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

# PUBLIC REPORT

## PIONIN A-729-K

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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 Energy.

This 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:


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# TABLE OF CONTENTS

SUMMARY ..... 3
CONCLUSIONS AND REGULATORY OBLIGATIONS ..... 3
ASSESSMENT DETAILS ..... 5
1. APPLICANT AND NOTIFICATION DETAILS ..... 5
2. IDENTITY OF CHEMICAL ..... 5
3. COMPOSITION ..... 5
4. PHYSICAL AND CHEMICAL PROPERTIES ..... 5
5. INTRODUCTION AND USE INFORMATION ..... 6
6. HUMAN HEALTH IMPLICATIONS ..... 7
6.1. Exposure Assessment ..... 7
6.1.1. Occupational Exposure ..... 7
6.1.2. Public Exposure ..... 7
6.2. Human Health Effects Assessment ..... 7
6.3. Human Health Risk Characterisation ..... 7
6.3.1. Occupational Health and Safety ..... 7
6.3.2. Public Health ..... 8
7. ENVIRONMENTAL IMPLICATIONS ..... 8
7.1. Environmental Exposure & Fate Assessment ..... 8
7.1.1. Environmental Exposure ..... 8
7.1.2. Environmental Fate ..... 8
7.1.3. Predicted Environmental Concentration (PEC) ..... 8
7.2. Environmental Effects Assessment ..... 9
7.2.1. Predicted No-Effect Concentration ..... 9
7.3. Environmental Risk Assessment ..... 10
BIBLIOGRAPHY ..... 11

# SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

| ASSESSMENT REFERENCE | APPLICANT(S) | CHEMICAL OR TRADE NAME | HAZARDOUS CHEMICAL | INTRODUCTION VOLUME | USE |
|---|---|---|---|---|---|
| LTD/1928 | Cintox Australia Pty Ltd | PIONIN A-729-K | ND* | < 0.1 tonne per annum | Component of packaging film |

*ND = not determined

# CONCLUSIONS AND REGULATORY OBLIGATIONS

**Hazard classification**
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

**Human health risk assessment**
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

**Environmental risk assessment**
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

**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.
- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

**Regulatory Obligations**

*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 chemical 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 chemical, 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 importation volume exceeds one hundred kilograms per annum notified polymer;
- ecotoxicological data for the notified polymer becomes available;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of packaging materials, or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer 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.

*(Material) Safety Data Sheet*
The (M)SDS of a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

# ASSESSMENT DETAILS

## 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cintox Australia Pty Ltd (ABN: 63 122 874 613)
Suite 1, Level 2
38-40 George Street
PARRAMATTA NSW 2150

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1,000 Da (1 tonne or less per year).

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, analytical data, impurities, additives/adjuvants and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

## 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
PIONIN A-729-K (70% notified polymer in water)

MOLECULAR WEIGHT
500-1500 Da

ANALYTICAL DATA
Reference IR spectrum was provided.

## 3. COMPOSITION

DEGREE OF PURITY
> 99%

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: brown paste (70% notified polymer in water)

| Property | Value | Data Source/Justification |
|---|---|---|
| Melting Point/Freezing Point | Not determined | Expected to be < 0 °C |
| Boiling Point | Not determined | Decomposition expected to occur prior to boiling |
| Density | ~ 1,000 kg/m$^3$ | Estimated by the notifier |
| Vapour Pressure | Not determined | Expected to be low based on molecular weight |
| Water Solubility | Soluble | (M)SDS |
| Hydrolysis as a Function of pH | Not determined | Contains hydrolysable functionalities |
| Partition Coefficient (n-octanol/water) | Not determined | Expected to partition to phase boundaries based on surface activity |
| Adsorption/Desorption | Not determined | Expected to adsorb to soil and sediment based on surface activity |

| Property | Value | Data Source/Justification |
|---|---|---|
| Dissociation Constant | pKa1 = 1.85<br>pKa2 = 6.35 | Estimated based on the parent acid |
| Flash Point | Not determined | Introduced only in formulated products. Not expected to be flammable under normal conditions of use |
| Autoignition Temperature | Not determined | Introduced only in formulated products. Not expected to autoignite under normal conditions of use |
| Explosive Properties | Not determined | Contains no functional groups that imply explosive properties |
| Oxidising Properties | Not determined | Contains no functional groups that imply oxidising properties |

DISCUSSION OF PROPERTIES

*Reactivity*
The notified polymer is expected to be stable under normal conditions of use.

***Physical hazard classification***
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

## 5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured or reformulated in Australia. The notified polymer will be imported as a component of a polymer film (at < 1% concentration) either on a roll or as pre-formed packaging units for local filling and repackaging.

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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | < 0.1 | < 0.1 | < 0.1 | < 0.1 | < 0.1 |

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The imported film or pre-formed packaging units containing the notified polymer will be packed in plastic bags which will be further packaged into cardboard boxes.

USE
The notified polymer will be used as a component of packaging film at < 1% concentration for packaging materials. The finished products will be available for commercial and consumer use.

OPERATION DESCRIPTION
The notified polymer will not be manufactured or reformulated in Australia.

Local operations will include filling and sealing of packaging units using specially designed machinery. Two layers of film will be loaded into the moulding chamber of the filling machine and contents will be injected in between the two layers, followed by sealing the edges. The finished products will be transferred to a secondary machine for packaging.

Consumers will take one packaging unit from an outer packaging and place it into the appropriate equipment. Once in the equipment the packaging film containing the notified polymer will release the contents.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

CATEGORY OF WORKERS

| *Category of Worker* | *Exposure Duration (hours/day)* | *Exposure Frequency (days/year)* |
|---|---|---|
| Transport and storage | 2-4 | 24 |
| Plant operators | 8 | 200 |
| Maintenance | 1-2 | 12 |
| Retail | 8 | 200 |

EXPOSURE DETAILS

*Transport, storage and retail workers*
Transport, storage and retail workers are expected to only be exposed to the notified polymer in the unlikely event of an accidental rupture of containers.

*Filling workers*
Workers involved in repackaging the finished films and maintenance of machinery may come into dermal contact with the notified polymer (at < 1% concentration) when unpacking and loading the film containing the notified polymer onto the filling machine. The packaging process for filling the packaging units is largely automated. The notifier states that exposure is expected to be minimised by the use of appropriate PPE including goggles, gloves and coveralls.

*End use*
Workers in professions using products containing the notified polymer may be exposed to the notified polymer (at < 1% concentration). Dermal exposure is expected when removing the packaging unit from an outer packaging and placing it into the equipment. Dermal contact with the packaging unit will be brief with exposure expected to be less than 1 minute per day and only to the fingers. The notified polymer is expected to be bound in the packaging unit when dry and transfer to the skin during dermal exposure is expected to be low. However there is potential for dermal exposure to the notified polymer where the packaging units are in contact with water. Dermal exposure may be minimised if workers are using PPE such as gloves.

#### 6.1.2. Public Exposure
The public will have similar but less frequent potential than workers for exposure to the notified polymer at < 1% concentration in packaging materials (exposure discussed above).

### 6.2. Human Health Effects Assessment
No toxicity data were submitted. The notified polymer has a relatively high molecular weight (> 500 Da), is a salt and water soluble, therefore it is not expected to be systemically available following dermal exposure.

The notified polymer has surfactant properties therefore there is potential for skin and eye irritation effects. However the notified polymer does not contain structural alerts for skin sensitisation.

***Health hazard classification***
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

### 6.3. Human Health Risk Characterisation

#### 6.3.1. Occupational Health and Safety
Dermal exposure to the notified polymer at < 1% concentration is expected during normal handling such as loading the film to the filling machine, packaging, removing the packaging unit and placing it into equipment. There was no toxicity data available on the notified polymer. However, based on the low concentration (< 1%) of the notified polymer in the film and low bioavailability of the notified polymer bound in the dry film, local

effects or systemic toxicity from exposure to the notified polymer is expected to be very low and should be further mitigated by the use of personal protective equipment (PPE) such as gloves. Based on the assessed low exposure under the use pattern, the risk to workers from the use of the notified polymer is not considered to be unreasonable.

### 6.3.2. Public Health

Consumers are expected to have similar but less frequent potential than workers for exposure to the notified polymer at < 1% concentration in packaging materials (risk characterisation discussed above). Use of PPE when handling the packaging units is not expected; however, this will not significantly increase the risk to the public, as the polymer is bound in the packaging film. Therefore, the risk to the public from the use of the notified polymer is not expected to be unreasonable.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

### 7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported as a component of finished packaging film. No reformulation will occur in Australia; however, filling and repackaging of contents into finished packaging units will occur. There is unlikely to be any significant release to the environment from transport, repackaging and storage, except in the case of accidental spills. In the event of spills, the product containing the notified polymer is expected to be collected and disposed of to landfill in accordance with local government regulations.

The repackaging process will involve packaging unit filling and sealing operations that will be highly automated. Therefore, significant release of the notified polymer from this process to the environment is not expected. Wastes containing the notified polymer generated during repackaging include film off-cuts and spilt materials. It is estimated by the notifier that up to 2% of the import volume of the notified polymer (or up to 2 kg) may be released to the environment as repackaging off-cuts. These are expected to be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

Based on the end use of the packaging materials containing the notified polymer, the majority of the notified polymer is expected to be released to the aquatic compartment through sewers.

RELEASE OF CHEMICAL FROM DISPOSAL

A minor amount of the notified polymer may be disposed of to landfill as domestic waste.

### 7.1.2. Environmental Fate

No environmental fate studies were submitted for the notified polymer. Based on its end use, the majority of the notified polymer is expected to enter the sewer system, before potential release to surface waters nationwide. Based on its molecular structure and high water solubility, the notified polymer is expected to be readily biodegradable. This is supported by the ready biodegradability results of related alkyl ether sulphate (AES) surfactants (58-100% in 28 days following OECD TG 301 test guidelines; Schöberl *et al*., 1988). Release to surface waters is unlikely to occur, as partitioning to sludge and sediment is expected under environmental pH based on its surfactant properties. The notified polymer is not expected to bioaccumulate due to its surfactant properties and expected ready biodegradability. Therefore, in surface waters the notified polymer is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon and phosphorus.

The majority of the notified polymer will be released to sewer after use. A small proportion of the notified polymer may be applied to land when effluent is used for irrigation, or when sewage sludge is used for soil remediation. The notified polymer may also be applied to land when disposed of to landfill as collected spills and solid wastes. The notified polymer in landfill, soil and sludge is expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon and phosphorus.

### 7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 100% release of the notified polymer into sewer systems nationwide and no removal within sewage treatment plants (STPs).

| Predicted Environmental Concentration (PEC) for the Aquatic Compartment | | |
|---|---|---|
| Total Annual Import/Manufactured Volume | 100 | kg/year |
| Proportion expected to be released to sewer | 100% | |
| Annual quantity of chemical released to sewer | 100 | kg/year |
| Days per year where release occurs | 365 | days/year |
| Daily chemical release: | 0.274 | kg/day |
| Water use | 200.0 | L/person/day |
| Population of Australia (Millions) | 20.496 | million |
| Removal within STP | 0% | |
| Daily effluent production: | 4,099 | ML |
| Dilution Factor - River | 1.0 | |
| Dilution Factor - Ocean | 10.0 | |
| PEC - River: | 0.061 | µg/L |
| PEC - Ocean: | 0.006 | µg/L |

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m$^2$/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m$^3$). Using these assumptions, irrigation with a concentration of 0.06 µg/L may potentially result in a soil concentration of approximately 0.40 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 2.02 µg/kg and 4.04 µg/kg, respectively.

### 7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. Ecotoxicity endpoints for related surfactants of the alkyl ether sulphate (AES) group are summarised in the table below.

| *Endpoint* | *Result* | *Assessment Conclusion* |
|---|---|---|
| Fish Toxicity | | |
| $C_{12\text{-}15}$ $AE_3S$ [1] | 96 h LC50 = 1.0-2.5 mg/L | Toxic to fish (acute) |
| $C_{14\text{-}16}$ $AE_{2.25}S$ [2] | 45 d NOEC = 0.39 mg/L | Harmful to fish (chronic) |
| Daphnia Toxicity | | |
| $C_{13.67}$ $AE_{2.25}S$ [3] | 96 h EC50 = 1.17 mg/L | Toxic to aquatic invertebrates (acute) |
| $C_{13.67}$ $AE_{2.25}S$ [3] | 21 d NOEC = 0.37 mg/L | Harmful to aquatic invertebrates (chronic) |
| Algal Toxicity | | |
| $C_{12\text{-}14}$ AES [4] | 72 h EC50 = 32 mg/L | Harmful to algae |

[1] Reiff *et al*., 1979
[2] Little, 1981
[3] Maki, 1979
[4] Verge *et al*., 1996

Based on the above ecotoxicological endpoints for related surfactants, the notified polymer is expected to be acutely toxic and chronically harmful to aquatic life. However, there is insufficient data on the physico-chemical properties of the notified polymer to determine the extent of the analogy between the notified polymer and the related surfactants. Therefore, the applicability of these results to the notified polymer needs to be treated with caution, and should be considered to be a conservative worst-case representation for the notified polymer. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is not formally classified for acute and chronic toxicities.

#### 7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for daphnia. A conservative safety factor of 1,000 was used given only acute and chronic endpoints for analogue substances are available.

| Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment | | |
|---|---|---|
| NOEC (*Daphnia*, 21 d) | 0.37 | mg/L |
| Assessment Factor | 1,000 | |

| | | |
|---|---|---|
| Mitigation Factor | 1.00 | |
| PNEC: | 0.37 | µg/L |

### 7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

| Risk Assessment | PEC µg/L | PNEC µg/L | Q |
|---|---|---|---|
| Q – River | 0.061 | 0.37 | **0.164** |
| Q – Ocean | 0.006 | 0.37 | **0.016** |

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. The notified polymer is expected to be readily biodegradable, and is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in packaging materials, the notified polymer is not expected to pose an unreasonable risk to the environment.

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