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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Irgastat P20/Polymer in Irgastat P 22

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

TABLE OF CONTENTS

Irgastat P20/Polymer in Irgastat P 22

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Ltd
235 Settlement Road
Thomastown Victoria 3074
ABN: 97 005 061 469

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
Molecular Formula
Structural Formula
CAS Number
Polymer Constituents
Details of use
Volume
Molecular Weight
Composition details
Customer details

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, China.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Pebax MH 1657

MARKETING NAME(S)
Irgastat P 20
Irgastat P 22 (50% notified polymer)

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >10000

3. COMPOSITION

PLC CRITERIA JUSTIFICATION
The notified polymer contains only low concern functional groups.

Criterion	*Criterion met (yes/no/not applicable)*
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 chemical will be imported as colourless pellets (100%) or white to off-white granules (50%) and then formulated into thermoplastic polymers.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1 – 10	1 – 10	1 – 10	1 – 10	1 – 10

USE
The notified polymer will be used as a component in thermoplastic polymers.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will be present in Irgastat P 20 at a level of 100% and in Irgastat P 22 at a level of 50%. It will be imported as odourless colourless pellets in 25-kg paper bags (Irgastat P 20) or as odourless white to off-white granules in 2 x 20 kg bags in a fibreboard box (Irgastat P 22). The products will be imported by sea and air and transported by road from the Port of Melbourne or Melbourne airport to the Ciba Specialty Chemicals warehouse site at Thomastown in Victoria. From the Thomastown site, the products will be delivered by road to one customer in Victoria.

Irgastat P 20 and Irgastat P 22 will be compounded at the customer site into a styrenic compound via a twin screw extrusion process. The recommended use levels are 8 – 25% for Irgastat P 20 and 4 – 15% for Irgastat P 22. The end compound will be bagged off into 25-kg plastic bags for export to Japan and Taiwan for use in applications such as computer housing. There will be no local sales of the product.

During the compounding process, the colourless pellets will be combined with other raw materials to form coloured plastic pellets known as masterbatch. The plant operator manually weighs out the pellets and transfers the requisite amount into plastic bags. These pellets and other ingredients are transferred into a mixer. The mixer is sealed during mixing. After mixing, the extruder operator releases the mixture from the sealed dispenser into the twin screw extruder. In the extruder, the mixture is melted and extruded through die holes in long spaghetti-like strings, passes through a cooling water bath into a pelletiser and classifier, which cuts the strings into pellets, which are graded and conveyed to a hopper for storage. A quality control technician scoops a portion of the masterbatch into a sample container for testing. The quality of the pellets is tested against a number of quality control tests using standard laboratory procedures. Following quality control testing, a packaging operator will bag the masterbatch into 25-kg bags, ready for export distribution.

The number of workers at the customer site exposed to the sales product is expected to be no more than 2. This is composed of two plant operators - expected exposure for each operator is 30-60 minutes per week for 48 weeks. The customer has procedures in place to ensure there is minimal exposure to the notified polymer. Local exhaust ventilation operates throughout the workplace and all workers on the shop floor are issued with safety glasses, industrial clothing, footwear and industrial gloves. Local exhaust ventilation is available on the shop floor.

6. EXPOSURE INFORMATION

6.1. Summary of Occupational Exposure

Dermal and ocular exposure can occur during certain formulation processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers.

Workers may be exposed to dust particles generated from the compounding of the resin. Dermal exposure to the pellets may also occur. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers.

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

6.2. Summary of Public Exposure

The notified polymer will not be available to the public as the final masterbatch product containing the notified polymer will be exported overseas. However, there is potential exposure in the form of finished articles being exported back to Australia (e.g. computer housing). Therefore, there is potential for extensive public exposure to finished articles comprised partly of the notified polymer.

6.3. Summary of Environmental Exposure

6.3.1. Environmental Release

Since the notified polymer will not be manufactured locally, there will be no environmental exposure associated with this process in Australia.

It is estimated that the loss of the notified polymer as residue in empty pellet containers to be up to 0.1% and due to spills during production to be up to 0.1% (up to a total of 10 kg per annum). Spilled material, being solid and in pellet form, will typically be collected with a broom and bagged, and may be melted and reprocessed or disposed to landfill as normal industrial waste via a waste contractor. The import bags containing the residues may be recycled or sent to landfill.

6.3.2. Environmental Fate

Some scrap plastic may be reprocessed and reused in commercial applications. We estimate that less than 1% of the plastic waste from commercial processing would be released to the environment after recycling, therefore, up to 100 kg per year may be disposed to landfill as scrap plastic or pellets. The majority of the notified polymer will be incorporated into moulded or extruded plastic articles which will be eventually disposed to landfill at the end of their useful lives.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa	Odourless, transparent to opaque granules (Irgastat P 20) Odourless, white to off-white granules (Irgastat P 22)
Melting Point/Glass Transition Temp	195 – 208°C (Irgastat P 20)
Density	1140 kg/m^3 at 20°C (Irgastat P 20)
Water Solubility	Not soluble at 20°C. No hydrophilic groups present.
Dissociation Constant	Not applicable.
Particle Size	Not determined as the substance is granular (pellets) and does not contain dust.
Reactivity	Not expected to be reactive under normal conditions.
Degradation Products	Carbon monoxide, carbon dioxide, ammonia, hydrogen cyanide are possible thermal degradation products.

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

No toxicological data were submitted. Based on similar products, the notified polymer is expected to be non-irritating to eyes and skin.

8.2. Human Health Hazard Assessment

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

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No ecotoxicological data were submitted. The MSDS for Irgastat P 20 indicated the notified polymer is not readily biodegradable.

9.2. Environmental Hazard Assessment

The notified polymer is likely to be non-ionic under normal environmental condition. Poly non-ionic polymers with NAMW >1000 are of low concern to the aquatic environment. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

10. RISK ASSESSMENT

10.1. Environment

Almost all of the notified polymer will be used to manufacture a styrenic compound for export to Japan and Taiwan. Once incorporated into moulded articles (e.g. computer housing), the notified polymer is expected to be inert and is unlikely to pose a risk to the environment. It is anticipated that the majority of the wastes generated during the manufacture of articles will be collected and reused.

Almost all of the notified polymer imported (1 – 10 tonnes per annum including from spills, container residues, waste from processing of plastic scrap and the plastic articles at the end of their useful lives) will eventually be disposed to landfill as inert solid waste. In landfill, the polymer contained in waste or the articles is expected to be immobile due to its inert state and poor water solubility. Although not expected to be readily biodegradable, it is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified polymer due to abiotic or slow biotic processes to give water vapour, and oxides or carbon and nitrogen.

Based on the proposed use pattern, the release of the notified polymer to the environment is expected to be very low. The use pattern of the notified polymer will result in limited if any exposure to the aquatic environment. While no ecotoxicity data are available, due to limited release to water it is unlikely that the polymer would exist at levels which could pose a threat to aquatic organisms. The high molecular weight indicates a low potential for bioaccumulation.

Based on the reported exposure levels and use pattern, the polymer is not considered to pose a risk to the environment when it is stored, transported and used in the proposed manner.

10.2. Occupational Health and Safety

The OHS risk presented by the notified polymer is expected to be low, given the expected low hazard of the polymer, the engineering controls, the good work practices and safety measures including the use of appropriate personal protective equipment by workers.

10.3. Public Health

The notified polymer will not be available to the public. Members of the public may make dermal contact with products containing the notified polymer. However, the risk to public health will be negligible because the notified polymer is bound within a matrix and unlikely to be bioavailable.

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 described in the notification.

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

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.

Disposal

- The notified polymer can be used without reconditioning or may be disposed with domestic refuse according to local regulations.

- Contaminated packaging can be recycled once completely emptied.

Emergency procedures

- Spills/release of the notified polymer should be handled by sweeping or shovelling up. The collected material should be placed in a sealable, labelled container and recycled if possible or disposed of to landfill.

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.
- [list of circumstances]

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.