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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

CROMOPHTAL Yellow HRP

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT
CROMOPHTAL Yellow HRP

1. APPLICANT

Ciba Specialty Chemicals Pty Limited of 235 Settlement Road, THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for 'CROMOPHTAL Yellow HRP'.

2. IDENTITY OF THE CHEMICAL

CROMOPHTAL Yellow HRP is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of exact import volume have been exempted from publication in the Full Public Report and the Summary Report.

Other Names:	Pigment Yellow 9128A C.I. Pigment Yellow 191:1
Trade Name:	CROMOPHTAL Yellow HRP
Method of Detection and Determination:	identity by ultra violet/visible (UV/Vis) infrared (IR) nuclear magnetic resonance and mass spectra, assay by high performance liquid chromatography (HPLC) and microanalysis

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	yellow powder
Melting Point:	> 360°C
Specific Gravity:	1.5792
Vapour Pressure:	6.5×10^{-9} kPa at 25°C
Water Solubility:	1235.1 mg/L at 20°C
Partition Co-efficient (n-octanol/water):	$\log P_{ow} = -1.43$

Hydrolysis as a Function of pH:

no hydrolysis observed at pH 4, 7 or 9 at 50°C

Adsorption/Desorption:

not determined (see comments below)

Dissociation Constant:

not determined (see comments below)

Particle Size:

< 2 µm	2.2% (by volume)
< 10 µm	9.6%
2 - 201 µm	97.1%
> 201 µm	0.7%

volume of median diameter: 48 µm

Surface Activity:

72.9 mN/m at 19°C and 0.1 g/100 mL

pH:

7±1.5 (suspension in water)

Flash Point:

not determined

Flammability Limits:

non-flammable

Autoignition Temperature:

327.5 °C

Explosive Properties:

not explosive

Reactivity/Stability:

not determined

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines (1, 2) at facilities complying with OECD Principles of Good Laboratory Practice.

No data has been provided on the adsorption/desorption properties of the chemical. The notifier claims that adsorption will occur if the notified chemical is released. Based on the chemical's high water solubility and low partition coefficient, it is thought that the chemical will not strongly adsorb to soils or sediment. However, metathesis of the associated cations with calcium (or similar cations) markedly reduces the solubility of the anionic pigment (further discussed under Environmental Fate and Effects sections).

The notified chemical contains acidic groups that would remain totally dissociated in water due to their strong acidity.

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (2).

4. PURITY OF THE CHEMICAL**Degree of Purity:**

> 98.0

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. CROMOPHTAL Yellow HRP will be imported in powder form, at a concentration of greater than 98%, and will be used as a pigment in the cadmium-free colouration of thermoplastics, particularly polyolefins.

It is estimated that less than 2 tonnes of the notified chemical will be imported annually for each of the first five years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported into Australia in 20 kg cardboard cartons lined with antistatic plastic. It will then be transported by road to industrial establishments for formulation into masterbatch. There is not expected to be any exposure to the notified chemical during storage and distribution, except in the event of a spill.

Occupational exposure is likely to occur only during weighing and batching operations at masterbatch manufacturers. Once initially processed, the notified chemical will be encapsulated in a polymer matrix.

Formulations will first be established on a laboratory scale, using a limited number of trials. The total amount of pigment powder involved is usually less than 0.1 kg. Inhalation, dermal and ocular exposure may occur during these processes, however, this is an infrequent procedure with one to two laboratory technicians potentially being exposed to the notified chemical for less than an hour at a time. Additionally, laboratory staff may need to test the incoming raw material pigment as it is imported. This should only result in exposure for less than an hour every few months.

The primary source of exposure during reformulation will be to the pigment powder during the weighing and batching operations. Exposure by dermal, inhalation and ocular routes may occur when weighing the required raw pigment, fillers, carrier polymer and additives and loading them into solid phase mixers. Local exhaust ventilation will be in place over the pigment loading area to capture any airborne particles. The mixing will be by high speed impeller blades in a closed system. After discharge from the mixer, the pre-blend is fed from the hopper of an extruder into the feed zones of mixing screws that will melt the polymer, dispersing the pigment and other ingredients within the molten polymer. Under high pressure and heat, the melt will be forced through an extrusion head, the hot strands being water cooled, pelletised, dried and packed into bags. The pigment will be totally encapsulated within the polymer at concentrations between 1 and 20%. As this is mainly an automated process there is very little potential for exposure to the notified chemical

after the weighing and loading the raw materials has occurred. Process workers will be potentially exposed to the notified chemical for less than an hour per batch.

Once the pigment has been dispersed and encapsulated in polymer, there should not be any further exposure to the notified chemical. The masterbatch granules can then be utilised by plastic companies for the production of coloured plastic articles.

The concentration of the notified chemical in the final plastic articles is usually between 0.1 and 0.5%.

7. PUBLIC EXPOSURE

Public exposure during storage and distribution of the notified chemical is not expected to occur, except in the event of a spill.

End uses for such coloured plastics containing the notified chemical may include packaging film, plastic containers, housewares, electronics and appliance parts, furniture, toys and sporting goods. After reformulation into masterbatch and use in the colouration of plastics, CROMOPHTAL Yellow HRP is no longer in powder form but is encapsulated by polymer and public exposure is expected to be negligible.

Under normal conditions of use, practically no waste is generated during the incorporation of CROMOPHTAL Yellow HRP into formulated products. Reformulation will be conducted in closed/sealed mixers or under local exhaust ventilation with dust collectors/air filters, and therefore, no public exposure to the notified chemical is expected to occur. The notifier has estimated that less than 10 kg/year will be released to the environment (air and water) during the manufacture of masterbatch. Residues from dust collectors may be disposed to landfill in accordance with relevant local, state and federal government regulations. Plastic 'scrap' arising from the manufacture of coloured plastic items is reprocessed into lower quality articles. The notifier has indicated that due to the variety of plastic products coloured with CROMOPHTAL Yellow HRP, the ultimate fate of such products cannot be assessed with accuracy. However, it is expected that the bulk of such articles will be disposed of as household garbage by incineration, landfill or recycling.

Industrial use and disposal of the notified chemical are not expected to result in any significant public exposure. The notified chemical will enter the public domain in the form of coloured plastics. In such products, CROMOPHTAL Yellow HRP is encapsulated within the polymer matrix and is not bioavailable. Thus, although there may be widespread public contact with such plastic products, public exposure to the notified chemical is expected to be negligible.

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 (< 2.5 kg per annum) of the chemical will remain in the packaging in which the chemical is imported. The packaging containing the trace of the notified chemical will be disposed of to landfill. These landfill sites will be distributed in Sydney, Brisbane and Melbourne.

A master batch is a solid mixture of one or more compounds in a suitable carrier polymer. The concentration of the notified chemical in master batches is expected to be between 1 and 20% (depending on the end use application; 1 to 10% for moulding/extrusion and 5 to 20% for film/tape). The process for formulating a master batch consists of weighing and blending of CHROMOPHTAL yellow HRP, 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. Waste from master batch formulation, consisting of dirty spilt material or purging material, is estimated to be less than 10 kg per annum. This material will be disposed of to landfill sites in Sydney, Brisbane and Melbourne.

After incorporation into master batches, the notified chemical will be completely dissolved and encapsulated in the polymer matrix. A trace amount (< 1 kg per annum) of the chemical will remain in the bags used to transport the master batches to plastic processors. Empty bags are disposed of as industrial waste (landfilled or incinerated) or recycled.

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 (in Adelaide, Sydney, Brisbane and Melbourne). The notifier estimates that such waste streams would be less than 1 kg per annum of the notified chemical. Based on previous experience, a more realistic estimate would be less than 1 kg per annum at each site of processing site (ie < 25 kg per annum of the notified chemical at the maximum rate of import).

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 water and oxides of carbon, nitrogen and sulphur.

A small amount (< 39 kg per year) will be disposed of to landfill as waste from the formulation master batches or production of plastic items. Any chemical which is not bound within a polymer matrix has the potential to be mobile within landfill, due to its high water solubility and its low partition coefficient. Metathesis of the ammonium ions with calcium (or similar) ions markedly reduces the water solubility of the anionic pigment (see discussion below for the acute immobilisation test for *Daphnia magna*). This reduction in water solubility would be expected to mitigate the mobility of the pigment in landfill.

Leaching (migration) studies on plastics containing the notified chemical have shown that only small amounts of the chemical are leached from the plastics. The leaching properties of the chemical (0.5% w/w) in high density polyethylene were investigated with four food simulants according to EEC Directives 82/671/EEC and 90/128/EEC. For all four food simulants the level of single sided migration was observed to be around 50 ng/kg food simulant, after 10 days at 40°C.

The substance was also examined for biodegradation potential using EEC Directive 92/69, Part C.4-E (Closed Bottle Test) (3), and OECD Test Guideline 301D (1). The substance exhibited 8% degradation after 28 days, indicating that it is not readily biodegradable under the conditions of the test. It was also found that the substance was not inhibitory to microorganisms under these conditions.

No testing of the bioaccumulation potential of the notified chemical was conducted. The notifier argues that the chemical does not have the potential to bioaccumulate, based on the low value of the partition coefficient (4). It is agreed that any potential for bioaccumulation would be limited by the low value of the partition coefficient (5, 6). The potential bioaccumulation of the notified chemical would be further mitigated by the low environmental release of the notified chemical.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of CROMOPHTAL Yellow HRP

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD ₅₀ > 2 000 mg/kg	(7)
acute dermal toxicity	rat	LD ₅₀ > 2 000 mg/kg	(8)
skin irritation	rabbit	slight irritant	(9)
eye irritation	rabbit	slight irritant	(10)
skin sensitisation	guinea pig	non-sensitiser	(11)

9.1.1 Oral Toxicity (7)

<i>Species/strain:</i>	rat/Sprague-Dawley
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	15 days
<i>Method of administration:</i>	single dose of 2 000 mg/kg administered by gavage; vehicle was distilled water
<i>Clinical observations:</i>	piloerection was observed in all rats within 5 minutes of dosing and through the remainder of day 1; yellow discolouration of the faeces was observed on day 2
<i>Mortality:</i>	none
<i>Morphological findings:</i>	none
<i>Test method:</i>	EEC Directive 92/69/EEC (3)
<i>LD₅₀:</i>	> 2 000 mg/kg

Result: the notified chemical was of low toxicity when administered orally in a limit test in rats

9.1.2 Dermal Toxicity (8)

Species/strain: rat/Sprague-Dawley

Number/sex of animals: 5/sex

Observation period: 15 days

Method of administration: a dose of 2 000 mg/kg was applied in water to an intact skin site; the site was covered with a semi-occlusive dressing; after 24 hours the dressing and residual test article were removed

Clinical observations: discolouration of the test site was evident throughout the observation period for all animals; there were no signs of systemic toxicity

Mortality: none

Morphological findings: none

Test method: EEC Directive 92/69/EEC (3)

LD₅₀: > 2 000 mg/kg

Result: the notified chemical was of low toxicity when administered dermally to rats in a limit test

9.1.3 Inhalation Toxicity

Not performed

9.1.4 Skin Irritation (9)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3/female

Observation period: 4 days

Method of administration: 0.5 g of the moistened test article was applied to a shaved test site; site was covered with a gauze pad and semi-occlusive dressing; after 4 hours the dressing was removed and the

	residual test article washed away
<i>Draize scores (12):</i>	all animals showed very slight erythema 60 minutes following application of the test substance; this was accompanied by very slight oedema in 2 of the 3 animals; these effects had cleared by the 24 hour reading
<i>Test method:</i>	EEC Directive 92/69/EEC (3)
<i>Result:</i>	the notified chemical was a slight skin irritant in rabbits

9.1.5 Eye Irritation (10)

<i>Species/strain:</i>	rabbit/New Zealand White
<i>Number/sex of animals:</i>	3/female
<i>Observation period:</i>	7 days
<i>Method of administration:</i>	approximately 76 mg (0.1 mL) of the undiluted test substance was placed in the conjunctival sac of one eye of each animal; the untreated eye served as a control; irritation was assessed at 1 hour, 1, 2, 3, 4 and 7 days according to the criteria of Draize (12).
<i>Draize scores (12) of unirrigated eyes:</i>	a slight dulling of the cornea was noted in two animals at the 1 hour time point; conjunctival redness (Draize score of 1) and chemosis (Draize score of 1 or 2) were also noted in all animals at this time point; the slight conjunctival redness persisted through to the day 1 reading; all other Draize scores were zero
<i>Test method:</i>	EEC Directive 92/69/EEC (3)
<i>Result:</i>	the notified chemical was a slight eye irritant in rabbits

9.1.6 Skin Sensitisation (11)

<i>Species/strain:</i>	Guinea pig/Dunkin/Hartley
<i>Number of animals:</i>	15 female (10 test; 5 control)
<i>Induction procedure:</i>	Day 1: 3 pairs of intradermal injections: - 0.1 mL Freund's complete adjuvant

(FCA): distilled water (1:1(v/v))

- 0.1 mL of 7.5% concentration of test material in distilled water
- 0.1 mL of 7.5% concentration of test material in FCA: physiological saline(1:1 (v/v))

Day 7: test area treated with 10% (w/w) sodium lauryl sulfate in petrolatum

Day 8: occluded application of filter paper soaked in 0.4 mL test material (70% in distilled water) for 48 hours

Challenge procedure:

Day 22: occluded application of filter paper soaked in 0.2 mL test material (35% and 70% in distilled water) for 24 hours

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	24 hours*	48 hours*	24 hours	48 hours
35%	0/10**	0/10	0/5	0/5
70%	0/10	0/10	0/5	0/5

* time after patch removal

** number of animals exhibiting positive response

Test method:

EEC Directive 92/69/EEC (3)

Result:

the notified chemical was not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (13)

Species/strain:

rat/Sprague-Dawley

Number/sex of animals:

30/sex; control and high dose groups: 10/sex
low and mid dose groups: 5/sex

Method of administration:

gavage; vehicle was aqueous methylcellulose (1% w/v)

Dose/Study duration::

dose levels were based on the results of a 7-day range finding study in rats (14)
test material administered daily for a total of

28 days:

control: 0 mg/kg/day
low dose: 15 mg/kg/day
mid dose: 150 mg/kg/day
high dose: 1 000 mg/kg/day

all animals were sacrificed at the end of the treatment period, with the exception of 5 animals from control and high dose groups, which were maintained for an additional 2 week recovery period before sacrifice

Clinical observations:

no treatment related clinical signs of toxicity were noted in any of the animals throughout the study; there was yellow discolouration of the faeces for animals receiving 1 000 mg/kg/day from day 2 until the end of the treatment period

Clinical chemistry/Haematology:

assessment of haematology and clinical biochemistry parameters and urinalysis indicated that no significant treatment related effects were noted in the parameters measured.

Histopathology:

macroscopic examination revealed yellow green contents in the stomach, caecum or entire gastro-intestinal tract for several animals from the high dose group; this finding was considered to indicate the presence of the test substance in the gastro-intestinal contents and was not a manifestation of toxicity; no histopathological changes related to treatment with the test substance were detected in this study at the highest dosage level of 1 000 mg/kg/day.

Test method:

EEC Directive 84/449/EEC (15), and OECD Guidelines No. 407 (1)

Result:

the notified chemical did not exhibit any significant organ toxicity when administered orally to rats for 28 days

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (16)

Strains:

Salmonella typhimurium TA 1535, TA 1537, TA 1538, TA 98 and TA 100; *Escherichia coli* WP2uvrA

<i>Concentration range:</i>	the assay was performed in two independent experiments with or without induced rat liver and un-induced syrian hamster liver (S9) microsomal activation; the test substance and controls were tested in triplicate at the following concentrations: 312.5, 625, 1 250, 2 500 and 5 000 µg/plate.
<i>Test method:</i>	EEC Directive 92/69/EEC (3)
<i>Result:</i>	<p>the notified chemical was not toxic towards the tester strains at 5 000 µg/plate; there were no significant increases in revertant colony numbers at any dose level, either in the presence or absence of metabolic activation;</p> <p>the notified chemical is not considered to be mutagenic in bacteria</p>

9.3.2 *In vitro* Mammalian Cytogenetic Test - Human Lymphocytes (17)

<i>Species/strain:</i>	cultured human lymphocytes
<i>Doses:</i>	experiments were performed at the following doses: 18.8, 37.5, 75 and 150 µg/mL without metabolic activation (S9-mix) and 37.5, 150, 225 and 300 µg/mL with S9-mix; two positive controls were used
<i>Test method:</i>	similar to EEC Directive 92/69/EEC (3)
<i>Comments:</i>	<p>in the absence of S9-mix the highest selected (non-cytotoxic) concentration was 150 µg/mL; in the presence of S9-mix, the highest concentration that could be used for analysis was 225 µg/mL for both the 18 hour and 32 hour harvest</p> <p>in both the absence and presence of S-9 mix, there were no chromosomal aberrations at fixation intervals of 18 hours and 32 hours</p>
<i>Result:</i>	the notified chemical did not show any evidence of clastogenic activity in a chromosomal aberration test in human lymphocytes <i>in vitro</i>

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low acute toxicity in rats by oral ($LD_{50} > 2\,000$ mg/kg) or dermal ($LD_{50} > 2\,000$ mg/kg) administration. The notified chemical was a slight skin and eye irritant in rabbits and was not a skin sensitiser in guinea pigs. There were no significant toxicological effects in rats from repeat oral administration for 28 days.

The notified chemical was found not to be mutagenic by bacterial reverse mutation assay or genotoxic by chromosomal aberration assay in cultured human lymphocytes *in vitro*. No *in vivo* studies were performed.

According to the *Approved Criteria for Classifying Hazardous Substances* (18), CROMOPHTAL Yellow HRP would not be classified as hazardous, in relation to the toxicological end points measured.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out to OECD Test Methods (1).

Species	Test	Results
Zebra fish <i>Brachydanio rerio</i>	acute toxicity (96 hour)	NOEC \geq 135 mg/L
<i>Daphnia magna</i>	acute immobilisation (48 hour)	NOEC \geq 5.2 mg/L
algae <i>Scenedesmus</i> <i>subspicatus</i>	growth inhibition (72 hour)	Ec ₅₀ = 260 mg/L Er ₅₀ > 230 mg/L NOEC <10 mg/L
micro-organisms in aerobic activated sludge	respiration inhibition (3 hour)	EC ₅₀ > 100 mg/L

The effect of the notified chemical was only determined at one concentration (135 mg/L) in the 96 hour acute toxicity test for fish. At this concentration no effect on the fish was observed over the 96 hour duration of the test. Thus, the notified chemical can be regarded as practically non-toxic to fish.

The effect of the notified chemical was only determined at one concentration (nominal concentration of 120 mg/L, measured concentration 5.2 mg/L) for the 48 hour acute immobilisation test for *Daphnia*. The solubility of the notified chemical in the test media was markedly reduced from its solubility in water. The decrease in solubility probably reflects a salting out of the notified chemical due to the presence of calcium (236 mg/L) or similar cations in the test media. No toxic effects were observed at concentration well above the solubility (5.2 mg/L) of the chemical in the test media.

Data presented in the above table for algal growth inhibition test was determined by extrapolation as 50% inhibition was not achieved. The effect of the notified chemical

was examined at five concentrations (10, 21, 47, 100 and 230 mg/L) and a control. Microscopic investigation of the test and control cultures revealed no abnormalities in the lower level test concentrations (10, 21 and 47 mg/L). However, some slight effects on growth were observed even at the lowest concentration. This effect may arise from the intense colour of the test solutions, resulting in the interception of light (shading effect) by the chemical that is necessary for algal growth. The two highest test levels (100 and 230 mg/L) appeared to contain fewer cells and at 230 mg/L turgidity was noted. The results of the test indicate that the notified chemical is practically non-toxic to algae.

In the 3 hour activated sludge respiration inhibition the effect of the notified chemical was examined at a nominal concentration of 100 mg/L. At this concentration only 2 to 3% inhibition was observed. As the test media contained cations, including calcium (400 mg/L), it is likely the majority of the notified chemical was present as an insoluble salt, as was observed in the acute immobilisation test for *Daphnia*.

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 it is possible that a low level of leaching may occur. This is not expected to be significant and the majority of the notified chemical is expected to remain within the plastic articles. Any chemical which is not bound within a plastic matrix has the potential to leach from landfill. This potential would be mitigated by the presence of calcium (or similar) ions in landfill, which markedly reduces the water solubility of the anionic pigment through a salting out effect.

Waste from the manufacture of master batches and plastic articles (< 39 kg per annum) will be disposed of to landfill where it is expected that it will be immobile.

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

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

During the importation and transportation of the notified chemical, there is unlikely to be any worker exposure, except in the event of a spill. This may be minimised by the recommended practices for spillage given in the MSDS. The occupational risk posed to these workers is negligible.

The major potential for exposure to the notified chemical is during its use in the manufacture of coloured masterbatch for thermoplastic polymers. There is potential for direct dermal exposure through handling or through dust generation.

Toxicological tests in rats indicate that it is unlikely that the notified chemical will pose a hazard to humans on repeated or prolonged exposure and unlikely to exhibit acute toxicity. Should dermal or ocular contact occur, the notified chemical may

cause slight skin and eye irritation, based on results of rabbit studies. Tests in guinea pigs indicated there is little potential for skin sensitisation in humans. It should be noted that the potential for dust explosion exists when handling the notified chemical in powdered form, and airborne dust levels should be kept to a minimum (see MSDS). Given the low toxicity of the notified chemical, the occupational risk for workers in this area is low.

The further processes for making thermoplastic masterbatch are conducted within sealed systems that are unlikely to present any significant opportunity for exposure to the notified chemical. At the end of the process, the notified chemical will be encapsulated in polymer and therefore will not be bioavailable.

The notified chemical will enter the public domain in the form of coloured plastic articles. In such products, CROMOPHTAL Yellow HRP is encapsulated within the polymer matrix and is not bioavailable. Thus, although there may be widespread public contact with such products, public exposure to the notified chemical is expected to be negligible.

Based on the information provided it is considered that CROMOPHTAL Yellow HRP will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to CROMOPHTAL Yellow HRP the following guidelines and precautions should be observed:

- It is good work practice to wear industrial clothing which conforms to the specifications detailed in Australian Standard (AS) 2919 (19) and occupational footwear which conforms to Australian and New Zealand Standard (AS/NZS) 2210 (20) to minimise exposure when handling any industrial chemical;
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly and put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (21).

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