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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Cyclooctene Homopolymer

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Cyclooctene Homopolymer

1. APPLICANT

Process Chemicals Australia Pty Ltd. of 105/10 Edgeworth David Avenue, HORNSBY NSW 2077 has submitted a Polymer of Low Concern notification statement in support of their application for an assessment certificate for Cyclooctene Homopolymer.

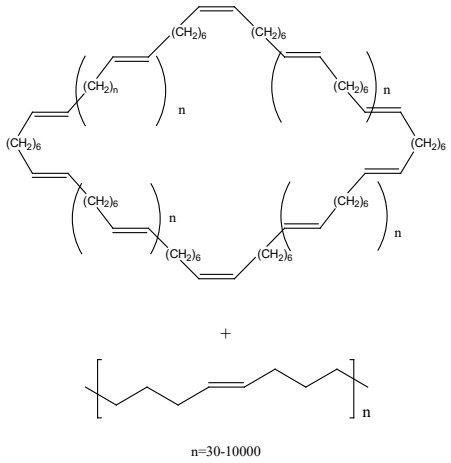
No claims for exempt information were made by the notifier.

2. IDENTITY OF THE CHEMICAL

The polymer meets the criteria for assessment as a Synthetic Polymer of Low Concern under Regulation 4A of the *Industrial Chemicals (Notification and Assessment) Act (1989).*

Chemical Name:	Cyclooctene homopolymer
Chemical Abstracts Service (CAS) Registry No.:	25267-51-0
Other Names:	Trans-polyoctenamer; Polyoctenylene; Polyoctenamer Rubber.
Marketing Names:	Vestenamer 8012; Vestenamer 6213 (See Comments below)
Molecular Formula:	$-(C_4H_7=C_4H_7)-_n$

Structural Formula:



Number-Average Molecular Weight (NAMW):	Vestenamer 8012: 14 400 (see Comments below); Vestenamer 6213: Not determined
Weight-Average Molecular Weight (WAMW):	Vestenamer 8012: 75 000 (see Comments below); Vestenamer 6213: 95 000
Polydispersity:	Vestenamer 8012: 5.21 Calculated (see Comments below)
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	No data
Molecular Weight < 1 000:	0.5%

Weight Percentage of Ingredients:

Chemical Name	Cyclooctene , homopolymer (99.5%)
CAS No.	25267-51-0

Method of Detection and Determination:	Gel Permeation Chromatography (GPC) for the NAMW and percentage of species with NAWM < 1 000.
Spectral Data:	A GPC trace and printout and a reflectance Fourier Transform Infra-Red (IR) spectrum were supplied.

Comments on Chemical Identity

The notified polymer consists of linear and cyclic macromolecules in a 75% to 25% ratio that cannot be separated or distinguished. It is produced by polymerisation of cyclooctene, which is in turn synthesised from 1,3-butadiene.

Vestenamer is available in two grades of crystallinity, Vestenamer 8012 and Vestenamer 6213. The degree of crystallinity is dependent on the cis/trans ratio of double bonds, which is controlled by polymerisation conditions. Crystallinity increases as the trans content increases.

The structures within the notified polymer were able to be determined from the information supplied by the notifier. A slight variation to the cyclic structure as provided in the Vestenamer product bulletin (Degussa-Huls Engineering Plastics (undated)) was made, noting that the cyclic structure has a molecular weight of less than 1 000.

The GPC trace for Vestenamer 8012 was used to determine the NAMW, percentage of low, molecular weight species and polydispersity. From the GPC trace, the NAMW 14 400 and the WAMW was 67 100. However, following further information supplied by the notifier the WAMW was 75 000. Polydispersity calculated for Vestenamer 8012 was 5.21.

3. PHYSICAL AND CHEMICAL PROPERTIES

	Vestenamer 8012	**Vestenamer 6213**
Appearance at 20°C & 101.3 kPa:	Light, opaque pellets	
Melting Point:	54 ± 4ºC	< 36ºC
Glass Transition Temperature:	-65 ºC	-75 ºC
Crystallinity at 23ºC:	30%	10%
Cis/Trans ratio of double bonds:	20:80	40:60
Specific Gravity at 20ºC:	0.91	0.89

Vapour Pressure:	Not applicable	
Water Solubility:	Not determined (see comments below)	
Partition Co-efficient (n-octanol/water):	Not determined	
Hydrolysis as a Function of pH:	Not determined	
Particle Size	Cylindrical or lenticular granules < 6 mm	
Charge Density	Not applicable (no charged group)	
Adsorption/Desorption:	Not determined	
Dissociation Constant:	Not determined	
Flash Point:	Not applicable	
Flammability Limits:	Not determined	
Autoignition Temperature:	> 400 °C (from Material Safety Data Sheet (MSDS)	
Explosive Properties:	Not explosive (from MSDS)	
Reactivity/Stability:	Decomposition begins at 275 °C; No hazardous reactions.	Decomposition begins at at 250°C; No hazardous reactions.

Comments on Physico-Chemical Properties

Water solubility was not determined. The notifier claims that the notified polymer is very hydrophobic, therefore insoluble in water. No polar groups are present.

The notifier claims that the polymer will be chemically and environmentally inert when incorporated as a constituent of rubber compounds. While the polymer contains double bonds which may cause oxidation reactions, it does not contain charged groups or functionality capable of being readily ionised.

4. PURITY OF THE CHEMICAL

Degree of Purity: >99.5%

Hazardous Impurities: None

Non-hazardous Impurities (> 1% by weight): None

Maximum Content of Residual Monomers:

Chemical Name	CAS No.	Weight %
Cyclooctene	931-88-4	80 ppm
Cyclooctane	292-64-8	0.3
Aliphatic hydrocarbons	unknown	0.2

5. USE, VOLUME AND FORMULATION

The notified substance will not be manufactured in Australia but will be imported by sea as granules in 25 kg plastic bags, palletized and shrink-wrapped into Australia in containers. The polymer is to be used as a processing aid in the manufacture of a wide range of rubber compounds and products such as tyres, conveyor belts, recycled rubber, shoe soling and rubber rollers.

The estimated import volume of the notified polymer will be up to 20 tonnes during the first year increasing by approximately 5 tonnes per year thereafter.

The notifier indicated that the material will be used at no more than ten sites in Australia.

Rubber processing involves: weighing and mixing of raw materials, including the notified polymer; shaping by moulding, extrusion or calendering; vulcanisation; finishing; and packaging and shipping of the final rubber product. The notified polymer is formulated with other raw materials and rubber products at a final concentration of 2 to 5% of the total weight.

6. OCCUPATIONAL EXPOSURE

Number of Workers
The notifier estimated that approximately 10 to 20 workers will be involved in transport and storage of the notified polymer, and in rubber manufacturing operations.

Dockside and Transport
The packaged, palletized and shrink-wrapped polymer, will be removed from the import containers and delivered to the notifier's warehouse(s) for storage until required by and delivered to customer sites. No repackaging or reformulation will occur at the warehouse(s). Transport and storage workers would only be exposed to the notified polymer in the event of a spill.

Rubber manufacture
At the customer site, the import bags are opened, the required quantities of polymer are weighed and added to a mixer. These processes are not described in the submission, however, if manual methods are involved then skin contact with the pellets is possible. Dust exposure is unlikely given both the low glass transition temperature and crystallinity of the notified polymer. Since rubber manufacturing involves thermal processing with generation of hazardous fumes and dusts, all subsequent stages of rubber manufacture would be in enclosed systems and skin and inhalation exposure to volatiles of the notified polymer is not expected. Additionally, local exhaust ventilation would be positioned to capture at point of source volatiles and aerosols originating from extrusion, calendering and vulcanisation.

Following vulcanisation, the notified polymer is fixed within the rubber matrix and therefore not available for separate exposure during handling of rubber products. Therefore, no worker exposure to the notified polymer from handling of finished products is expected.

7. PUBLIC EXPOSURE

In the event of a transport accident any spillage of polymer pellets could be readily recovered by sweeping. Significant public exposure in this circumstance is considered unlikely.

Public contact with the products containing the notified polymer may be widespread and frequent if the notified polymer is commercially successful. As the notified polymer is chemically bound into the matrix of rubber products however, exposure is likely to be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

Release to the environment may occur during reformulation when the bags are opened, required quantities are weighed and added to mixing machinery. The notifier estimates that 0.01-0.05% of the notified polymer would remain as residues in the bags. The notifier did not estimate the amount of residue obtained from cleaning equipment, spills or wastage but this assessment estimates residue of 1 to 2%. The notifier has indicated that all residues would be disposed of by recycling into other rubber compound products or sent to landfill.

Except in the case of accident, it is not expected that either the polymer or the rubber formulation containing the polymer would be released to the environment during storage and transportation. The MSDS contains adequate instructions for handling a spill.

Fate

If any of the uncured polymer formulation was released by spills, it would be expected to associate with the organic component of soils and sediments because of its predominantly hydrophobic nature and assimilate into these materials. Biological membranes are not permeable to polymers of very large molecular size and as such, bioaccumulation of the notified polymer would not be expected if quantities of the uncured polymer were to be released into the water compartment.

Any of the notified polymer released to the sewer within the cured and insoluble polymer matrix (rubber) is expected to associate with the sewer plant sludge, to be either deposited into landfill or incinerated.

When deposited into landfill either as residues or discarded rubber products, the organic components of the cured rubber including the notified polymer would be inert and immobile, but could nevertheless be expected to be very slowly degraded through the biological and abiotic processes operative in these facilities. The polymer also contains double bonds, which would undergo oxidation reactions.

9. EVALUATION OF TOXICOLOGICAL DATA

Only summary reports were available for the following studies.

9.1 Acute Toxicity (Degussa-Huls Engineering Plastics (undated))

Summary of the acute toxicity of Vestenamer 8012 and Vestenamer 6213

Test	*Species*	*Outcome*
acute oral toxicity	rat	LD 50 > 12 500 mg/kg
skin irritation	rabbit	Non-irritant
eye irritation	rabbit	Non-irritant

9.2 Repeated Dose Toxicity (Huls 1990a)

Species/strain: Rats/Wistar

Number/sex of animals: 10/sex/group (treatment and control groups)

Method of administration: Vestenamer 8012 or 6213 *ad libitum* for 90 consecutive days

Dose/Study duration: 0, 1 000, 2 000, 4 000 mg/kg bw/day (Vestenamer 8012);
4 000 mg/kg bw/day (Vestenamer 6213);

Test method: OECD TG 407

Clinical observations:
Animals from all treatment groups, except for males treated with 2 000 mg/kg bw/day of Vestenamer 8012, revealed a slight increase in food consumption, which did not lead to increased food conversion or body weight gain. A significant decrease in body weight gain was detected at the end of the 90-day exposure period in the group (males) treated with 4 000 mg/kg bw/day of Vestenamer 8012.

No mortalities occurred during the study period and no treatment related changes in general body health or ophthalmoscopic changes were detected in any of the animals.

Clinical chemistry/Haematology
Minor decreases, with only a few animals exceeding the normal range, in inorganic phosphate, calcium and potassium in the blood were detected in treatment groups. Slight changes in organ weight were observed in treatment groups.

Histopathology:
No treatment related gross pathological or histological effects could be detected in the animals at the end of the 90-day treatment period.

Comment:
The significant decrease in body weight gain observed in the males treated with 4 000 mg/kg bw/day of the test substance as well as the marginal decrease in certain blood parameters are not taken to be toxic effects of Vestenamer but secondary effects of the high dosages (greater than 7% Vestenamer) in the food, resulting in malsorption.

Under the test conditions, treatment with Vestenamer did not result in systemic toxicity and no target organs could be identified.

Result:
Based on the observations reported for Vestenamer 8012 and 6213, the No Observed Adverse Effect Level (NOAEL) was determined to be 4 000 mg/kg bw/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay-Ames Test (Huls 1990b)

Strains:	TA 1535, TA 1537, TA 1538, TA 98 and TA 100
Concentration range:	up to 5 000 μg/plate
Metabolic activation:	S9 mix
Test method:	Guideline 87/449/EEC, method B.14
Comment:	No detectable mutagenic effects when tested at concentrations up to 5 000 μg/plate.
Result:	The notified polymer was considered non-mutagenic under the conditions of the assay.

9.3.2 HGPRT test in Chinese Hamster Ovary Cells (Huls 1991a)

Cell line:	Chinese Hamster Ovary cells
Doses:	Up to 30 μg/mL, without metabolic activation; Up to 125μg/mL, with metabolic activation
Metabolic activation:	S9
Test method:	OECD TG 476
Comment:	Treatment with the test substance in two independent assays did not result in a reproducible statistically or biologically significant increase in the mutation frequency of the HGPRT locus.

Result:	The notified polymer was considered non-mutagenic under the conditions of the assay

9.3.3 Metaphase Analysis in V79 cells *in vitro* (Huls 1991b)

Cell line:	Chinese Hamster Lung (V79) cells
Doses:	up to 500 μg/mL tested in the absence and presence of metabolic activation; harvest times of 12, 17 and 24 hours after the beginning of treatment.
Metabolic activation:	S9
Test method:	OECD TG 473
Comment:	The test substance did not induce chromosomal aberrations in V79 cells either in the presence or absence of metabolic activation.
Result:	The notified polymer was considered non-clastogenic under the conditions of the assay

9.3.4 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Volkner 1989a; Volkner 1989b)

Species/strain:	Mice/strain not specified
Number and sex of animals:	5/sex/ test group each for Vestenamer 8012 and Vestenamer 6213
Doses:	24 hour exposure: 500, 1 670, 5 000 μg/kg bw; 48 hour exposure: 5 000 μg/kg bw; 72 hour exposure: 5 000 μg/kg bw vehicle control: 1% carboxymethylcellulose positive control: not specified.
Method of administration:	Oral; single dose of 20 mL/kg bw
Test method:	OECD TG 474
Comment:	In a series of pre-experiments, 5 000 μg/kg bw was estimated to be the maximum attainable dose. Slight toxic reactions were observed in the animals. However, no cytotoxic effects were observed following treatment with the

	test substance. No substantial enhancement in the frequency of the detected micronuclei was observed following treatment with the test substance at all exposure periods. The positive control, not specified, induced a distinct increase in micronucleus frequency.
Result:	Vestenamer 8012 and Vestenamer 6213, were considered non-clastogenic under the conditions of the assay.

9.4 Overall Assessment of Toxicological Data

The toxicological assessment is based on summary data provided by the notifier.

The notified polymer was of very low acute oral toxicity in rats with an LD50 of greater than 12 500 mg/kg bw. The notified polymer was reported as non irritating to rabbit eye or skin.

Oral administration of the notified polymer to rats in a 90-day subchronic toxicity study resulted in minor haematological and body weight effects, which were likely to be a result of secondary effect resulting in malsorption. Based on these findings, an NOAEL of 4 000 mg/kg bw was established.

The notified polymer was non genotoxic *in vitro* or *in vivo*.

The notified polymer is not considered a hazardous substance according to the NOHSC *Approved Criteria for Classifying hazardous Substances* (NOHSC 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were submitted.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

It is difficult to predict the amount of notified polymer that would be released to the environment as the notifier has not supplied estimates of the amount of material expected to be released from the reformulation process or the likely percentages of polymer that would be disposed of to landfill rather than recycling. However, the release is likely to be small (approximately 2%) and dispersed, hence, not significant at any one site. The majority of the material would be encapsulated in a cured polymer matrix and is expected to be insoluble and inert. Most of this solid waste would be deposited into landfill.

However, some of the polymer may be released into sewers as a consequence of cleaning equipment, where it would become incorporated into sewerage treatment plant sludge which would eventually be either incinerated or placed into landfill.

The polymer is unlikely to present a hazard to the environment when it is incorporated into the rubber compound and cured. There will be some release from the end products in a dispersed fashion as products such as tyres and belts wear with time and use. Such rubber objects will be consigned to either recycling plants or landfill at the end of their useful lives and the notified substance will share their fate.

The main environmental hazard would arise through spillage in transport accidents that may release small quantities of the polymer to drains and waterways. However, the polymer should quickly become immobile on association with the soil/sediment layer.

The low environmental exposure of the polymer as a result of the proposed use indicates the overall environmental hazard should be low

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer is of very low acute oral toxicity and is non irritating to rabbit eye or skin. An NOAEL of 4 000 mg/kg/day was determined in a 90 day oral study. Genotoxicity was not observed *in vitro* or *in vivo*.

On the data supplied, the notified polymer is not determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying hazardous Substances* (NOHSC 1999).

Occupational Health and Safety

Transport and Storage

Exposure to the notified polymer is not expected during transport or storage as long as the packaging remains intact. Exposure after a spill would be controlled by use of the recommended practices for spillage clean-up given in the MSDS supplied by the notifier. The notified polymer is not considered a hazardous substance and both its crystallinity and glass transition temperature precludes the formation of dusts when handled. Therefore, no significant risk is posed to workers who may make contact with the polymer pellets (6 mm).

Occupational Exposure

During rubber processing, skin contact with the polymer pellets is possible during weighing and charging of mixing vessels with the polymer: the polymer is incorporated at 2 to 5% by weight in rubber compounds. The notified polymer is not considered a hazardous substance and in its pellet form unlikely to generate dust when handled. Therefore, no significant risk is posed to workers who may make contact with the polymer in pellet form.

The rubber processing industry is an environment in which hazardous fumes and dusts are generated. Existing ventilation control measures will control exposure to volatiles arising from the notified polymer during processing. Therefore, the risk of adverse health effects from the notified polymer during thermal processing is considered minimal. After vulcanisation, the notified polymer is chemically fixed within the rubber matrix and not available for separate exposure during handling of finished rubber products. Therefore, no significant risk is posed to workers handling finished rubber products.

Public Health
Despite possible widespread and frequent contact with rubber products containing the notified polymer, public exposure is likely to be minimal due to the notified polymer being chemically bound into the matrix of the rubber. Any exposure which does occur is unlikely to lead to adverse effects given the low toxicity of the notified polymer in animal studies and the high NAMW and the water insolubility which are likely to preclude absorption across biological membranes. Based on its toxicology and physico chemical characteristics and the proposed use pattern, Cyclooctene Homopolymer is not considered to pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Cyclooctene Homopolymer the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia 1987) and AS 3765.2 (Standards Australia 1990); impermeable gloves or mittens should conform to AS 2161 (Standards Australia 1978); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand 1994);

- Spillage of the notified chemical should be avoided. Spillages should be swept up promptly and stored in containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion; and

- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under subsection 64(1) of the Act, secondary notification will be required if the polymer characteristics cease to satisfy the criteria under which it has been accepted as a Synthetic Polymer of Low Concern. Secondary notification of the notified polymer shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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Standards Australia/Standards New Zealand (1992). Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Sydney/Wellington, Standards Association of Australia/Standards Association of New Zealand.

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Volkner, W. (1989b). Micronucleus assay in bone marrow cells of the mouse with Vestenamer 6213, CCR, Cytotest Cell Research GMBH & Co. KG.