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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Cristamid MS 1700

This Self 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 Heritage. The data supporting this assessment will be subject to audit by NICNAS.

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Arkema Pty Ltd (ABN/ACN 44 000 330 772)
Ground Floor
600 Victoria Street
Richmond VIC 3121

NOTIFICATION CATEGORY
Self Assessment: 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, Additives, Use Details, Manufacture/Import Volume, Quantity of finished product using notified chemical and Detailed technical function of notified chemical.

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)
CEC Permit No. 586, June 2004

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Polyamide Semi aromatic (PASA)

MARKETING NAME(S)
Cristamid MS 1700

3. COMPOSITION

Criterion	*Criterion met*
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. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported into Australia by ARKEMA as polymer pellets of Cristamid MS 1700 in 25 kg foil lined plastic bags, 40 bags to a pallet. The Cristamid MS 1700 will be landed and transported in mixed containers and warehoused in Melbourne or Sydney.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 50	< 50	<150	< 150	< 150

USE

ARKEMA Cristamid MS 1700 polyamide resins are a family of high-performance LCP polymers for precision molding. Other forms of polyamide (nylon) have been in use for over 60 years in food related applications without ill effect. The ARKEMA Cristamid MS 1700-polyamide resins offer strengthened thermoplastic with enhanced physical properties compared to conventional polyamides. Cristamid MS 1700 resins are used for consumer and engineering products market requiring precision manufacture and performance, resilience, low shrinkage, toughness, and thermoplastic melt-processibility, enabling novel designs and precision applications.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will be imported as Cristamid MS 1700 and used in manufacturing of injection molded parts.

The Cristamid MS 1700 will be packed in 25 kg foil lined polymer bags, or 500 kg cardboard box on pallet depending on customers equipment and specification. Deliveries may be by the 25 kg foil lined polybags on pallet (40 x 25 kg bags) or Poly-lined Bulk box (typically 500 kg).

The Cristamid MS 1700 is stored in a humidity controlled, heated drying room or dehumidifying dryer for a minimum of 24 hours at 50°C to ensure moisture does not affect molding quality.

Once dried the resin is loaded into the drying hopper either manually or by suction where the Cristamid MS 1700 resides till gravity fed into the molding machines pre-heating chamber thence screw fed into the heating chamber immediately prior to extrusion or injection molding. Greatest efficiency in this industry is required to compete with molded product manufactured in Asia and Europe giving preference to long runs, automatic machinery, hot sprue or no sprue and bulk raw material supply to minimise costs and potential waste.

6. EXPOSURE INFORMATION

6.1. Summary of Occupational Exposure

Cristamid MS 1700 as supplied by ARKEMA as polymer beads and are not considered HAZARDOUS according to the criteria of NOHSC. Skin contact will be the primary route of potential exposure with mechanical abrasion being the likely form of injury.

Molding Cristamid MS 1700 requires heating the resin and molding machine between 270°C to 305°C; care should be taken to protect the hands and other exposed parts of the body when handling molten polymer or recently molded parts.

Transport and warehouse workers may come into dermal and ocular contact with the notified polymer through accidental breakage of the poly lined, kraft paper bag. The solid clear to translucent white to pale yellow pellets of Cristamid MS 1700 provide a potential slipping hazard and in limited circumstances may cause physical abrasion when the inert pellets touch the skin or eyes.

Workers will use mechanical assistance or vacuum transport to transfer the polymer pellets from the suppliers bag or box to the molding devices drying/holding hopper set at minimum of 20-60°C with a recommended residence time of 24 hours to ensure elimination of atmospheric moisture.

The product is fed into the automatic moulding machine. An exhaust/filter system and cowl is situated above the machine inlet and outlet to capture any off gassing created by a small amount (< 0.1%) of polymer naturally degrading in the molding equipment prior to extrusion. Fumes from the decomposition are noxious.

Workers operating molding equipment should wear heat resistant gloves, eye protection and heat resistant industrial clothing. The high pressures and temperature 270°C to 305°C at which the molding equipment operates requires caution by operators and maintenance staff to prevent injury from hot polymer or hot parts before they cool.

Workers following the MSDS recommendations for PPE will be protected from any hazards from hot polymer or the associated molding machinery.

6.2. Summary of Public Exposure

The notified polymer is intended for use as an molding resin and will only be available to the general public in its final form as a moulded part that has only intermittent contact with the users skin. Water solubility is critical to creating systematic toxicity to humans, and the notified polymer demonstrates very low water solubility, <5 ppm.

6.3. Summary of Environmental Exposure

6.3.1. Environmental Release

Manufacturing of moulded articles:

During manufacture by injection molding, there is potential for small releases through sprue waste. The polymer of the sprue is cut or broken from the moulded article and ground down into pellets to be recycled. Typically the waste polymer for disposal will be the 1-2 kg charge in the extruder required to "flush out" any residual polymers. In both these cases good practice will either eliminate or minimise waste to ensure economic survival.

The expected release to the environment will be:

1) Initial purge to start-up the extrusion process.
2) <10gram sprue, which can be reground and recycled therefore this step is zero release or converted into a hot sprue or mold designed for zero sprue. Maximum waste = 3.3 ton
3) 2 Kg purge to changeover the extruder to new polymer at the end of run. Typically manufacturers seek long production runs of 1 week at 24 hours. Conservative maximum waste = 500 kg.
4) Any substandard or defective molding will be recycled therefore almost zero release
5) Residual pellets in the bag or box used to supply the Cristamid MS 1700 resin at a generous 100 kg.
6) In an unlikely worst case scenario where the polymer is not recycled the total release to the environment to be land filled = 3300 kg + 500 kg + 100 kg = 3900 kg per annum.
7) With recycling and careful control of used packaging the total polymer land filled will be <10 kg per annum.
8) The above recycle from all sources may be disposed as an extender into low quality nylon molding or engineering parts.

Disposal of moulded articles end of life:

Cristamid MS1700 will be used to make disposable parts used for biohazard applications and will be disposed by incineration.

6.3.2. Environmental Fate

Water solubility is critical to creating systematic toxicity to the aquatic environment.

The polymer is not water soluble, and if released to water, would partition to sediments. The high molecular weight and insolubility underpin a predicted low potential for bioaccumulation.

The dispersed use pattern combined with the volume lost to the environment will be exceedingly low. The notified polymer contains no hydrolysable groups in the environmental pH range. The structure is made of groups that are not expected to biodegrade. In landfill, solid wastes containing the polymer will be immobile and will not be expected to leach into the aquatic compartment, but should slowly degrade by biotic and abiotic processes and become associated with the soil matrix.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Clear glass like with slight haze
Melting Point/Glass Transition Temp	GTT = 170°C by DSC
Density	1.06 g/cm³ (ISO 483)
Water Solubility	<5 mg/L at 20°C from data (ARKEMA)
Dissociation Constant	pKa is not applicable as insoluble
Particle Size	N/A
Reactivity	Not an oxidiser. Not expected to be reactive under normal environmental conditions.
Degradation Products	At recommended processing temperatures, small amounts of fumes may evolve from the resins. When resins are overheated, more extensive decomposition may occur. Adequate ventilation shouldbe provided to remove the fumes from the work area. CO, CO_2 and NO_x are typically released when Cristamid MS 1700 compound is burnt. Typically, Cristamid MS 1700 will not degrade until the temperature is greater than 280°C.

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

No toxicological data were submitted.

8.2. Human Health Hazard Assessment

The notified polymer meets the criteria for a PLC and can therefore be considered to be of low hazard. The Cristamid MS 1700 polymers inherent insolubility and molecular size prevent the polymer creating systematic toxicity to humans by the skin. The same properties prevent absorption through the gastrointestinal tract.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No ecotoxicological data were submitted. Based on the negligible solubility the polymer has no mechanism to become ecotoxic and contains no functional groups that are likely to be ecotoxic without solubility.

9.2. Environmental Hazard Assessment

Poly-non-ionic polymers of NAMW >1,000 are of low concern to the aquatic environment. The insolubility the notified polymer in the environmental pH range means that it will not be readily released into the aquatic environment.

10. RISK ASSESSMENT

10.1. Environment

The majority of the notified polymer will be incorporated into the internal parts of a molded object and hence will be mostly unavailable for exposure to the environment. Wastes generated during article manufacture are expected to be minimal. Estimated at a maximum of 4.0 tonnes per annum. Normally it is expected that 95 to 99% of the waste will be preferably disposed of by recycling. Alternately disposed by landfill in a dispersed manner as an insoluble solid, thereby minimising the environmental risk. Waste containing the notified polymer may be disposed by incineration to recover fuel value.

At end of life the used polymer may be disposed to landfill where it will slowly degrade and become associated with the soil matrix. All degradation products are expected to be relatively inert and non-ecotoxic.

The environmental risk presented by the notified polymer is expected to be low based on low hazard and aquatic exposure.

10.2. Occupational Health and Safety

The OHS risk presented by the notified polymer is expected to be low, based on low hazard of polymer meeting the definition of PLC due to high MW and low solubility combined with low opportunity for exposure, engineering controls and personal protective equipment used by workers.

10.3. Public Health

The general public will use the articles manufactured using Cristamid MS 1700. The expected properties of the polymer conform to the definition of a PLC with High Molecular weight inhibiting crossing of cellular boundaries, no reactive groups, and very low solubility. These properties do not present an unreasonable risk to human health.

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

When used as a medical device there is public health concern that requires further specialist approval by the Australian Therapeutic Goods Administration before allowing public use in this application.

There is Negligible Concern to public health when used as a precision engineering polymer as these uses are usually in internal mechanical and electrical workings with limited ability of the public to touch the polymer.

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 and high temperature processes in the manufacture thermoplastic molding.

- Extrusion/injection molding equipment should have extractor fans off take cowls positioned over the machine inlets and output heads as small amounts of thermally degraded polymer form hot gases that should be exhausted from the building.

- Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards. Personal protective equipment required during extruder operation are:
  - Eye protection (safety glasses or goggles) used according to AS/NZS 1336 (1997) and manufactured to performance AS/NZS 1337 (1992)
  - Impermeable gloves conforming to AS/NZS 2161 (2000)
  - Industrial clothing AS 2919 (1987) and footwear conforming to AS/NZS 2210 (1994)
  - Breathing protection when working above a hot extruder i.e., maintenance according to AS/NZS 1715 (1994) and manufactured to performance AS/NZS 1716 (2003).

- 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 the molder/manufacturer to minimise environmental exposure during product manufacture using the notified chemical:
  - Undertake work in designated areas only
  - Collect all wastes and recycle where possible, otherwise contain in open drums and allow material to be recycled, burnt or dispose of to landfill.

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified polymer:
  - Exhaust ventilation of all drying hoppers and molding machines
  - Do not empty polymer waste into general refuse
  - Ensure no residual pellets remain in packaging before disposal.

Disposal

- Spill clean-up with broom or vacuum

- Disposal of scrap presents no special problems and can be by incorporation with nylon resin for low quality molding or use as molding machine purge, landfill as a non hazardous waste or incineration in a properly operated incinerator. Disposal to landfill should comply with local, state, and federal regulations using only approved waste

management contractors.

Emergency procedures

- Spills/release of the notified polymer should be shovelled into metal containers. Decisions should be made if the material can be recycled into lower tolerance molding.
- Organize emergency training on an annual basis.

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.