

File No PLC/686

April 2007

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

FULL PUBLIC REPORT

Polymer in Lotader 4503 and Lotader 3430

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

This Full Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

**Director
NICNAS**

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. PLC CRITERIA JUSTIFICATION	3
4. PHYSICAL AND CHEMICAL PROPERTIES	4
5. INTRODUCTION AND USE INFORMATION	4
6. HUMAN HEALTH IMPLICATIONS	5
6.1. Exposure Assessment	5
6.2. Toxicological Hazard Characterisation	6
6.3. Human Health Risk Assessment	7
7. ENVIRONMENTAL IMPLICATIONS	7
7.1. Exposure Assessment	7
7.2. Environmental Hazard Characterisation	7
7.3. Environmental Risk Assessment	7
8. CONCLUSIONS	8
8.1. Level of Concern for Occupational Health and Safety	8
8.2. Level of Concern for Public Health	8
8.3. Level of Concern for the Environment	8
9. MATERIAL SAFETY DATA SHEET	8
9.1. Material Safety Data Sheet	8
10. RECOMMENDATIONS	8
10.1. Secondary Notification	9

FULL PUBLIC REPORT

Polymer in Lotader 4503 and Lotader 3430

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Arkema Pty Ltd (ABN 44 000 330 772)
Ground Floor, 600 Victoria Street
Richmond VIC 3121

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, Manufacture/Import Volume, and Site of Manufacture/Reformulation

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA TSCA (2004), and Japan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polymer in Lotader 4503 and Lotader 3430

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >10,000 Da

REACTIVE FUNCTIONAL GROUPS

Functional Group	Category	Equivalent Weight (FGEW)
Carboxylic anhydride	High Concern	<5,000 Da

Note: While the FGEW of these high concern groups is <5,000 Da, the notified polymer meets the PLC criteria because its Mn is >10,000 Da (no restrictions on reactive functional groups).

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Colourless, amorphous, rubbery solid pellets
Melting Point	84°C
Density	940 kg/m ³ at 20°C
Water Solubility	0.883 g/L at 20°C (at pH 5.8) Test conducted according to OECD TG 120. Conducted at 1 g/L and 10 g/L on two different batches of the polymer. The 1 g/L test showed higher extractability than the 10 g/L tests.
Hydrolysis as a function of pH	Not hydrolysable in the environmental pH range (pH 4-9). Test conducted according to OECD TG 111. The notified polymer contains hydrolysable groups but less than 10% was found to hydrolyse between pH 4.5-9 at 50°C. Slow hydrolysis was observed at high temperatures and pH values. The maximum hydrolysis was observed at pH 9. However, even under these conditions, the $t_{1/2}$ = ~30 days at 50°C and ~1 year at 25°C.
Particle Size	~5 mm pellets
Reactivity	The polymer contains two functional groups which are susceptible to hydrolysis, but not under ambient environmental conditions. The more reactive of the two groups, the anhydride groups, represent a smaller proportion of the molecule than the less reactive group.
Degradation Products	The notified polymer is stable at ambient temperature. At high temperatures (above 300°C), thermal decomposition occurs, releasing carbon monoxide, carbon dioxide and organic vapours.

5. INTRODUCTION AND USE INFORMATION

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>	<150	<200	<200	<200	<200

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer is manufactured in Carling, France. It will be imported as a component of the products Lotader 4503 and Lotader 3430. The products containing the notified polymer will be imported in pellet form, packaged in 25 kg waterproof poly-lined bags and 500 kg and 1,000 kg Octabins with a waterproof liner, depending on each specific customer's equipment and specifications. It will be imported by sea through the capital cities of VIC, NSW, SA, QLD and WA.

Reformulation/manufacture processes

The notified polymer will not be manufactured in Australia. It will be imported and sold to either:

- end users in the flexible packaging manufacturing industry, with two-stage compounding/final extrusion machines, or
- resin compounding firms.

Extrusion onto film

The principal processing method will be co-extrusion. Large web extruders between 2 metres and 5 meters wide will be used, with the layer containing the notified polymer typically being extruded on top of a base carrier film, forming a "sandwich" of polymer films. The base film may be cast in a prior step or may be from a master roll. Onto this base film, several layers of film may be extruded simultaneously or sequentially.

Imported pellets containing the notified polymer may be stored in a humidity controlled, heated drying room, silo or dehumidifying dryer for a minimum of 24 hours at 50°C to remove moisture. Pellets may be moved to these sites via vacuum transfer or stored in their import packaging. Once dried, the pellets will be either manually loaded by workers using vacuum transfer or fed from the silo into a hopper. The pellets will reside in the hopper until used.

From this point onwards, the operation is highly mechanised. The hopper gravity feeds the pellets into an extruder that heats and melts the polymer at 130-190°C. The molten polymer will then be forced through a broad nip, depositing a layer onto the base film. The layers will then be firmly forced together by a pressure roller. Workers do not typically touch the finished composite films.

Resin compounding

Specialty blended resins may also be formulated from Lotader 4503 or Lotader 3430 in Australia. Compounding will require heating of the resins and moulding machine above 200-320°C, in a similar process to the extrusion process described above. When the compounded polymer blend exits the extruder, either it will be used directly in film formation, or a pelletiser will be used to form pellets of the blended resin.

Waste resin from the compounder may be recycled by re-pelletising it with polyethylene waste for low value extrusion into profiles or injection moulding or extrusion.

Use

The notified polymer will be used as a coating adhesive, as a coating adhesive improver, or for the modification of thermoplastic polymers to make them adhesive. It will be used between layers of mainly polyethylene and propylene copolymers and other materials (e.g. polyester, nylon, paper, metallised film or aluminium foil) in lamination, creating a stronger film barrier than any single-layer film would provide alone.

The notified polymer will be applied to substrate films by extrusion lamination, and at the elevated temperatures that will be used in this process, the anhydride groups of the notified polymer may react or chelate with metal ions or materials with hydroxyl functionality in the substrate(s) to form a high-level adhesion interaction.

The notified polymer will be present in imported adhesive formulations, and will be used mainly in the food and wine packaging industry. The initial users of the notified polymer will be flexible packaging companies with extrusion laminating equipment, the number of which is not expected to exceed 30 companies in Australia. Other potential uses include manufactured films for articles, medical products and tamper-proof packaging.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Extruder operators are expected to experience the highest exposure to the notified polymer, which is expected to be primarily dermal, although ocular exposure is possible. The notified polymer will be poured from bags into hoppers and extruded with little or no contact with the operators skin.

The notified polymer is formulated in pellets, which do not generate dust upon handling and transportation. The notified polymer within these solid, plastic pellets will be unavailable to cause significant exposure.

Compounding of the notified polymer requires the heating of pellets to above 200-320°C, and workers will wear heat resistant gloves, eye protection and heat resistant industrial clothing to protect against the hot machines. These measures will also prevent exposure to the notified polymer. An exhaust/filter system will be situated above the extrusion machine inlet and outlet to capture any toxic gases generated by the thermal degradation of the notified polymer in the equipment prior to extrusion.

Workers handling finished rolls of laminate will not be exposed to the notified polymer, as it will be sandwiched between other films, which are typically on the outer surfaces.

End user workers in packaging firms and customer industries (e.g. in the food processing industry) that handle finished laminates will not be exposed to the notified polymer, as it will be sandwiched

between other films.

Transport and warehouse workers would only be exposed in the unlikely event of accidental breakage of the waterproof bags or rigid containers. Under this circumstance, dermal or ocular exposure to the imported notified polymer pellets is possible.

PUBLIC EXPOSURE

The notified polymer is intended only for use in industry and as such direct public exposure to the notified polymer pellets will not occur. The notified polymer will only be sold to the public in the form of finished packaging (eg food packaging).

Members of the public will not be exposed to the notified polymer from finished packaging under normal conditions, as it will be sandwiched between other films that are typically on the outer surfaces of packaging films. The notified polymer will not be used in food-contact applications; rather, it will be used to adhere food contact-approved films to other substrates.

6.2. Toxicological Hazard Characterisation

No toxicological data were submitted under the PLC notification category, and the notifier has declared that they hold no information in regards to its possible toxicity. The notified polymer met the US EPA criteria for a PMN exemption, and is in use in the US and EU without any evidence of adverse effects.

The notified polymer contains carboxylic anhydride reactive functional groups. The primary hazard of these groups is the induction of sensitisation in exposed individuals. These are, therefore, high concern reactive functional groups under the PLC criteria, and would require a functional group equivalent weight (FGEW) of >5,000 Da for the notified polymer to qualify as a PLC. This is based on the concern of these compounds in regards to their toxicity, as expressed by the US EPA in their category of concern¹.

However, the FGEW calculated for these groups of the notified polymer is <5,000 Da. Applying this criterion alone, the notified polymer is potentially hazardous. However, as the notified polymer has an Mn >10,000 Da, it meets the PLC criteria (no restriction on RFGs for polymers with Mn >10,000 Da). Therefore, it is presumed to present a low hazard.

However, the polydispersity index of the notified polymer is high, and ~20% of the notified polymer's molecular weight distribution is of molecular weight <10,000 Da. Therefore, the possibility of a sensitisation hazard being presented by the notified polymer cannot be excluded. However, less than 2% of the notified polymer is of molecular weights <1,000 Da, so based on the US EPA criteria, a low concern is probable in the absence of inhalation exposure. The notifier has advised that the imported granules of the notified polymer are amorphous, rubbery and non-crystalline (between 0-35°C), and have been observed anecdotally to not generate dusts upon handling and transport.

The notifier has indicated that under normal processing conditions (up to 200-320°C during compounding), degradation of the notified polymer releases fumes or vapours, the components of which may vary with processing time and temperature. These fumes may produce eye, skin and/or respiratory tract irritation and, with repeated or prolonged exposures, nausea, drowsiness, headache and weakness.

The notified polymer meets the PLC criteria and therefore it can be considered to be of low hazard.

¹ US EPA (2002). TSCA New Chemicals Program (NCP) Chemical Categories. <http://www.epa.gov/opptintr/newchems/pubs/cat02.htm>.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The only workers that will be exposed to the notified polymer under normal circumstances are extruder operators. The OHS risk presented by the notified polymer is expected to be low, based on its presumed low hazard, its formulation in rubbery pellets, and on the PPE worn by the workers.

Workers in packaging firms and customer industries will handle the produced laminates. The notified polymer will be sandwiched between the other films, as it is used as an adhesive. In these laminates, the carboxylic anhydride functional groups of the notified polymer will have reacted with the substrate films, and thus the notified polymer should not be liberated.

Noxious fumes and vapours that are produced during the processing of the notified polymer are expected to be controlled with local and general exhaust ventilation. Such fumes are common during the extrusion processing of polymers.

PUBLIC HEALTH

The notified polymer does not pose a significant risk to public health when used in the proposed manner, as the public should not experience any exposure.

Should food-contact films be damaged, and foodstuffs contact the notified polymer, it is unlikely to migrate into foods from the surface film, due to its relative water insolubility and strong degree of bonding to the film substrates. Upon prolonged contact with water-containing foods, hydrolysis of any residual anhydride groups in the notified polymer is likely, which may increase its solubility and possible migration into foods. However, if this were to occur, this degraded form of the notified polymer is unlikely to pose any serious health risks, as it is not likely to be absorbed or toxic.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

No manufacture or reformulation is expected to occur in Australia. However, the polymer will be extrusion or injection moulded in Australia to form final products. Cleaning of the die will lead to a small amount of waste but this is expected to be re-pelletised and re-used. Excess moulded material will be trimmed; this is expected to be amount to 3% (<6 tonnes per annum) and will be disposed of to landfill. As the polymer is in pellet form, little if any is expected to remain in the import packaging.

The remaining polymer is expected to be used in packaging material. Polymer film used in packaging at the end of its useful life is expected to be disposed of as domestic waste to landfill with little or no recovery¹.

¹ National Packaging Covenant Council, Independent Assessment of Kerbside Recycling in Australia Revised Final Report - Volume I, NOLAN-ITU Pty Ltd, January 2001.

ENVIRONMENTAL FATE

The polymer in landfill is expected to undergo in-situ degradation by biotic and abiotic process to form landfill gases, including methane, oxides of carbon; and water vapour.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. PLCs without significant ionic functionality are of low concern to the aquatic environment.

7.3. Environmental Risk Assessment

It is expected that most of the polymer will be landfilled at the end of its useful life. Packaging that is disposed of incorrectly may enter the environment and waterways. However, the polymer is a PLC without significant ionic functionality, which is of low concern to the aquatic environment. The polymer is likely to eventually undergo *in situ* decomposition by abiotic and biotic processes to form methane, oxides of carbon; and water vapour. Based on the reported use pattern the polymer does not pose an unacceptable risk to the aquatic environment.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

The notified polymer is not expected to pose a significant risk to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

The notified polymer presents no significant risk to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

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

9. MATERIAL SAFETY DATA SHEET

9.1. 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.

10. 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.
- If the notified polymer is used in circumstances where respirable dusts containing it may be formed, the appropriate engineering and personal respiratory protective equipment should be implemented to prevent inhalation exposure of workers, according to the hierarchy of controls.
- 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 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.

Disposal

- The notified polymer should be disposed of by authorised landfill.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by physical collection and re-use to the maximum extent practicable. Residues may be swept, whilst avoiding creating dust.

10.1. 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.
 - the number-average molecular weight (Mn) of the imported polymer is <10,000 Da.

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.