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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Chromabond S 403E

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

- 1.1 APPLICANT(S)
ISP (Australasia) Pty Ltd (ABN 27 000 011 923)
73-75 Derby Street
Silverwater NSW 2141
- 1.2 NOTIFICATION CATEGORY
Synthetic Polymer of Low Concern
- 1.3 EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, CAS Number, Molecular and Structural Formulae, Molecular Weight and Polymer Constituents.
- 1.4 VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.
- 1.5 PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Early Introduction Permit (EIP) No: 336 issued on 30 June 2004
- 1.6 NOTIFICATION IN OTHER COUNTRIES
Canada, USA and Japan

2. IDENTITY OF CHEMICAL

- 2.2 OTHER NAME(S)
E-4557.01
SI0280.01
- 2.3 MARKETING NAME(S)
Chromabond S 403E

3. COMPOSITION

- 3.6 PLC CRITERIA JUSTIFICATION
- | <i>Criterion</i> | <i>Criterion met
(yes/no/not applicable)</i> |
|--|--|
| Molecular Weight Requirements | Yes |
| Functional Group Equivalent Weight (FGEW) Requirements | Yes |
| Low Charge Density | Yes |
| Approved Elements Only | Yes |
| No Substantial Degradability | Yes |
| Not Water Absorbing | Yes |
| Low Concentrations of Residual Monomers | Yes |
| Not a Hazard Substance or Dangerous Good | Yes |

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

4.2 MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	10	10	10	10	10

4.3b USE

As a component of laundry detergent products.

5. PROCESS AND RELEASE INFORMATION**5.1. Operation Description**

The notified polymer is imported into Australia in a form of liquid product at a concentration of 35%, packed in 200 kg drums, which are transported by road to the reformulation site. Transport workers are unlikely to be exposed to the notified polymer under normal working conditions, except in the unlikely event of damaged containers and spillage.

The notified polymer is incorporated into the final consumer detergent products in open or closed systems. In the case of reformulation into a liquid detergent, the imported liquid product will either be pumped directly into the main mixing vessel, or pumped into a premix vessel and mixed with other ingredients prior to pumping into the main mixing vessel. In the case of reformulation into powder detergent, the imported liquid product will be pumped from the drum into a stainless steel vessel where it will be sprayed through a nozzle onto the powder product. The liquid spraying process is a closed system, which is heat ventilated to the atmosphere through a wet scrubbing system that minimizes the release of particulates. Once the notified polymer is incorporated into the detergent product, the final product is packed into appropriate consumer packaging (1 or 2 kg powder detergent in boxes and 1 or 1.5 L liquid detergent in plastic bottles) using enclosed and automated packaging equipment. The notified polymer will be present in the final consumer detergent products at a level of 0.5-0.8%.

Local exhaust ventilation is in operation during reformulation and packaging. Filling machines are enclosed and automated. Workers will wear chemical goggles, faceshield, protective clothing and boots. Chemical cartridge respirator or supplied air breathing apparatus is also worn as required.

The packaged products will be sent to retail distribution centres for storage until distribution to retail outlets.

6. EXPOSURE INFORMATION**6.1. Summary of Environmental Exposure****RELEASE OF POLYMER AT SITE**

Environmental release during importation, storage and transportation is unlikely except in the event of accidental spillage. Reformulation is expected to take place at 1 site in Australia. Release of waste polymer generated in this process is expected to be less than 2% (less than 200 kg annually), which would include 1% remaining in empty import containers and 1% resulting from cleaning of plant equipment and spills.

RELEASE OF POLYMER FROM USE

The majority of the polymer will be released to sewer in laundry wash water. In the laundry wash water much of the polymer will complex with excess or loose dye from the fabric.

Empty user containers (cardboard boxes or HDPE bottles), containing any residue product, will be disposed of in the general household waste which will go to landfills. It is estimated that less than 1% of the notified polymer will be released in this manner.

6.2. Summary of Occupational Exposure

Dermal and ocular exposure may occur during reformulation, quality control and packaging of the final consumer product. Workers may also be exposed to dust particles generated from the production of laundry powder. However, exposure would be low since majority of the reformation and packaging

operations involve automated and enclosed processes. The use of personal protective equipment and the engineering control in place will minimise exposure to the workers at the reformulation site.

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

6.3. Summary of Public Exposure

Laundry products containing the notified polymer are for sale to the general public; hence public exposure will be widespread and repeated. Members of the public will have dermal contact and possibly accidental ocular contact with products containing the notified polymer when handling the laundry products. Inhalation exposure to laundry powder can also occur when using the product.

The potential for exposure of the public to the notified polymer during normal industrial storage, handling and transportation is negligible, except in the case of an accident. The packaging will also protect the contents from being released during normal handling and storage.

7. PHYSICAL AND CHEMICAL PROPERTIES

6.1	Appearance at 20°C and 101.3 kPa	Whitish brown powder; White opaque flowing emulsion (35% notified polymer)
6.2a	Melting Point	Not determined. The notified polymer will be imported as an emulsion in water.
6.3	Density	1150 kg/m ³ at 25°C
6.5	Water Solubility	Water soluble
6.15	Reactivity	Stable under normal environmental conditions. It can react with strong acids, strong bases, excessive heat and reducing agents.
6.15	Degradation Products	Toxic vapours such as cyanides, nitrogen oxides, carbon monoxide may be released upon thermal decomposition.

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological end-points were submitted:

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity	no	no
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity	no	no
Rabbit, skin irritation	slightly irritating	no	yes
Rabbit, eye irritation	non-irritating	no	no
Human Repeat Insult Patch Test (HRIPT), skin irritation and skin sensitisation (5% notified polymer)	limited evidence of sensitisation.	no	yes
Rat, oral repeat dose toxicity - 28 days.	NOAEL 25 mg/kg bw/day	no	yes
Genotoxicity - bacterial reverse mutation	non mutagenic	no	no
Developmental and reproductive effects	No reproductive effects	no	no

8.1.1. Discussion of observed effects

The notified polymer has low oral and dermal toxicity, and is not irritating to the eyes. It is slightly irritating to the skin as shown by transient skin irritation effects such as moderate to slight erythema and slight oedema.

In a human repeat insult patch test, there was no evidence of skin sensitisation potential observed in human volunteers exposed dermally to 5% notified polymer. One subject reported itchiness and rash was visible on the arm during the study but was fully recovered after 5 days. Another subject had papules on the patch and tape area at induction session, and was withdrawn from study.

The notified polymer gave a negative result in a bacterial mutation study.

In a 4-week repeat dose oral toxicity study in rats, one male in the high dose group died during Week 3, due to possible gavage accident as evidenced by haemorrhage in the submucosa of the trachea. There were no differences in body weights, cumulative body weight gains and food consumption of treated animals when compared with the control group.

Histopathological examinations of the kidneys showed hyaline droplets formation in all treated males with renal tubular degeneration or necrosis present in male high dose group only. The urinalysis showed higher urine sodium concentration and excretion in high dose groups compared with the control group, which may correlate with the histopathological renal findings, although the renal findings were only apparent in treated males. Splenic extramedullary hematopoiesis was also increased (non-dose response) in all treated males. However, in the absence of changes in haematological parameters and spleen weight suggests that the splenic effect is not of toxicological significance. A significant increase in liver to body weight percentages in all treated female groups and in submaxillary salivary gland weight in low dose females were also reported. Again, in the absence of correlative histopathological observations, these changes are not considered to be treatment related.

The no observed adverse effect level (NOAEL) was established as 250 mg/kg bw/day, based on the higher urine sodium concentration and excretion observed in high dose group. A separate study to determine the accumulation of a rat specific protein, α_2 -microglobulin, during the administration of the notified polymer was conducted. From the study, it was concluded that the renal effects present in all treated males were due to the accumulation of protein droplets within the proximal tubule cells and referred to as hyaline droplet nephropathy. With chronic exposure, the hyaline droplet accumulation advances to mild tubular necrosis, proximal tubule cell hyperplasia and eventually renal cancer exclusively in male rats. However, because the α_2 -microglobulin is unique in male rats, this nephropathy and associated histopathological renal effects are not predictive of a similar risk for humans.

A developmental and reproductive study in mice treated intravenously (2 weeks) or by inhalation exposure to the notified polymer (8 months) did not affect the duration of pregnancy, embryonal mortality and possible off spring deformities. Treatment with the notified polymer did not reveal overt toxicity on the fertility and vitality of two generations of offspring.

Overall, the observed effects from the above studies were indicative of low hazard.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. The submitted toxicity data support the conclusion of low hazard.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

The following toxicological studies were submitted:

<i>Endpoint</i>	<i>Result and Conclusion</i>
Ready Biodegradability	Not biodegradable: 20 mg/L after 28 days, 6% degradation: DOC removal, mean 8% (C. I. 3 – 14%)
Fish Toxicity	96 h EC ₅₀ >1000 mg/L, NOEC = 1000 mg/L
Daphnia Toxicity	48 h EC ₅₀ >1000 mg/L, NOEC = 1000 mg/L
Algal Toxicity	3 day ErC ₅₀ = 2800 mg/L (95% C. I. 1600 – 4600 mg/L) NOEC = 85 mg/L (estimated)

All results were indicative of low hazard.

9.2. Environmental Hazard Assessment

The ecotoxicological studies indicate that the notified polymer is non-toxic to aquatic organisms. Despite the polymer not being biodegradable it is not expected to bioaccumulate because of its high molecular weight, which precludes absorption through biological membranes.

Waste polymer is expected to partition into the water column due to its water solubility. Based on its high molecular weight and water soluble nature, the polymer is predicted to have a low K_{ow} and K_{oc} values. It will not hydrolyse in the environment, since there are no hydrolysable groups present.

The environmental hazard posed by the notified polymer is low.

10. RISK ASSESSMENT

10.1. Environment

The products containing the notified polymer will be used throughout Australia. The major environmental exposure is expected to be due to the disposal of laundry wash water to sewer. The amount of excess dye present in the fabric will inversely impact on the amount of free polymer released into the sewer. If a worst case scenario is considered with no complexing with dye or removal of the notified polymer in the sewage treatment plant, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated to be 6.85 µg/L.

Amount entering sewer annually	10 tonnes
Population of Australia	20 million
Amount of water used per person per day	200 L
Number of days in a year	365
Estimated concentration in sewer	6.85 µg/L

Based on dilution factors of 1 and 10 for inland and ocean discharges of STP-treated effluents, the PECs of the notified polymer in freshwater and marine water may approximate 6.85 or 0.685 µg/L, respectively.

From the ecotoxicity data above, the lowest EC₅₀ is for fish and daphnia (EC₅₀ > 1000 mg/L). Since there are studies for three trophic levels a safety factor of 100 is used, thus the PNEC (lowest EC₅₀ ÷ safety factor) is 10 mg/L. The risk quotient (RQ = PEC/PNEC) for inland waters is 6.85 × 10⁻⁴ and for ocean is 6.85 × 10⁻⁵. Abiotic or slow biotic processes are expected to degrade the notified polymer eventually.

Since the RQ is significantly below 1, there is considered to be little risk associated with the use of this polymer.

10.2. Occupational Health and Safety

The majority of reformulation and packaging operations involve automated and enclosed processes. However, where dust particles are generated, the level of atmospheric nuisance dust should be maintained as low as possible. The NOHSC exposure standard for atmospheric dust is 10 mg/m³.

Transport and storage workers are unlikely to be exposed to the notified polymer except when accidental breakage of laundry packaging occurs.

Overall, the OHS risk presented by the notified polymer during reformulation into laundry detergents (liquid and powder) is expected to be low. The notified polymer may be present in formulations containing hazardous ingredients. If these formulations 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.

10.3. Public Health

Public exposure to the notified polymer in the form of laundry detergents will be widespread and repeated. Dermal contact will be the major route of exposure but accidental ocular and inhalation exposure can also occur while using the products containing the notified polymer. However, the risk to public health is low given the low concentration of the polymer present in the products, the intermittent exposure during use, and the expected low toxicity of the polymer.

11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

11.1. Environmental Risk Assessment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

11.2. Human Health Risk Assessment

11.2.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

11.2.2. Public health

There is Low Concern to public health when used as a component of laundry products.

12. MATERIAL SAFETY DATA SHEET

12.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

13. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.
 - Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- Service personnel should wear cotton or disposable gloves and ensure adequate

ventilation is present when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.

- Atmospheric monitoring should be conducted to measure workplace concentrations of nuisance dust during reformulation of the notified polymer into laundry products.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer 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.

Environment

- The following control measures should be implemented by soap manufacturer to minimise environmental exposure during laundry soap manufacture of the notified polymer:
 - All process equipment and storage areas should be bunded with only process drains within the area.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills or release of the notified polymer should be handled by qualified personnel.
- Spills should not be flushed into surface water or sewer system.
- Spill should be taken up mechanically or with an adsorbent material (sand, diatomaceous earth, universal adsorbent or saw dust) and placed in a sealable labelled container ready for disposal.

13.1. Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under subsection 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.or
- (2) Under subsection 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.

No additional secondary notification conditions are stipulated.