

File No: SAPLC/108

February 2010

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

FULL PUBLIC REPORT

Lotader 6200

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**Director
NICNAS**

Part 2 –PLC Self Assessment

Lotader 6200

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT

Arkema Pty Ltd (ABN 44 000 330 772)
313 Canterbury Rd
CANTERBURY VIC 3126

NOTIFICATION CATEGORY

Self Assessment: Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details and Site of Manufacture/Reformulation

NOTIFICATION IN OTHER COUNTRIES

Lotader 6200 is already listed in US, China, Canada, Japan, Korea, Philippines. Exempted of registration in Europe (polymer)

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

2-Propenoic acid, ethyl ester, polymer with ethene and 2,5-furandione

MARKETING NAME(S)

Lotader 6200

CAS NUMBER

41171-14-6

MOLECULAR WEIGHT (MW)

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

REACTIVE FUNCTIONAL GROUPS

Functional Group	Category	Equivalent Weight (FGEW)
Acid anhydride	High Concern	3163

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/Glass Transition Temp	70-102°C Method: Differential Scanning Calorimetry in accordance with DIN 51007 (Thermal analysis (TA); differential thermal analysis (DTA); principles)
Density	940 kg/m ³ at 20°C
Water Solubility	Average for 5 batches of an acceptable analogue was 0.074% C w/w. Test conducted according to OECD TG 120.
Particle Size	~ 5 mm pellets
Degradation Products	None under normal conditions of use
Reactivity	Stable under normal environmental conditions. 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. Test conducted according to OECD TG 111 on 5 batches of an acceptable analogue.

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>	50	100	100	100	100

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will be imported as a component of the product Lotader 6200. The Lotader 6200 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 customers 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 resin compounding firms.

Specialty blended resins will be formulated using the notified polymer. Compounding of the blended resin will require heating of the ingredients in an extrusion machine (compounding machine) between 120°C and 180°C. Then the compounded polymer will be extruded directly in film (sheet) or pelletised.

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.

Direct Extrusion onto sheets :

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 (or directly picked up from their import packaging), 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 120°C-200°C. The lotader is the minor phase of the

blend (10%). The mixture is then forced through a die, depositing a monolayer onto a chill roll producing a sheet and then a roll of finished material

Thermoforming :

Rolls of finished sheets of material (Lotader blend) are then used in a second step in order to produce packages by thermoforming. Initial sheets are heated up (not higher than 170°C-180°C) and then formed in a cold mold to get the final shape of the package. It's used for the packaging of a wide range of products.

Injection molding :

Another way of processing is to inject pellets made of the blended resin. The hopper gravity-feeds the pellets into an injection molding machine that heats and melts the polymer at 120°C-200°C. After melting in the molding machine, the molten resin will then be forced through a nozzle to feed a cold mold giving the shape of finished goods (cups, others...).

Use

The notified polymer will be used as a component of plastic films or containers for the packaging of dry and/or fatty food (moisture content up to 15%) and non-food items and for use at temperatures up to 40 °C.

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, which is imported in pellet-form, 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 120°C-200°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 gases generated by the thermal degradation of the notified polymer in the equipment prior to extrusion. The normal extrusion temperature of 120-200 ° C is well below the decomposition temperature of >320° C.

Workers handling finished rolls (or pellets) will not be exposed to the notified polymer, as it will be dispersed as a minor phase within a major phase (matrix).

End user workers in packaging firms and customer industries (e.g. in the food processing industry) that handle finished articles will not be exposed to the notified polymer, as it will be dispersed as a minor phase within a major phase (matrix).

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 (e.g. food packaging).

Members of the public will not be exposed to the notified polymer from finished packaging under normal conditions, as it will be dispersed as a minor phase within a major phase (matrix).

6.2. Toxicological Hazard Characterisation

No toxicological data were submitted.

The notified polymer contains carboxylic acid anhydride reactive functional groups. The primary hazard of these groups is the induction of sensitisation in exposed individuals. Although the notified polymer contains groups indicative of a possible sensitisation hazard and has a functional group equivalent weight (FGEW) of <5,000 Da, the polymer does meet the PLC criteria (as it has a Mn >10,000 Da) and can therefore be considered to be of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The only workers that will be exposed to the notified polymer pellets 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 sheets or pellets. The notified polymer will be dispersed within a matrix, as it is used as a modifier. In these blends, 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 foodstuffs contact the notified polymer, it is unlikely to migrate into foods from the surface film, due to its relative water insolubility and cross-linking with other components in the packaging material. When used for food contact, the application concerns dry and/or fatty foods. 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, this degradation should not happen in the case of contact with dry food.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The polymer will be extruded 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. The remaining polymer is expected to be cross-linked with other polymer components during the manufacture of 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 recovery.

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 notified 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 lacks significant ionic functionality and is presumed to be 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 is not expected to pose an unacceptable risk to the aquatic environment.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

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

8.2. Level of Concern for Public Health

There is No Significant Concern to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

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

9. 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.

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.

Environment

Disposal

- The notified polymer should be disposed of by authorized 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

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

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

- (1) Under Section 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.
 - the notified polymer is used in the packaging of food items that contain >15% moisture or that need heating above 40 °C.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of plastic films or containers or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
 - the notified polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.