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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

CROMOPHTAL Yellow 113A

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989,* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Human Services and Health.

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For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 565-9466 **FAX (61) (02) 565-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

CROMOPHTAL Yellow 113A

1. APPLICANT

CIBA-GEIGY Australia Ltd. of have submitted a standard notification for assessment of CROMOPHTAL Yellow 113A.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, CROMOPHTAL Yellow 113A is not considered to be hazardous. Therefore, the chemical name, CAS No., molecular and structural formulae, molecular weight and spectral data have been exempted from publication in the Full Public Report and the Summary Report. Additionally, the composition of the chemical and the import volume have also been exempted from these reports to maintain confidentiality.

Other names: CROMOPHTAL Yellow 113A
TKP 5007

Trade name: CROMOPHTAL Yellow GT-AD

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	yellow powder
Odour:	not specified
Melting Point/Boiling Point:	> 292°C. The chemical is not stable in an air atmosphere above ~200 °C or possibly 155°C
Specific Density:	1.22 kg/m^3
Vapour Pressure:	4 x 10^{-27} kPa at 25°C (by calculation)
Water Solubility:	0.011 mg/L at 20°C and pH 6
Fat Solubility:	2-4 mg/100 g fat at 37°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	> 6.2
Hydrolysis as a function of pH:	not performed
Adsorption/Desorption:	not performed
Dissociation Constant pKa:	not performed
Flash Point:	not performed

Flammability Limits: non-flammable

Autoignition Temperature: > 400°C

Explosive Properties: not explosive

Reactivity/Stability: not determined

Particle size distribution : 50% < 13 µm
< 2 µm 9.0% (w/w)
2-5 µm 12.5% (w/w)
5-10 µm19.0% (w/w)
10-20 µm 29.5% (w/w)
20-50 µm 27.0% (w/w)
> 50 µm3.0% (w/w)

Comments on physico-chemical properties:

The tests for hydrolytic stability, adsorption/desorption and dissociation were not performed. The partition coefficient of the chemical is lower than expected for a chemical with low water solubility. It was argued that since the notified chemical has low water solubility, it is likely that the level of entry into the soil would be very low. The test for hydrolysis was argued not to be applicable as the low water solubility of the notified chemical prevented preparation at concentrations that could be measured.

Hydrolytic Stability: the notified substance has an amide functionality and is therefore susceptible to hydrolysis. No results were provided as no suitably sensitive analytical was available. This is acceptable, due to the very low solubility (< 10 ppb measured) of the notified substance in water. Hydrolysis is unlikely to occur at significant rates under environmental conditions.

Soil Adsorption/Desorption: The method of use will not present opportunities for the release of significant quantities of the notified chemical into the environemt which could result in soil contamination. If release occurs, strong adsorption is expected.

Dissociation Constant: Dissociation tests were not conducted due to the low solubility and relatively high molecular weight of the notified substance.

4. PURITY OF THE CHEMICAL

This information is exempted from the full public and summary reports.

5. INDUSTRIAL USE

The notified chemical will be used for plastic colouration. The high cost of this class of pigment will restrict its use for high quality applications where high fastness properties are required. Less than 10 tonnes is expected to be imported over the next 5 years.

The notified substance will be imported in 20 kg cardboard cartons lined with anti-static plastic. It will arrive by air freight and be transported by road to industrial establishments.

It is estimated that 4-6 masterbatch manufacturers will use the notified chemical. The total number of employees (plant operators and laboratory technicians) potentially exposed to the notified chemical is expected to be less than 24. Additionally, a number of plastic processors will be using formulated products containing the notified chemical.

Occupational exposure will mainly occur during weighing and batching operations during the masterbatch process.

Formulations are first established on a laboratory scale, using a limited number of trials, using less than 200 g usually. Exposure to the compound is expected to be less than one hour in duration. Additionally, laboratory staff may need to test the incoming raw powder, leading to approximately one hour's exposure every few months.

During storage, exposure is expected to be minimal, and result only from accidental spillage or mishandling of containers.

The primary source of exposure during reformulation will be to the pigment powder aerosols during weighing and batching operations. The masterbatch process consists of weighing and blending of polymer, pigment powder and additives, which is carried out in sealed mixers to avoid dusting. The pre-blending process is followed by an extrusion method which completely encapsulates the pigment into the molten polymer, which is then cooled. No information was provided on whether local exhaust ventilation, but based on knowledge of the industry, it is unlikely that there is.

Once the pigment is dispersed and encapsulated in polymer, exposure potential of employees at the plastic processors is reduced, as the masterbatch (completely encapsulated in polymer) offers ease of handling, colour control and dustfree operations.

7. PUBLIC EXPOSURE

Public exposure during storage and distribution of the notified chemical is not expected to occur.

The notified chemical will initially be reformulated to produce coloured masterbatches, which will be used by manufacturers of plastics. 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 use of coloured masterbatches by the manufacturers of plastics is not expected to result in significant public exposure as negligible waste is expected to occur, and the notified chemical will be embedded in the polymer.

Disposal of any waste chemical will be by incineration and landfill, and is not expected to result in significant public exposure.

Public exposure to the notified chemical as a result of contact with end-use products is not expected to occur as it will be embedded in the polymer matrix of plastic materials. The notified chemical is practically insoluble in water, fat and common solvents, and therefore has negligible potential for migration from finished products, or dermal absorption.

8. ENVIRONMENTAL EXPOSURE

Release

The notified substance will be imported in 20 kg cardboard cartons lined with anti-static plastic. It will arrive by air freight and be transported by road to industrial users. Spills that occur during transport or handling will be cleaned up according to the MSDS and consigned to secure landfill or incinerated.

The notified substance is a yellow pigment and will be used in the colouration of speciality plastics. An estimated 4-6 industrial sites will use the notified substance in the formulation of masterbatches (pigment concentrate). A small number of additional plastics manufacturers will use these masterbatches in their formulations.

During masterbatch formulation, pigment (notified chemical) loading will typically range between 1-10%. During subsequent handling, wastage should be minimised as the masterbatch formulation is marketed in a granulated/pelletised form. In the final processed plastic typical concentrations of notified chemical are 0.1 to 0.2%. Off-cuts from plastics processing will be reprocessed into lower grade products.

The market for products containing the notified chemical will be limited due to the relatively high cost of this chemical compared to existing chemicals. One potential application for the notified substance is to replace the use of cadmium-containing colourants.

Fate

A 28 day test for biodegradation was performed in accordance with EEC guidelines using two test samples, both containing approximately 40 mg/L (nominal) of the notified substance. Results showed limited degradation of CROMOPTHAL Yellow 113A (< 11% for both samples), indicating that biodegradation in landfill is unlikely, particularly as encapsulation within a polymer matrix is expected.

The potential for environmental release of the notified substance is very limited, estimated at < 1 kg/year at each formulation site. During masterbatch preparation, the pigment becomes encapsulated within a polymer resin, thereby limiting the availability of pigment for release to the environemt. Pigmented plastics will be ultimately be consigned to landfill. Leaching is unlikely due to the physico-chemical properties of the notified chemical identified above, and the immobilisation resulting from the encapsulation of the pigment within the cured polymer matrix (plastic).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of CROMOPTHAL Yellow 113A

Test	Species	Outcome	Reference
Oral Toxicity	Rat	LD_{50} > 2000 mg/kg	(1)
Dermal Toxicity	Rat	LD_{50} > 2000 mg/kg	(2)
Skin Irritation	Rabbit	Not irritating	(3)
Eye Irritation	Rabbit	Slight irritant	(4)
Skin Sensitisation	Guinea-pig	Non-sensitiser	(5)

9.1.1 Oral Toxicity (1)

This study was performed in accordance with European Economic Community (EEC) Directive 92/69/EEC (6).

Wistar rats (5/sex) were given a single oral dose of CROMOPTHAL Yellow 113A at a dose level of 2000 mg/kg in propylene glycol as the vehicle. Animals were observed for 14 days and necropsied on day 15.

No mortalities were recorded. Clinical signs consisted of hunched posture and rough fur in all animals except one female, and lethargy in one male. These were only observed on day 1. Body weight gains were considered to be comparable to normal untreated animals.

Macroscopic examinations found no abnormalities.

In conclusion, the oral LD_{50} of CROMOPTHAL Yellow 113A in rats was > 2000 mg/kg.

9.1.2 Dermal Toxicity (2)

This study was performed in accordance with European Economic Community (EEC) Directive 92/69/EEC (7).

Wistar rats (5/sex) were given a single dermal dose of CROMOPTHAL Yellow 113A at a dose level of 2000 mg/kg in propylene glycol as the vehicle, applied to a clipped area of the back for a 24 hour period. The application was covered with a semi-occlusive dressing. Animals were observed for 14 days and necropsied on day 15.

One male death was recorded on day 2.

No clinical signs were observed during the study. Body weight gains were reduced in most animals during the first week of treatment.

Macroscopic examinations found no abnormalities in any treated animals including the animal that died.

In conclusion, the dermal LD_{50} of CROMOPTHAL Yellow 113A in rats was > 2000 mg/kg.

9.1.3 Skin Irritation (3)

This study was performed in accordance with OECD Guideline No. 404 (8).

A single dose of 0.5 g CROMOPTHAL Yellow 113A (moistened with distilled water) was applied by semi-occlusive application to the closely-clipped dorsa of 3 male New Zealand White rabbits. Four hours later the dressings were removed and the test substance removed with a tissue moistened with tap water. Skin reactions were assessed 1, 24, 48 and 72 hours after removal of dressing.

No mortalities were recorded.

No skin irritation was observed after 4 hours of application of notified chemical. Erythema was difficult to score because of the staining caused by the notified chemical.

There was no evidence of corrosive effects. No systemic toxicity symptoms were observed.

The study indicated that Cromophtal Yellow 113A was not a skin irritant in rabbits.

9.1.4 Eye Irritation (4)

This study was performed in accordance with OECD Guideline No. 405 (9).

A single dose of 35 mg of CROMOPTHAL Yellow 113A was instilled in the conjunctival sac of one eye (not specified which) of each of 3 male New Zealand White rabbits. The other eye remained untreated and served as the reference control. The eyes were examined 1, 24, 48 and 72 hours after instillation of the test substance.

No mortalities were recorded.

Conjunctival redness was observed in all animals one hour after instillation and had resolved by 72 h in all animals. Treatment of the eyes with 2% fluorescin 24 hours after instillation revealed no corneal damage.

There was no evidence of ocular corrosion. No symptoms of systemic toxicity were observed.

From the calculated maximum Draize (10) score of 2, CROMOPTHAL Yellow 113A was considered to be a slight eye irritant in rabbits.

9.1.5 Skin Sensitisation (5)

This study was performed in accordance with OECD Guideline No. 406 (11). The test used was that of Magnusson and Kligman (12). The Himalayan albino guinea-pig was used.

Induction

On day 1, 20 guinea-pigs were injected intradermally on the clipped dorsal skin of the scapular region as follows: A) CROMOPTHAL Yellow 113A, 5% w/v, in oleum arachidis, B) a 1:1 mixture of Freund's Complete Adjuvant (FCA) in distilled water, and C) CROMOPTHAL Yellow 113A, 5% w/v, in a 1:1 (v/v) mixture of FCA and distilled water.

On day 7, the application site was pretreated with 10% sodium lauryl sulphate in vaseline. On day 8, the scapular region was treated again, with a 2 x 4 cm patch saturated with Cromophtal Yellow 113A (50% w/w in vaseline) applied over the injection sites and covered with dressing for 48 hours. Skin reactions were assessed immediately after removal of the dressing. Controls were treated identically to test animals with the omission of test substance.

No test or control animals showed erythema or oedema after removal of the patch.

Challenge

Test and control animals were challenged two weeks after the epidermal application ie. on day 22. Test substance at a concentration of 30% in vaseline and vaseline vehicle alone was applied to clipped and shaved flanks of each guinea-pig, and occluded with a dressing for 24 hours. Skin sensitisation was assessed 24 and 48 hours after removal of dressing.

No test or control animals showed positive results after removal of the dressing.

In conclusion, CROMOPTHAL Yellow 113A is classified as a non-sensitiser in albino guinea-pigs according to the grading of Magnusson and Kligman.

Other Results

No symptoms of systemic toxicity and no mortalities were observed in this study.

9.2 Repeated Dose Toxicity (13)

9.2.1 28-Day Oral Toxicity Study in Rats

This study was performed in accordance with OECD Guideline No. 407 (14).

CROMOPTHAL Yellow 113A was administered orally to Wistar rats (5/sex/group) at doses of 0, 50, 200 or 1000 mg/kg/day for 28 days. The vehicle used was propylene glycol. All animals were necropsied on day 28. The control and high dose (HD) groups contained 5 additional animals per sex for the recovery period of 28 days. Clinical signs, body weights, and food consumption were measured regularly. Clinical and ophthalmoscopic examinations were performed. After necropsy, organ weights were measured, and macroscopic and histopathological examinations were performed.

No treatment-related effects were observed throughout the study.

It was concluded that the notified chemical did not exhibit organ toxicity after repeated oral administration for 28 days.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assays (15)

This study was performed in accordance with OECD Guidelines No. 471 and 472 (16).

Strains used were *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100 and *Escherichia coli* strains WP2 and WP2 *uvrA*. The assays were performed in two independent experiments both without and with metabolic activation provided by rat liver S9. Each concentration including controls was tested in triplicate. The following concentrations were tested: 33.3, 100, 333.3, 1000, 2500 and 5000 µg/plate. Positive reference controls used were a) sodium azide, 4-nitro-o-phenylene-diamine and methyl methane sulfonate in the absence of metabolic inactivation and b) 2-aminoanthracene in the presence of metabolic activation.

At the highest investigated concentration, 5000 µg/mL, slight toxic effects were observed as evidenced by a reduction in revertant numbers in the strains TA 1535 and WP2 *uvrA* with S9 mix, and strains TA 98 and WP2 without S9 mix in experiment 1. In experiment 2, a slight toxic effect was observed in strain TA 98 without S9 mix at the highest concentration examined.

No increase in revertant colony numbers was observed for any of the strains at any dose level of Cromophtal Yellow 113A used, either in the absence or presence of metabolic activation.

The positive controls produced the expected responses.

In conclusion, under the conditions of these assays CROMOPTHAL Yellow 113A did not induce point mutations by base pair changes or frameshifts in any of the four *Salmonella typhimurium* and two *Escherichia coli* strains used.

9.3.2 Chromosomal Aberrations in Chinese Hamster Ovary Cells (17)

This study was performed in accordance with OECD Guideline No. 473 (18).

Two independent experiments were carried out.

The chromosomes were prepared 18 h and 28 h after initiation of treatment with CROMOPTHAL Yellow 113A formulated in dimethylsulphoxide (DSMO). The

exposure time was 4 h with metabolic activation provided by rat liver S9 and 18 h and 28 h without metabolic activation. In both experiments, cultures without metabolic activation were treated with 3,0, 10, or 30 µg/mL (experiments 1 and 2) and harvested at 18 h (all concentrations) or 28 h (highest concentration only). Concentrations of 10, 30 or 100 µg/mL were incubated with metabolic activation (experiments 1 and 2) and harvested at 18 h (all concentrations) or 28 h (300 µg/ml only; experiments 1 and 2). All experiments were conducted in duplicate. One hundred metaphases per culture were scored for structural chromosomal aberrations. Positive controls used were ethylmethanesulfonate without metabolic activation or cyclophosphamide with metabolic activation.

In both independent experiments, there was no biologically and statistically relevant increases in cells with structural chromosomal aberrations after treatment with CROMOPTHAL Yellow 113A at both fixation intervals either with or without metabolic activation.

The positive control mutagens produced the expected responses.

In conclusion, under the assay conditions described, CROMOPTHAL Yellow 113A did not induce structural chromosomal aberrations in Chinese hamster ovary cells.

9.4 Overall Assessment of Toxicological Data

Animal studies indicate that CROMOPTHAL Yellow 113A has low acute oral and dermal toxicity in rats (LD_{50} > 2000 mg/kg). It was not a skin irritant in rabbits nor was it a skin sensitiser in guinea-pigs. It produced mild irritation of the eye in rabbits. In a 28-day oral toxicity study in rats, no treatment-related effects were observed up to the highest dose used (1000 mg/kg/day). Overall, CROMOPTHAL Yellow 113A had low toxicity.

Genotoxicity studies indicated that it had no mutagenic potential *in vitro*. No *in vivo* studies were performed.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following tests to assess the environmental effects of CROMOPTHAL Yellow 113A were performed according to OECD and EEC test guidelines. Results are summarised in Table 2.

Table 2. Environmental Effects of CROMOPHTAL Yellow 113A on Aquatic Species

Test	Material	Species	Result *
96 hour acute toxicity	Yellow 113A	Rainbow trout *Oncorhynchus mykiss*	NOEC > 10 mg/L LC_{50} > 10 mg/L
48 hour immobilization test OECD TG 202	Yellow 113A	Water flea *Daphnia magna*	EC_{50} > 10mg/L NOEC < 10mg/L
Algal Growth Inhibition OECD TG 201	Yellow 113A	Algae *Scenedesmus subspicatus*	E_bC_{50} and E_uC_{50} > 10 mg/L LOEC = 10mg/L
30 minute respiration inhibitory test	Yellow 113A	Activated sludge	no significant inhibition (< 10%); max. test conc. 200.8 mg/L

* Concentrations reported are nominal unless otherwise noted.

The test solutions for the fish, daphnia and algal studies all used Tween 80 as the dispersing agent and nominal concentrations of 0.46, 1.0, 2.1, 4.6 and 10 mg/L. Higher concentrations were not studied

because analytical studies had shown that 10 $mg.L^{-1}$ was the maximum level achievable using 100 mg/L of Tween 80. All studies reported settling of the notified chemical from the two highest concentrations studied. In the fish, the maximum nominal concentration studied was determined to be equivalent to a maximum mean measured value of 3.5 mg/L .

No significant toxic effects were noted in the fish study at any of the test concentrations studied. At the highest nominal concentration, 1-3 fish showed lower swimming activity and stayed mainly at the bottom of the aquarium during the 24-72 h observations. This transitory behaviour was possibly attributable to temporary irritation caused by the high concentration of emulsified pigment. After 96 h the behaviour of the fish was no different to that of the controls.

At the maximum concentration studied, 15% of the *Daphnia* were immobilised after 48 h. The three *Daphnia* concerned were stuck to the test substance and settled to the bottom of the test tank.

For the algal growth inhibition test, the LOEC was determined to be equivalent to the maximum concentration studied due to the observation of a slight, but statistically relevant inhibition. This inhibition may have resulted from indirect effects caused by changes in the quality of transmitted light due to colouration (observed) of the test solution by the pigment.

The 30 minute respiration inhibition test for activated sludge showed no significant inhibition (< 10%), indicating microbial populations in sewage treatment works are unlikely to be adversely affected by the pigment. Undissolved test particles were observed at the surface of the test solution.

The results reported above indicate that at the maximum achievable water concentration, the notified chemical should have no adverse effects on aquatic organisms. The observation of floating particulates and settling, indicate partitioning of the notified chemical to the sediment is likely, thereby limiting its potential for exposure.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard of CROMOPTHAL Yellow 113A can be rated as negligible. The proposed application and associated usage patterns will limit environmental exposure to negligible levels. Release of unbound pigment is estimated at < 1 kg per annum at each formulation site (maximum of 6).

During masterbatch formulation and subsequent processing the notified chemical is encapsulated within polymer resins. Plastic scraps will generally be collected and reformulated into lower grade product. The plastic products will be disposed of by landfill or recycled at the end of their useful lives. In landfill the pigment will not leach due to its low solubility and high partition coefficient (log P_{ow} > 6.2). Furthermore, the encapsulation of the pigment within the polymer resin further reduces its leachability.

The low level environmental exposure of the pigment as a result of normal use, together with its lack of significant biological activity, indicate the environmental hazard should be negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified substance will be imported in 20 kg cardboard cartons lined with anti-static plastic. It will arrive by air freight and be transported by road to industrial establishments. Exposure during this phase is unlikely unless there is a spillage.

During storage, exposure is expected to be minimal, and result only from accidental spillage or mishandling of containers.

Occupational exposure will mainly occur during weighing and batching operations during the masterbatch process. Use of the notified substance will be limited in terms of numbers handling and the time period of use. Formulations are first established on a laboratory scale, using a limited number

of trials, using less than 200 g usually. Exposure to the compound is expected to be less than one hour in duration. Additionally, laboratory staff may need to test the incoming raw powder, leading to approximately one hour's exposure every few months.

The primary source of exposure during reformulation will be to the pigment powder aerosols during weighing and batching operations. The respirable fraction of the notified chemical is high with ~40% ≤ 10 μm in diameter. The masterbatch process consists of weighing and blending of polymer, pigment powder and additives, which is carried out in sealed mixers to avoid dusting. The pre-blending process is followed by an extrusion method which completely encapsulates the pigment into the molten polymer, which is then cooled.

The toxicological profile of CROMOPTHAL Yellow 113A indicates that it is unlikely to be a hazard to workers. As long as workers follow control and precautionary measures according to the MSDS, the notified substance will not pose a significant risk to occupational health.

During the masterbatch process, the pigment is dispersed and completely encapsulated in polymer, thus reducing exposure potential of employees at the plastic processors and is considered to pose a low risk to plastics workers.

Public exposure to the notified chemical as a result of contact with end-use products is not expected to occur as it will be embedded in the polymer of plastic materials. If public exposure were to occur exposure levels would be low, and the low fat solubility of the notified chemical suggests that dermal absorption is unlikely. There is negligible risk to public safety resulting from use of the notified chemical.

Based on the information provided it is considered that CROMOPTHAL Yellow 113A will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to CROMOPTHAL Yellow 113A the following guidelines and precautions should be observed:

. If engineering controls and work practices are insufficient to reduce exposure to dye solutions containing CROMOPTHAL Yellow 113A to a safe level, the following personal protective equipment should be used:

  - respiratory protection conforming to Australian Standards (AS) AS 1715 (19) and AS 1716 (20),

  - eye protection conforming to AS 1336 (21) and AS 1337 (22),
  - impervious handgloves conforming to AS 2161 (23), and

  - protective clothing conforming to AS 3765.1 (24) and AS 3765.2 (25)

. Good work practices should be implemented to avoid generation of dust.

. Good personal hygiene practices should be observed.

. A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

If the notified chemical is to be used in products intended for food storage, it is recommended that the company submit an appropriate application to the National Food Authority.

If conditions of use are varied, greater exposure of the public may occur. In such circumstances further information may be required to assess the hazards to public health.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for CROMOPTHAL Yellow 113A was provided in Worksafe Australia format (26).

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of CROMOPTHAL Yellow 113A 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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