemical. Plastic scrap is generally reprocessed into lower quality articles. Dirty spilt or purging material is generally sent to municipal landfill. Based on previous experience, *Environment Australia* believes a realistic

estimate would be less than 1 kg per annum at each site of processing site. The notifier estimates the masterbatches may be used at up to 100 parts manufacturers Australia wide.

**Fate**

The notified chemical is intended for use as a colourant in plastics. As such, the fate of the majority of the chemical will share the fate of the plastic articles into which it is incorporated. The fate of which will be disposal to landfill or incineration at the end of their useful lifetimes. Incineration would destroy the chemical, and create typical decomposition products of oxides of cerium and sulphur.

A small amount (less than 150 kg per year) will be disposed of to landfill as waste from the formulation master batches or production of plastic items. This will be bound within the plastic matrix and remain immobile. Waste disposed of as residues in packaging (less than 4 kg per annum) is expected to hydrolyse to give a poorly soluble solid which is also expected to be immobile.

No testing of the bioaccumulation potential of the notified chemical was conducted. The notifier argues that due to the physical properties of the substance, an assessment of the bioaccumulation potential of the chemical cannot be accurately predicted. The reactivity of the chemical with water would preclude its bioaccumulation.

## 9. EVALUATION OF TOXICOLOGICAL DATA

### 9.1 Acute Toxicity

The notifier states that all toxicological tests were performed using the 1 mm granules of the notified chemical pounded to a fine powder.

**Summary of the acute toxicity of Cerium sulphide**

| *Test* | *Species* | *Outcome* | *Reference* |
|---|---|---|---|
| acute oral toxicity | rat | $LD_{50}$ > 2 000 mg/kg | (3) |
| acute dermal toxicity | rat | $LD_{50}$ > 2 000 mg/kg | (5) |
| skin irritation | rabbit | slight to moderate skin irritant | (6) |
| eye irritation | rabbit | slight irritant | (9) |
| skin sensitisation | guinea pig | non-sensitiser | (10) |

#### 9.1.1 Acute Oral Toxicity – Limit Test (3)

*Species/strain:* rat/Sprague-Dawley

| | |
|---|---|
| *Number/sex of animals:* | 5/sex |
| *Observation period:* | 14 days |
| *Method of administration:* | a single dose of 2 000 mg/kg of the test substance administered by gavage; vehicle was paraffin oil |
| *Clinical observations:* | hypoactivity of the animals observed up to 48 hours post-treatment |
| *Mortality:* | none |
| *Morphological findings:* | none |
| *Test method:* | according to OECD guidelines – limit test (4) |
| *$LD_{50}$:* | > 2 000 mg/kg |
| *Result:* | the notified chemical was of very low acute oral toxicity in rats |

### 9.1.2 Acute Dermal Toxicity – Limit Test (5)

The study report was not provided for this test. The following is taken from the notifiers summary

| | |
|---|---|
| *Species/strain:* | rat/CD-Sprague-Dawley |
| *Number/sex of animals:* | 5/sex |
| *Observation period:* | 14 days |
| *Method of administration:* | a dose of 2 000 mg/kg was applied in 1% (w/v) aqueous methylcellulose to an intact skin site; the site was covered with a occlusive dressing; after 24 hours the dressing and residual test material were removed |
| *Clinical observations:* | red staining at the dose site was observed in some animals upon removal of the dressing (day 2) which persisted through day 8;<br><br>slight erythema and oedema noted in one male; slightly low bodyweight gains were observed on day 8 for 4 males and 3 males |

| | |
|---|---|
| *Mortality:* | none |
| *Morphological findings:* | none |
| *Test method:* | according to OECD guidelines – limit test (4) |
| *$LD_{50}$:* | > 2 000 mg/kg |
| *Result:* | the notified chemical was of low dermal toxicity in rats |

### 9.1.3 Acute Inhalation Toxicity

Study not done. Since the notified chemical in Neolor is in fine powder form with a particle size less than 2 μm, it could be anticipated that the notified chemical will be respirable and may pose a substantial inhalation hazard.

### 9.1.4 Skin Irritation (6)

| | |
|---|---|
| *Species/strain:* | rabbit/New Zealand White |
| *Number/sex of animals:* | 3 males |
| *Observation period:* | 9 days |
| *Method of administration:* | a single dose of 500 mg of the test substance applied to a 6 $cm^2$ clipped area of the skin of the right flank; the site was covered with a semi-occlusive dressing; after 4 hours the dressing and residual test material were removed |

*Draize scores (7):*

| | Time after treatment (days) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| ***Animal #*** | ***1*** | ***2*** | ***3*** | ***4*** | ***5*** | ***6*** | ***7*** | ***8*** |
| ***Erythema*** | | | | | | | | |
| ***1*** | C1 | 0 | 0 | - | - | - | - | - |
| ***2*** | C1 | 0 | 0 | - | - | - | - | - |
| ***3*** | C2 | C2 | 2 | 2 | 1 | 0 | 0 | 0 |
| ***Oedema*** | | | | | | | | |
| ***1*** | 0 | 0 | 0 | - | - | - | - | - |
| ***2*** | 0 | 0 | 0 | - | - | - | - | - |
| ***3*** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

[a] see Attachment 1 for Draize scales

C1 = red colouration of the skin which could obscure an eventual erythema at grade 1
C2 = red colouration of the skin which could obscure an eventual erythema at grades 1 to 2
- = cutaneous reaction not evaluated

*Test method:* according to OECD guidelines (4)

*Comment:* no oedema was observed during the study; in all 3 animals, a red colouration of the treatment site by the test substance had prevented evaluation of very slight to well-defined erythema during 24 and 48 hour time intervals; in 2 animals no skin reactions were observed from day 2 onwards; the 3rd animal exhibited well defined to very slight erythema from day 3 to 7; on day 8 there was no skin reactions observed in any of the animals

*Result:* the notified chemical was a slight to moderate irritant to the skin of rabbits; the mean scores for each type of dermal lesion were below the thresholds for classification as a skin irritant according to NOHSC Approved Criteria (8)

### 9.1.5 Eye Irritation (9)

*Species/strain:* rabbit/New Zealand White

*Number/sex of animals:* 3 males

*Observation period:* 72 hours

*Method of administration:* 100 mg of the test substance was introduced into the conjunctival sac of the left eye of each animal;

| | |
|---|---|
| | the eyes were not rinsed after administration |
| *Test method:* | according to OECD guidelines (4) |
| *Comment:* | slight chemosis was observed in all 3 animals one hour after application which was persistent in one animal at the 24 hour observation period;<br>redness, which could not be confirmed one hour after application due to the red colour of the test substance was persistent at 24 hours only in one animal |
| *Result:* | the test substance was a slight irritant to the rabbit eye; the mean scores for each type of ocular lesion were below the thresholds for classification as an eye irritant according to NOHSC Approved Criteria (8) |

**9.1.5 Skin Sensitisation (10)**

| | |
|---|---|
| *Species/strain:* | guinea pig/Dunkin Hartley White |
| *Number of animals:* | 10 males (test group), 5 males (control group) |
| *Induction procedure:* | test animals:<br>Day 1-three pairs of intradermal injections (0.1 mL) into the dorsal skin of the scapular region:<br><br>- Freund's complete adjuvant (FCA) 1:1 in water for irrigation<br>- the test substance, diluted to 5% with water for irrigation<br>- the test substance at 5% emulsified in a 50:50 mixture of FCA and water for irrigation.<br><br>Day 7- the same interscapular area was pre-treated with 0.5 mL of 10% w/w sodium lauryl sulphate in petrolatum<br><br>Day 8- filter paper saturated with 80% w/v test substance in distilled water was applied to the treated area and held under occlusive dressing for 48 hours<br><br>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

necrosis was recorded at sites receiving FCA in test and control animals; slight irritation was observed in test animals receiving the test substance, 5% w/v in water; slight erythema was observed in test animals following topical application with the test substance 80% w/v in distilled water; slight erythema was also observed in the control group

*Challenge procedure:* test and control animals
two weeks after the topical induction, the anterior left flank of each animal was treated with 80% w/v test substance in distilled water under occlusive dressing for 24 hours; the posterior left flank was treated with 40% w/v test substance in distilled water

*Challenge outcome:*

| | ***Test animals*** | | ***Control animals*** | |
|---|---|---|---|---|
| ***Challenge Concentration*** | ***24 hours**** | ***48 hours**** | ***24 hours*** | ***48 hours*** |
| 80% | 0/10** | 0/10 | 0/5 | 0/5 |
| 40% | 0/10 | 0/10 | 0/5 | 0/5 |

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

*Test method:* similar to OECD guidelines (4)

*Comment:* red staining was noted on all dose sites; the study authors state that this did not interfere with scoring

*Result:* the notified chemical was non-sensitising to guinea pig skin

## 9.2 Repeated Dose Toxicity (11)

*Species/strain:* rat/CD-Sprague Dawley

*Number/sex of animals:* treatment phase:
5/sex/group; low and mid dose groups; 10/sex/group; control and high dose groups;
recovery phase:
5 of each sex were retained from the control and

| | |
|---|---|
| | high dose groups; |
| *Method of administration:* | gavage; vehicle was maize oil |
| *Dose/Study duration::* | test substance administered daily for a total of 30 consecutive days:<br>0 mg/kg/day<br>15 mg/kg/day (low dose)<br>150 mg/kg/day (mid dose)<br>1 000 mg/kg/day (high dose)<br><br>all but 5/sex high dose and control group animals were sacrificed at the end of the treatment period; the remaining high dose and control group animals were sacrificed after a 2 week recovery period |
| *Mortality:* | none |
| *Clinical observations:* | salivation was noted in treated animals, particularly those animals receiving 1 000 mg/kg/day; red staining of the coat was visible in some high dose animals;<br>some residual red staining of the dorsal coat was noted during the recovery period;<br>bodyweight gains were low in high dose males during the first week of treatment but overall gains were similar to the controls for the remainder of the treatment period and during the recovery phase;<br>food consumption in the high dose group was slightly higher than the controls during the latter half of treatment but during the recovery phase was similar to controls;<br>overall efficiency of food conversion of high dose males and to a lesser extent females, was low compared to that of the controls during treatment;<br>higher water consumption was noted in high dose animals and, to a lesser, extent in females receiving 150 mg/kg/day; during recovery water consumption of high dose males remained slightly higher than the controls |
| *Haematology:* | significantly higher erythrocyte and platelet counts, lower mean cell haemoglobin and mean cell volumes were noted in high dose group animals; the mean cell haemoglobin concentrations of high dose females were also significantly lower than the |

| | |
|---|---|
| | controls, as were the mean cell volumes of males receiving 15 and 150 mg/kg/day; significant, though not dose related, shorter prothrombin times and activated partial thromboplastin times in all treated males; after recovery slightly lower mean cell haemoglobin concentrations were evident in high dose females and slightly shorter prothrombin times in males; |
| *Clinical chemistry:* | increased alanine amino-transferase activities noted in high dose animals and in females receiving 150 mg/kg/day; increased aspartate amino-transferase activities were noted in males receiving 1 000 and 15 mg/kg/day; low glucose and increased phosphorus concentrations were noted in high dose animals and increased urea concentrations in high dose males;<br>all changes were reversible after the recovery period; |
| *Urinalysis:* | increased urinary volumes, lower specific gravity and lower numbers of crystals in the urine were noted in high dose animals; females receiving 150 and 1 000 mg/kg/day had slightly more acidic urine than the controls; high dose males exhibited low concentration of urinary protein;<br>no inter-group differences were evident after the recovery period |
| *Macroscopic examination:* | thickening of the walls of the stomach and duodenum and prominent vasculature of the serosal surfaces of the stomach were noted in several high dose animals; thickening of the stomach wall was also noted in one male receiving 150 mg/kg/day;<br>the above changes persisted in one high dose male after the recovery period |
| *Histopathology:* | increase in the number of acute inflammatory cells in the submucosa of the cardiac stomach and duodenal mucosal hyperplasia was evident in most high dose animals and the latter change was also evident in one animal receiving 150 mg/kg/day; hyperplasia of the gastric keratinised mucosa and submucosal oedema were noted in a few high dose animals |

after the recovery period there were no changes that could be clearly attributed to treatment other than increased acute inflammatory cells evident in the submucosa of the cardiac stomach of two males in the high dose group, and in one male of the control group

*Organ weights:* no change in organ weights were noted

*Test method:* Similar to OECD guidelines (4)

*Result:* The notified chemical did not exhibit any significant organ toxicity in rats; changes in haematology and clinical chemistry parameters during treatment were reversible, except for the slightly lower mean cell haemoglobin concentrations in females and slightly shorter, though still within the normal expected range, prothrombin times in males; histopathological changes observed in high dose animals were also reversible; the study authors suggested these changes represent an irritant response following a reaction of the test substance in the acid environment of the stomach; macroscopic changes observed in some high dose animals were reversible, other than, in one animal;

based on the absence of findings at the low dose level, the NOEL was established at 15 mg/kg/day

## 9.3 Genotoxicity

### 9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (12)

*Strains:* *Salmonella typhimurium* TA 1537, TA 1535, TA 100 and TA 98; *Escherichia coli* WP2*uvrA*

*Metabolic activation system:* liver microsomal fraction (S9) of rats pretreated with Aroclor 1254

*Concentration range:* 62.5, 125, 250, 500 and 1 000 µg/plate

*Comment:* test substance is poorly soluble in any vehicle; precipitation occurred at concentrations greater than 125 µg/plate

| | |
|---|---|
| *Test method:* | according to OECD guidelines (4) |
| *Result:* | there was no significant increase in revertant colony numbers either in the presence or absence of metabolic activation |

### 9.3.2 Chromosomal Aberration Assay in Chinese Hamster Lung Cells (13)

| | |
|---|---|
| *Cells:* | Chinese Hamster Lung cells |
| *Metabolic activation system:* | liver microsomal fraction (S9) of rats pretreated with Aroclor 1254 |
| *Dosing schedule:* | with metabolic activation (S9 mix):<br>50, 100 and 200 µg/mL treatment = 6 hours, harvest time = 24 hours<br><br>without metabolic activation (S9 mix):<br>6.25, 12.5 and 25 µg/mL treatment = 6 hours, harvest time = 24 hours; 1.56, 3.13 and 6.25 µg/mL treatment = 24 hours, harvest time = 24 hours; 3.13, 6.25 and 12.5 µg/mL treatment = 48 hours; harvest time = 48 hours |
| *Test method:* | similar to OECD guidelines (4) |
| *Result:* | small, but statistically significant increases in the frequency of metaphases with chromosomal aberrations were observed at several test points, including all cultures treated for six hours with or without metabolic activation compared to the vehicle controls; the study authors did not consider these increases to be biologically significant under the protocol of the study*; however, treatment with known clastogens, Mitomycin C and cyclophosphamide showed marked increases in the frequency of aberrant metaphases which were biologically and statistically significant at 24 and 48 hours |

*when gap-type aberrations were excluded from the anlysis, only one culture (treated at 6.25 µg/ml for 24 hours without S-9 mix) showed a frequency of aberrant metaphases which exceeded the historical control range for CHL cells at the testing laboratory (0–7 without S-9 mix and 1–9% with S-9 mix); when gap type aberrations were included, several culture showed increases which just exceeded the historical control range (2-14% without S-9 mix and 3-13 with S-9 mix), but gaps were of questionable biological significance; the increases after 6 and 48 hours of treatment (with and without S-9 mix) were not clearly dose-related

| | |
|---|---|
| | the notified chemical was not considered to be clastogenic under the conditions of this chromosomal aberration test. |

### 9.3.3 Gene Mutation Assay in Chinese Hamster Cells (14)

| | |
|---|---|
| *Cells:* | Chinese Hamster cells (V79) |
| *Concentration range:* | 321.5, 625, 1 250, 2 500, and 5 000 µg/mL |
| *Metabolic activation system* | microsomal fraction (S9) of rats pretreated with Aroclor 1254 |
| *Comment* | plating efficiencies observed in treated culture ranged from 98.4% to 288.9% (first assay) and 82.2% to 218.2% (second assay) with no evidence of dose-related toxicity; there were a number of cases of very high plating efficiencies, at high concentrations of the test substance; this may have been due to aggregation of cells during counting, resulting in low cell counts at the time of plating and subsequently leading to high plating efficiency values |
| *Test method:* | according to OECD guidelines (4) |
| *Result* | no relevant increases of the mutant frequencies, as determined by the screening with 6-thioguanine, were found at any of the doses tested in the presence or absence of metabolic activation<br><br>the notified chemical was not considered to be mutagenic under the conditions of this test |

## 9.3 Overall Assessment of Toxicological Data

The test substance exhibited low acute toxicity in rats by oral administration ($LD_{50}$ > 2 000 mg/kg) and dermal administration ($LD_{50}$ > 2 000 mg/kg). The notified chemical was a slight to moderate skin irritant and a slight eye irritant in rabbits. The mean scores for each type of ocular or dermal lesion were below the threshold to warrant a health effects classification as eye/skin irritant according to NOHSC Approved Criteria. Acute inhalation studies were not performed. However, since the notified chemical is imported in the form of fine powder in the respirable size range of < 2 µm. It has the potential to be a substantial inhalation hazard. It was not a skin senitiser in guinea pigs.

In a 28-day repeat oral dose study in rats, the notified chemical did not exhibit any significant organ toxicity. Changes in haematology and clinical chemistry parameters during treatment were reversible, apart from slightly lower mean cell haemoglobin concentrations in females and slightly shorter, though still within the normal expected range, prothrombin times in males. Histopathological lesions observed in the stomach and duodenum of high dose animals were also reversible. The study authors suggested these might lesions represent a response to the irritancy of the test substance when reacting with the stomach acid. Based on the absence of findings at the low dose level, the NOEL was established at 15 mg/kg/day.

The notified chemical was found not to be mutagenic *in vitro* by bacterial reverse mutation assay, Chinese Hamster V79 cell mutation assay or genotoxic by chromosomal aberration assay in Chinese Hamster Lung cells. No *in vivo* studies were performed.

According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (8), the notified chemical would not be classified as hazardous, in relation to the toxicological end points measured. However, hazard due to inhalation cannot be ruled out.

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

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

| Species | Test | Concentrations[a] (mg/L) | Result (mg/L) | Reference |
|---|---|---|---|---|
| Zebra fish (Brachydanio rerio) | 96 h acute | 0, 1, 10, 32, 100 | $LC_{50}$ > 100 | (15) |
| Water Flea (Daphnia magna) | 48 h acute | 0, 1, 10, 32, 100 | $EC_{50}$ > 100 | (16) |
| Algae (Raphidocelis subcapitata ) | 96 h growth | 0, 1, 10, 32, 100 | IC50 = 6.51[b] (CI = 6.42-6.61) | (17) |

[a]Concentrations correspond to the initial amount of the notified chemical added to the test media. [b]Calculated by *Environment Australia* based on biomass data using linear interpolation.

The notified chemical rapidly hydrolyses in water. Test media for all tests were prepared by equilibrating varying amounts of the notified chemical with test media for 168 h to establish a steady state. After steady state was established, the solutions were filtered and the resulting water accommodated fraction was used in the ecotoxicity studies. Elemental analysis was conducted for cerium (using inductively coupled plasma-mass spectrometry; ICP-MS; quantification limit 0.03 mg/kg), sulphur (using ICP-atomic emission spectrometry; ICP-AES; quantification limit 3 mg/kg) and lithium (using flame atomic absorption spectrometry; FAAS; quantification limit 0.01 mg/kg) in these test solutions. The maximum concentration of the elements was achieved at the highest dose level and results are summarised below.

| Test Media | Maximum Concentration (mg/kg) | | | Reference |
|---|---|---|---|---|
| | Cerium | Sulphur | Lithium | |
| Zebra fish | 0.216 | 11.1 | 0.27 | (18) |
| Water flea | 0.017 | 3 | 0.25 | (19) |
| Algae | 0.0086 | 7.1 | 0.32 | (20) |

The concentration of sulphur and lithium were stable in all test media throughout the studies. The concentration of cerium decreased throughout the studies. This decrease was most pronounced in the fish study where the maximum concentration dropped by approximately 24%. In the algal test, the cerium concentration was stable throughout the study.

No effects were observed in either the fish or daphnia studies. In the algal study no growth inhibition was observed at the lowest dose. However all three of the higher doses showed around 60 and 80% inhibition in growth rate and biomass, respectively. The study did not calculate toxicity endpoints, arguing that these were not possible due to the nature of the data. *Environment Australia* has calculated the 50% inhibition concentration (IC50) based on the raw biomass data given in the study. The notifier has also provided a study (21) which indicates that the inhibition observed is removed on the addition of further nutrient salts to the test media. The inhibition appears to correlate with the level of phosphate in the solution. The study shows that after a steady state concentration of cerium and sulphur is established the level of phosphates in the test media is low. Treatment of the solution with nutrient salts increases the phosphate concentration and decreases the cerium concentration (measured after centrifugation). This would indicate that the phosphate and cerium interact and precipitate from solution. Presumably the phosphate is limiting in the initial preparation of the test media and the cerium is limiting when the additional salts are added. It is not possible to conclude whether it is the presence of the cerium or the lack of phosphate which causes the inhibition to the growth of the algae.

The ecotoxicity data for the notified chemical indicate that the chemical is not toxic to fish and daphnia up to the limit of its solubility. The algal study indicates that the notified chemical is moderately toxic to algae. However the inhibitory effect is mitigated in the presence of phosphate.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will be used as colourant in plastics, which will be injection moulded or extruded into plastic articles. Hence, the majority of the notified chemical will share the fate of the plastic articles that will be disposed of to landfill or incinerated at the end of their useful lifetime. In landfill the notified chemical is expected to remain within the plastic articles.

Waste from the manufacture of master batches and plastic articles (less than 150 kg per annum) will be disposed of to landfill where it is expected that the notified chemical will remain bound within a polymer matrix.

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

## 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is not expected to exhibit acute oral and dermal toxicity, and is not likely to be genotoxic or cause serious damage to health after repeated exposure. However, it is a slight eye irritant and a slight to moderate skin irritant. No inhalation toxicity studies were carried out. The notified chemical would not be classified as hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substance*s on the basis of the toxicological data submitted. However, hazard due to inhalation cannot be ruled out.

*Occupational Health and Safety*
During the importation, transportation, distribution and storage 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 minimised by workers following the recommended practices for spillage clean-up given in the MSDS supplied by the notifier.

During reformulation there is potential for dermal and ocular exposure by direct contact or by exposure to dust when the notified chemical is manually weighed and transferred to the mixer and when cleaning of mixer vessels at each establishment. The degree of exposure will depend on the efficiency of the local exhaust ventilation installed over the weighing and mixing areas, to capture any airborne particles. The MSDS recommends the use of chemical goggles and gloves during these activities, in order to control the risk of adverse health effects resulting from any dermal and eye contact with the notified chemical. The small particle size (< 2 μm) of the notified chemical in imported form would increase the potential for exposure via inhalation. Blending and transfer to the extruder occur within closed systems and exposure to the notified chemical is expected to be negligible during these operations.

To avoid the adverse health effects of high concentrations of dust in the workplace, airborne dust levels should not exceed the NOHSC exposure standard of 10 mg/m$^3$ (TWA), measured as inspirable dust. Employers are responsible for ensuring this exposure standard is not exceeded.

There are also inherent hazards based on the physico-chemical characteristics of the notified chemical and its presentation. These have implications for the handling and storage of the chemical. For instance the notified chemical should be stored away from acids, as contact with acids could lead to release of hydrogen sulphide. The potential for dust explosion exists when the notified chemical is in the particulate form. The MSDS stipulates the use of engineering controls (dust extraction system) and personal protection, such as particle respiration filters and safety spectacles when handling the notified chemical. In addition, the formation or spread of dust in the working environment is to be avoided.

The notifier has not provided any details of the processes involved in plastic part

manufacture using master batches containing the notified chemical. Limited exposure to the notified chemical is expected as it will be incorporated within the polymer material during these processes. However, in order to avoid worker exposure during injection moulding or plastic extrusion processing as well as during reformulation, workers should wear masks, goggles, gloves and industrial clothing as stipulated under the Recommendation Section.

The notifier states that no adverse health effects have occurred from the use of the notified chemical in Australia during its use under Section 21G (Commercial Evaluation Category) of the Act (22).

*Public Health*
The notified chemical is for industrial use only. The potential for public exposure to the notified chemical during transport and industrial use or from disposal is assessed as negligible. Although the public will make contact with plastic goods containing the notified chemical (at a low concentration) will be incorporated into the plastic resins, will not migrate outside the resin matrix and hence will not be bioavailable. Based on the use pattern of the notified chemical and its toxicological properties, cerium sulphide is considered not to pose a significant hazard to public health.

## 13. RECOMMENDATIONS

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

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (23) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (24);
- Industrial clothing should conform to the specifications detailed in AS 2919 (25) and AS 3765.1 (26);
- Masks should be selected and fitted in accordance with AS/NZS 1715 (27) to comply with AS/NZS 1716 (28);
- Impermeable gloves or mittens should conform to AS 2161 (29);
- All occupational footwear should conform to AS/NZS 2210 (30);
- 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.

Where there is potential for exposure to dust, the NOHSC exposure standard for nuisance dust should be adhered to. Workplace dust levels should be controlled to below 10 mg/m$^3$ (TWA) measured as inspirable dust, consistent with good hygiene practices.

The notifier's MSDS should be referred to for appropriate handling and storage conditions.

## 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* (31).

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 subsection 64(1) of the Act, secondary notification of the notified chemical shall be required if (i) a study (studies) on the inhalation toxicity of the notified chemical becomes available and (ii) information is available concerning adverse health effects associated with inhalation of the notified chemical.

Under subsection 64(2) of the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under this subsection occur.

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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 |