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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

ClearTint PC Yellow 485

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Street Address: 92 -94 Parramatta Rd CAMPERDOWN NSW 2050, AUSTRALIA
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Telephone: (61) (02) 9577 9514 FAX (61) (02) 9577 9465

Director
Chemicals Notification and Assessment

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1. APPLICANT

Asia Pacific Specialty Chemicals Limited of 15 Park Road Seven Hills NSW 2173 (ABN 32 000 316 138) and WOM International of 7/195 O'Sullivan Beach Road Lonsdale SA 5160 (ABN 14 002 708 830) have jointly submitted a limited notification statement in support of their application for an assessment certificate for ClearTint PC Yellow 85.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, purity and details of the polymer composition have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name: ClearTint PC Yellow 485

2. PHYSICAL AND CHEMICAL PROPERTIES

The physical and chemical properties tabulated below are for the notified polymer, unless otherwise indicated.

Appearance at 20°C & 101.3 kPa:	Dark yellow liquid
Boiling Point:	>140°C
Specific Gravity:	1.1
Vapour Pressure:	Not determined. Expected to be very low.
Water Solubility:	2000 mg/L at 25°C (analogue chemical)
Partition Co-efficient (n-octanol/water):	log K_{ow} = 2.97
Hydrolysis as a Function of pH:	Miscible with water, n-octanol, toluene, tetrahydrofuran and isopropylalcohol at 100, 200 and 2000 mg/L
Adsorption/Desorption:	Not determined. Due to its high solubility in n-octanol, it is expected to associate with soil and sediment.

Dissociation Constant:	Not determined. It is not expected to dissociate in water
Flash Point:	238°C
Flammability Limits:	The polymer is combustible, not flammable
Autoignition Temperature:	>350°C
Explosive Properties:	Not determined. It is expected to be stable under normal conditions of use
Reactivity/Stability:	Not determined. It is expected to be stable

3.1 Comments on Physico-Chemical Properties

The vapour pressure was not determined for the notified polymer. The notifier indicates the vapour pressure of the notified polymer is likely to be low considering its high molecular weight.

The water solubility was not determined for the notified polymer. The notifier indicates that a close structural analogue of the notified polymer (different ratios of polyoxyalkene units) has a water solubility in the order of 2000 mg/L. A water solubility calculation using a regression equation (log 1/S = 1.339log K_{ow} – 0.978, Lyman 1990) estimated the notified polymer would have a water solubility of approximately 1.5 g/L.

The notified polymer contains an ester linkage that could be expected to undergo hydrolysis under extreme pH. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely. The notifier has submitted information on the pH stability of the structurally related compound. Buffered solutions were prepared at pH 1.2, 4, 7 and 9 according to OECD TG 111 and test substance added at 200 mg/L. Additional samples were prepared at pH 1.2 and 4 and 2000 mg/L. The test solutions were stored at 40 ºC for 14 days with occasional shaking then extracted into chloroform and evaporated to dryness. The chloroform extracts were dissolved in THF. GPC analysis did not show any significant changes in molecular weight suggesting that the colourant is stable to hydrolysis in the pH range of 1.2 and 9.

The partition coefficient of the notified polymer was determined by OECD TG 117 (HPLC method). The partition coefficient indicates the notified polymer is hydrophobic in nature and partitions into the *n*-octanol phase.

No adsorption/desorption tests were provided. The notifier expects the notified polymer to be immobile in soil based on the estimated water solubility.

The notifier expects that the notified polymer will not undergo dissociation, as it does not contain any functional groups able to undergo dissociation.

4. PURITY OF THE CHEMICAL

Degree of Purity:	Very high
Maximum Content of Residual Monomers:	Chemical identity is exempt information. Concentrations of residual monomers are low as they would be expected to polymerise to form the notified polymer
Impurities:	Chemical identity is exempt information. Impurities are each present at less than 1%.
Additives/Adjuvants:	Chemical identity is exempt information. Each additive/ adjuvant is present at concentrations below the cut off levels for classification as a hazardous substance.

5. USE, VOLUME AND FORMULATION

The notified polymer, ClearTint PC Yellow 485, will not be manufactured in Australia. It will be imported as a component of a polypropylene masterbatch containing approximately 8% notified polymer in 20 kg (45 lb) polyethylene pail or 215 kg (475 lb) cardboard drum with polyethylene lining. The masterbatch containing the notified polymer is in a form of a non-dusty pellet measuring approximately 3mm long, 2.5 mm wide and 2.5 mm deep.

The notified polymer will be used as a colourant for polypropylene or polyethylene plastic articles such as packaging, storage containers, bottles and medical devices. The end use product will normally contain approximately 0.16% notified polymer.

The estimated import volume of the notified polymer is between 1 and 2 tonnes for the first year and 2 tonnes for the next 4 years.

6. OCCUPATIONAL EXPOSURE

Transport and Storage
Following importation, transport workers will deliver the masterbatch pellets containing approximately 8% notified polymer to customers ready for forming into plastic articles. The masterbatch will be transported from the wharf to the customer sites by road. Waterside, warehouse and transport and storage workers (2-4 workers, duration of exposure of 2-4 hours/year, 6-12 days/year) are unlikely to be exposed to the notified polymer unless the packaging is breached.

End Use
Approximately 20 process workers will have the potential for exposure to the notified polymer on a regular basis (maximum duration of exposure of 4 hours/day, 240 days/year). The masterbatch pellet is vacuum transferred from drums to the feeding hopper on the moulding machine and dispensed automatically at the desired rate into the hopper of an injection moulding machine. Once heated, the melted pellets are moulded to form the shape of the plastic article, then cooled.

The notifier indicates that the manufacture of plastic articles involves a highly automated

process. Skin contact may occur when opening containers and manually charging the polymer masterbatch into the heat-moulding machine. However, worker exposure is not anticipated since the notified polymer is encapsulated within the polypropylene masterbatch and would not be available for exposure.

Workers handling the masterbatch pellets containing the notified polymer will wear protective equipment including gloves, safety glasses and overalls. The moulding machines are enclosed and the process areas are fitted with local exhaust ventilation to capture fugitive vapours from the heated resin.

Handling of finished articles made from resin granules would not result in exposure to the notified polymer for workers as it will be encapsulated in the polymer matrix and not separately available for exposure.

7. PUBLIC EXPOSURE

During manufacture of plastic products, any spillage will be contained within bunded areas. Public exposure during the manufacturing process is negligible.

Extraction studies indicate that the chemical will not leach from the waste product. Public exposure through waste is negligible.

The notified polymer in finished articles is expected not to be biologically available and extraction studies indicate no release of the polymer from the articles. Public exposure through contact with products is expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The notifier expects that approximately 20 kg per annum of the notified polymer will be released through spills. It is anticipated that spills of the masterbatch pellets incorporating the polymer will be contained within the plant by bunding. Spills will be collected and reused, or disposed of to a licensed waste landfill site.

The moulding machines will be purged between separate colour runs producing scrap which will be recycled into other products.

Empty import drums containing residual polymer will be disposed of in landfill.

The majority of the notified polymer will be incorporated into polypropylene and polyethylene articles. Once incorporated within the moulded polypropylene and polyethylene products, the notified polymer is trapped within the polymer matrix and is unlikely to leach out.

8.2 Fate

Spills of polypropylene encapsulated polymer and waste generated from cleaning machinery will be collected and either reused or disposed of to landfill. The notified polymer has a log P_{ow} of 2.97, which indicates that it is hydrophobic and is likely to have a large soil/sediment adsorption coefficient. In landfill, the encapsulated polymer is unlikely to separate from the polypropylene or polyethylene. If it separated from the plastic article, it would become associated with the soil matrix and not leach into the aquatic compartment because of the low water solubility.

Empty import drums containing residual polymer will also be disposed of to landfill. The polymer would not be expected to escape from the drums; however, any free polymer would associate with the soil matrix and not leach into the aquatic compartment.

The majority of the notified polymer will be incorporated into polypropylene and polyethylene articles. The notifier has conducted extraction studies in accordance with USFDA (United States Food and Drugs Administration). The resin and ingredients were dry blended in a Hobart mixer, extruded under conditions typical for the particular polymer and finally injection moulded into plaques. The extraction tests were conducted at 40 and 100ºC using 10 and 95% aqueous ethanol solutions as extraction solvents. The plaques were emersed in the extraction solvent, heated to the test temperature and held for either 30 minutes or 10 days. In each test the colourant was not detected in the extraction solvent. Therefore, once incorporated within the moulded polypropylene and polyethylene products, the notified polymer is trapped within the polymer matrix and is unlikely to leach out. Although no ready biodegradability studies were conducted for this submission, it is expected that the polypropylene or polyethylene products will eventually degrade and that the released polymer will slowly degrade and become part of the soil matrix and not leach.

The polymer is not expected to cross biological membranes, due to its high molecular weight and expected low water solubility, and is not expected to bioaccumulate (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

The notifier submitted reports of a limited number of toxicological tests, which are sumarised below. Toxicity tests were carried out on the notified polymer and identified as Colourant 10283-22 (coloured viscous liquid) in the test reports.

9.1 Acute Oral Toxicity (Glaza, 1997)

Species/strain:	Rats/Crl:CD (SD) BR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	A single oral dose of 5000 mg/kg was given by gavage
Test method:	OECD TG 401 (limit test)
Mortality:	None
Clinical observations:	Red stained face, yellow urogenital area and soft stool
Morphological findings:	One male had multiple, clear fluid filled cyst of variable size in the cortical surface of both kidneys. This observation was considered incidental and not test-related, since there were no visible lesions observed in any of the remaining animals.
Comment:	All animals gained weight throughout the study. No test related lesions were observed at necropsy
LD_{50}:	>5000 mg/kg
Result:	the notified polymer was of very low acute oral toxicity in rats

9.2 *Salmonella typhimurium*/*Escherichia coli* Reverse Mutation Assay (Lawlor, 1997)

Strains:	*Salmonella typhimurium*: TA98, TA100, TA1535 and TA1537 *Escherichia coli*: WP2*uvr*A
Metabolic activation:	Liver S9 fraction from rats pre-treated with Aroclor 1254
Concentration range:	100 – 5000 μg/plate of test substance in deionised water Each concentration was tested in triplicate, with or without metabolic activation with S9. Appropriate strain specific positive control reference substances were used.

Test method:	OECD TG 471 and 472
Comment:	No toxicity was observed in any of the tested strains. There were no significant increases in the numbers of revertant colonies in the presence and absence of metabolic activation at any test concentration. The vehicle control for tester strain TA100 in the presence and absence of S9 were retested because the values were outside the acceptable range. Similarly, the mean positive control for tester strain WP2*uvr*A in the presence of S9 was retested because the values did not increase 3-fold. When retested, the values were acceptable and no increases in the number of revertants were observed with tester strain TA100 in the presence and absence of S9. Concurrent positive controls induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be satisfactory.
Result:	The notified polymer was non mutagenic under the conditions of the test

9.4 Overall Assessment of Toxicological Data

The notified polymer was of very low acute oral toxicity (LD_{50} >5000 mg/kg) in rats. It was not mutagenic in the bacterial strains tested. The notified polymer has a molecular weight greater than 1000 and is not expected to cross biological membranes.

Based on the information available, the notified is unlikely to be a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified polymer will be incorporated into moulded products, trapped within the polymer matrix and unlikely to leach.

The wastes generated during the manufacture process and from spills will be disposed of to landfill. The log K_{ow} of 2.97 suggests that in landfill the notified polymer will associate with the soil matrix and not leach into the aquatic environment. Furthermore, extraction tests show that the colourant is unlikely to leach from the polymer matrix. Therefore, once incorporated the notified polymer is expected to be immobile and pose little risk to the environment when

the articles are discarded and disposed of to landfill at the end of their useful lives.

The low environmental exposure of the notified polymer as a result of the proposed use indicates the overall environmental hazard should be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment
The acute oral toxicity of the notified polymer is low. It was not genotoxic in the bacterial strains tested.

The notified polymer has high molecular weight and is not expected to cross biological membranes. Based on the information available, the notified is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

Occupational Health and Safety
The preparation of the moulded and extruded finished articles from masterbatch pellets are performed in enclosed facilities fitted with local ventilation. There is potential for skin contact when opening containers and manually charging the polymer masterbatch into the heat-moulding machine. However, worker exposure is considered negligible since the notified polymer is encapsulated within the masterbatch pellets.

The potential for inhalation and eye exposure is low because of the low concentration (8%) of the notified polymer in the masterbatch and its non-dusty pellet form. Workers handling the pellets containing the notified polymer will wear protective equipment including gloves, safety glasses and overalls. Occupational exposure to the notified polymer either before or after the plastic articles are made is unlikely since the notified polymer is encapsulated within the finished plastic articles. In this form, the notified polymer is not bioavailable, hence no risk to workers is expected.

Exposure to the notified polymer is not expected during transport and storage as long as the packaging is intact. The risk of adverse health effects for transport and storage workers is considered to be low.

Public Health
Public exposure to the notified polymer is limited to contact with plastic products containing the polymer. In such products the polymer is not bio-available. This, and the low oral toxicity and lack of known irritancy, indicates that the threat to public health is not significant.

13. MATERIAL SAFETY DATA SHEET (MSDS) AND LABEL ASSESSMENT

13.1 MSDS

The MSDS for the notified polymer and products containing it were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a).

The MSDS were 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.

13.2 Label

The label for the notified polymer and products containing the polymer provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

14. RECOMMENDATIONS

Control measures (end-user)

No special precautions are required for the notified polymer, however, in the interests of good occupational health and safety, employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:

- exhaust ventilation during preparation of the moulded and extruded finished articles from masterbatch pellets
- enclosed moulding machines
- automated transfer or dosing equipment

Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:

- when charging the polymer masterbatch into the heat-moulding machine, prevent generation of dusts

Employees should wear the following personal protective equipment to minimise occupational exposure to the notified polymer:

- impervious gloves
- overalls
- safety glasses

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

A copy of the MSDS should be easily accessible to employees.

If products and mixtures containing [the notified chemical] are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Secondary notification

The NICNAS Director must be notified in writing within 28 days by the notifier, or other importer or manufacturer:

(1) Section 64(1) of the Act:
- if the notified polymer is manufactured in Australia
- if exposure of the notified polymer to the aquatic compartment increases

or

(2) Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise

The Director will then decide whether secondary notification is required.

15. REFERENCES

Connell DW (1990) General characteristics of organic compounds which exhibit bioaccumulation. In Connell DW, (Ed) Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

Lyman WJ, Reehl WF, Rosenblatt DH (1990) Regression Equations for the Estimation of Solubility, In Lyman WJ, Reehl WF, Rosenblatt DH, Handbook of Chemical Property Estimation Methods. American Chemical Society, USA.

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Glaza SM (1997) Acute Oral Toxicity Study of Experimental Colorant 10283-22 in Rats, Project No. CHW 70104416, Corning Hazleton Inc, Madison, Wisconsin.

Lawlor TE (1997) Mutagenicity Test with Experimental Colourant 10283-22 in the Salmonella-Escherichia coli/Mammalian-Microsome Reverse Mutation Assay with a Confirmatory Assay, Project No. 18311-0-409R, Covance Laboratories Inc, Vienna, Virginia.