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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer SF 1318

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 Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer SF 1318

1. APPLICANT

GE Plastics Australia Pty Ltd of 175 Hammond Road DANDENONG Vic 3175 has submitted a limited notification statement in support of their application for an assessment certificate for Polymer SF 1318.

2. IDENTITY OF THE CHEMICAL

Polymer SF 1318 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

2. IDENTITY OF THE CHEMICAL

Other Names:	SF 1318 1154-204
Trade Name:	SF 1318
Number-Average Molecular Weight:	> 1 000
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	< 5%
Molecular Weight < 1 000:	< 25%
Method of Detection and Determination:	Nuclear Magnetic Resonance (NMR) for identification; Gel Permeation Chromatography (GPC) to evaluate molecular weight distribution
Spectral Data:	NMR trace representative of relative proton chemical shifts was supplied

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	colourless to pale yellow liquid with little odour
Melting Point:	< -45°C
Freezing Point:	-40°C
Specific Gravity:	0.954 at 25°C
Vapour Pressure:	not available
Viscosity:	700 cs at 25°C
Water Solubility:	< 1% (insoluble)
Partition Co-efficient (n-octanol/water):	not available
Hydrolysis as a Function of pH:	stable
Adsorption/Desorption:	not available
Dissociation Constant:	not available
Flash Point:	138°C
Flammability Limits:	not available
Autoignition Temperature:	not determined
Explosive Properties:	not determined
Reactivity/Stability:	not reactive

Comments on Physico-Chemical Properties

The vapour pressure is expected to be low due to the large molecular weight of the polymer and the residual monomers.

The notifier states that testing in their laboratories found the solubility to be less than 1% in water. No details or conditions of this testing were supplied. The EPA expects that the water solubility will be very low due to the large molecular weight of the polymer and/or the long chain hydrophobic groups.

The notifier performed a simple stability test where polymer samples were mixed in neutral, acidic and alkaline solutions, and allowed to stand for 7 days at 25^{o}C. The polymer samples were analysed by GPC before and after the experiment. A slight increase in the molecular weight of the polymer was observed when it was placed in alkaline conditions (which is probably due to residual silanol condensation). There was no notable change to the polymer's molecular weight in the water (pH 7) sample. In spite of the presence of ester groups, the EPA does not expect the polymer to hydrolyse due to its expected low water solubility.

The partition coefficient is expected to be high due to the expected low water solubility.

Given the polymer's low water solubility and expected high partition coefficient, it is anticipated that the polymer will strongly adsorb to, or be associated with, soil and sediments.

The notified polymer does not contain any dissociable groups.

Flammability limits were not determined as the polymer was not considered as volatile.

4. PURITY OF THE CHEMICAL

Degree of Purity: high

Toxic or Hazardous Impurities: none

Non-hazardous Impurities (> 1% by weight):

These are not listed on Worksafe Australia's *List of Designated Hazardous Substances* (1) or, Toxline (2) or Sax and Lewis (3). The notifier has supplied a report (4) indicating that the oral LD_{50} for rats for one of the impurities is 4 930 mg/kg and a dermal toxicity in rats of LD_{50} > 15 800 mg/kg. According to Worksafe

Australia's *Approved Criteria for Classifying Hazardous Substances* (5) it is not classified as hazardous.

Maximum Content of Residual Monomers: see non-hazardous impurities

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia. It will be imported in the form of ready to sell drums (205 L). The notified polymer will be imported as the formulation SF 1318 in the quantities of greater than 1 tonne/annum but less than 100 tonnes/annum for the next five years.

The notified polymer is used in the USA and Europe as a component of skin care formulations and lipstick. Current overseas consumption is 27 000 kg/annum. It will be imported in a ready-to-use form, and sold for the purpose of incorporation by the skin care product formulators into end-use products.

6. OCCUPATIONAL EXPOSURE

The notified polymer is imported in 205 L drums which will normally be supplied direct to cosmetic manufacturers. Repacking will be limited to quantities of less than 100 kg/annum and will occur approximately 10 times per year. It is reformulated under ambient conditions with other ingredients to make skin care formulations. No additional ventilation is specified during decanting and reformulation. The expected low vapour pressure of the notified polymer should limit exposure. Following blending the cosmetic formulation is packaged for end use. The most likely route of exposure during blending and packaging will be via the skin. There is a limited possibility of inhalational exposure from mists during pressurised processes such as pumping.

Occupational exposure will be limited to personnel involved in the blending and packaging of cosmetics containing the notified polymer and quality control and testing staff. The notifier estimates this to be about 10 employees.

7. PUBLIC EXPOSURE

The notified polymer will be used in skin care cosmetic products at the level of up to 10%. Skin contact with cosmetic products will be the main route of public exposure to the notified polymer and therefore potential exposure is expected to be high.

Compared to the skin exposure from using skin care products containing the notified polymer, public exposure resulting from transport, reformulation, and

disposal is expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

The generation of waste should be limited to traces remaining from the clean-up of any transport/incident spills, residues in empty packaging and materials used in the cleaning of formulation equipment. Residues of the polymer in empty 200 L drums are expected to be less than 100 g, as the viscosity is such that it will very easily drain into formulation vessels. The notifier has explained that the nature of modern manufacturing processes are such that production schedules are constructed so that subsequent batches of product can accommodate the trace residues from the former product. This reduces the need for frequent cleaning of formulation equipment. Traces of the notified polymer in waste washings will be treated at the trade waste system of the plant, together with other chemicals and oils, prior to discharge to the sewer. The majority of the polymer in the waste washings will be removed with the skimmed oils, which will be disposed of by licensed waste contractors.

The use of the products containing the notified polymer will be widespread but diffuse as they will be applied in relatively small quantities to the face and body. The notifier has supplied data (adjusted from US estimates) on the exposure expected to environmental compartments from the washing/wiping off of the products. They are as follows:

- ∑ 40% may be lost to ablutions, thence the sewer.
- ∑ 30% may be lost to the ocean/sea.
- ∑ 20% may be lost to swimming pools.
- ∑ 10% may be lost to rivers and other natural swimming locations.

The EPA expects that the percentage lost to rivers and other natural swimming locations will be less. This component is more likely to be lost to the ocean/sea and/or swimming pools.

Cosmetics removed using cleanser on paper towel or cotton wool, and residues in empty packaging are expected to be disposed of with household garbage. This amount is expected to be relatively small.

Fate

The formulation of products containing the notified polymer will be undertaken at a small number of formulating plants. Spillages will be contained and absorbed by dry material which will be disposed of to landfill. Washings, after treatment at the trade waste system of the plant, will be sent to the sewer. The notified polymer is expected to partition to sediment/sludge of the waste water treatment plant, which will then be landfilled or incinerated. In landfill, the polymer is expected to sorb to sediment due to the expected low water solubility and high partition coefficient. Incineration of the polymer will produce water, oxides of carbon and sand.

Products containing the notified polymer will be released to the environment due to consumer use and subsequent washing/wiping off. The notifier has presented data on possible amounts released to individual compartments. This indicates that a significant amount of polymer (approximately 8 tonnes per year) will directly enter natural aquatic systems at maximum importation rates.

Another 8 tonnes of the polymer will be disposed to the sewer. It is expected that the majority of the polymer will be removed through the adsorption to, or association with, sludge. The notified polymer is expected to have a very low water solubility and it will be effectively removed during the waste water treatment process.
Small amounts are expected to remain as residues in containers within formulated products. The containers are expected to be sent to landfill, where the polymer is expected to remain immobile.

No biodegradation data has been provided and are not required under the Act. However, the notifier does not anticipate that the polymer will be biodegradable. Siloxane bond redistribution within the polymer in dry soils is not expected to occur as this route of degradation seems to be limited to straight chained polydimethylsiloxane fluids (6). Bioaccumulation is not expected as biological membranes are not permeable to polymers and chemicals of very large molecular size (7,8).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Polymer SF 1318

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg	9
skin irritation	rabbit	non-irritant	11
eye irritation	rabbit	non-irritant	13

9.1.1 Oral Toxicity (9)

Species/strain:	Sprague/Dawley rats
Number/sex of animals M/F:	5/5
Observation period:	14 days
Method of administration:	oral by gavage, dose of 5g/kg b.w.
Clinical observations:	none

Mortality:	none
Morphological findings:	none
Test method:	based on TSCA, 1989 (10)
LD_{50}:	> 5 000 mg/kg
Result:	low toxicity

9.1.2 Skin Irritation (11)

Species/strain:	New Zealand white rabbit
Number/sex of animals M/F:	3/3
Observation period:	72 hours
Method of administration:	0.5 ml of test substance to shaved skin for 4 hours under an impervious bandage
Draize scores (12): [a]	0

[a] see Attachment 1 for Draize scales

Test method:	based on TSCA, 1989 (10)
Result:	not a skin irritant

9.1.3 Eye Irritation (13)

Species/strain:	New Zealand white rabbit
Number/sex of animals M/F:	3/3
Observation period:	72 hours
Method of administration:	0.1 ml of test substance in one eye

Draize scores (12):	0
Test method:	based on TSCA, 1989 (10)
Result:	not an eye irritant

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (14)

Strains:	TA98, TA100, TA1535 and TA1537 with and without metabolic activation
Concentration range:	0.1-10 000 μg/plate
Test method:	based on TSCA, 1989 (10)
Result:	non mutagenic, controls gave appropriate response

9.3 Overall Assessment of Toxicological Data

The notified polymer was found to be of minimal toxicological significance in a range of short term studies. Rats were dosed at a rate of 5 000 mg/kg and no mortality was observed; this corresponds with an acute LD_{50} of > 5 000 mg/kg. In a skin irritation study in rabbits the notified polymer did not produce signs of irritation after contact with the skin for a period of 24 hours. An eye irritation study using rabbits did not produce signs of irritation. An Ames test (with and without metabolic activation) to determine the genotoxic (mutagenic) potential of the notified polymer was negative.

The above data would result in the notified polymer not being classified as hazardous according to the criteria of Worksafe Australia (5).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of NAMW > 1 000 according to the Act.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of notified polymer will be incorporated as an emollient into skin care products and cosmetics at concentrations up to 20%. Use of these products is expected to be widespread across Australia.

The notifier commented that due to current manufacturing processes, wastes through washings are reduced. Polymer wastes due to spillages and washings will be collected and treated at the trade waste system of the plant prior to discharge to the sewer. The skimmed oils, containing most of the notified polymer, will be disposed of to licensed waste contractors. Environmental exposure through product formulation is expected to be low, and therefore the hazard is expected to be low.

Release of the polymer directly to the aquatic components of the environment will occur through use. However, this release is expected to be very diffuse and at concentrations that are unlikely to be toxic to aquatic life.

Approximately 40% of the import volume of the polymer is expected to go to sewer through use. A predicted environmental concentration (PEC) for the polymer in sewage water across Australia is estimated at 8.1 ppb. However, this neglects adsorption to sludge, which is expected to be extensive. Hence the polymer will be handled as part of the normal solid waste recovery, and disposed of to landfill or through incineration. The actual concentration released is expected to be very low and is not expected to pose an environmental hazard. In landfill the polymer is not expected to be mobile or degrade due to its expected low water solubility.
The product containers used by consumers containing residues of the notified polymer are expected to be disposed of with normal household garbage by either landfill or incineration.

The overall environmental hazard can be rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer will not be manufactured in Australia but imported from the USA in 205L drums. The polymer has a relatively high NAMW of > 1 000 which should preclude absorption, there is a low level (< 5%) of low molecular weight species (< 500) so there is some potential for skin absorption. The notified polymer is imported as a relatively pure liquid with a low level of impurities. These impurities are not classified as hazardous on the basis of available toxicity data according to the criteria of Worksafe Australia (5).

A fairly limited range of toxicity data on the notified polymer indicates that it is of minimal toxicological concern. It has a low acute oral toxicity to rats with an LD_{50} in excess of 5 000 mg/kg. It produced no reaction in rabbit skin and eye irritation studies and is classified as non-irritant. No studies on sensitisation potential were provided by the notifier. A limited assessment of the genotoxic potential of the notified polymer (an Ames test) gave a negative result. On the basis of the available toxicity data for the notified polymer it would not be classified as hazardous according to the criteria of Worksafe Australia (5).

No toxicological information is available for the diester of the constituent monomers. Toxicity studies on the monomers showed that they would not be

classified as hazardous according to the criteria of Worksafe Australia (4) The presence of the monomers in cosmetic formulations at a concentration < 0.3 % is not expected to be of toxicological significance.

Occupational exposure will be limited to operations associated with the reformulation of the polymer into cosmetic products such as skin care creams. Exposure during transport and warehousing will only occur in the event of accidental release of the polymer from the shipping drums. Exposure will occur during repackaging, blending and packaging of the end products. Blending normally takes place under ambient conditions (is not heated) this and the expected low vapour pressure of the notified polymer should limit inhalational exposure during reformulation. The notifier has not specified engineering controls to limit inhalational exposure. These would only be necessary if mists are formed as may occur with leakage from pressurised systems. The main occupational exposure route will be dermal. The available toxicity data and the high molecular weight indicate this is unlikely to be of concern. The nature of the end use of the notified polymer, as a component of skin creams with long skin contact times, and the toxicological profile of the notified polymer indicates that occupational exposure poses minimal risks.

Then main route of public exposure to the notified polymer is by skin contact. The high molecular weight (NAMW > 1 000) of the notified polymer would preclude its absorption across biological membranes. The notified polymer contains relatively high levels of the diester of the monomeric components, this has a molecular weight in excess of 500, and dermal absorption is expected to be low. Furthermore the level of the diester in skin care products is relatively low. (< 2 %).

The notified polymer is currently used in the USA and Europe as a component of skin care formulations and lipsticks with a total annual consumption of 60 000 pounds. The proposed use of the notified polymer in skin care products is not expected to pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer SF 1318 the following guidelines and precautions should be observed:

- Safe practices, which should be followed when handling any chemical formulation include:
    - minimising spills and splashes;
    - practising good personal hygiene; and
    - practising good housekeeping and maintenance including bunding of large spills which should be cleaned up promptly with absorbents and put into containers for disposal.

It is expected that, in the industrial environment, protective clothing conforming to and used in accordance with Australian Standard (AS) 2919 (15) and protective footwear conforming to Australian/New Zealand Standard (AS/NZS) 2210 (16) should be worn as a matter of course.

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (17).

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 the Act, secondary notification of the notified chemical 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

1. National Occupational Health and Safety Commission 1994, *List of Designated Hazardous Substances* [NOHSC:10005(1994)], Australian Government Publishing Service Publ., Canberra.

2. Toxline Silver Platter 1995, *Toxline SilverPlatter CD-ROM database, January 1994-December 1995*, Silver Platter International N.V.

3. Sax, N. I. & Lewis, R. J. 1989, *Dangerous Properties of Industrial Materials*, Van Nostrand Reinhold, New York.

4. McNerney J M, Gross P and Babyak M 1961, Range Finding Toxicity Tests on TME and TDE for Celanese Corporation of America. Industrial Hygiene Institute of America Inc, New York, USA.

5. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)], Australian Government Publishing Service, Canberra.

6. Lehmann RG, Veraprath S, Annelin RB & Arnst JL, 1995. "Degradation of Silicone Polymer in a Variety of Soils". *Environmental Toxicology and Chemistry* 14(8):1299-1305.

7. Anliker R, Moser P & Poppinger D,1988. "Bioaccumulation of dyestuffs and organic pigments in fish. Relationships to hydrophobicity and steric factors". *Chemosphere* 17(8):1631-1644.

8. Gobas FAPC, Opperhuizen A & Hutzinger O,1986. "Bioconcentration of hydrophobic chemicals in fish: relationship with membrane permeation". *Environmental Toxicology and Chemistry* 5:637-646.

9. Fitzgerald G 1991, Toxikon Project Number 91G-0412, acute oral toxicity, Toxikon Woburn, MA, USA.

10. Toxic Substances Control Act (TSCA), USA, 1989, 40 CFR, Part 798

11. Fitzgerald G 1991, Toxikon Project Number 91G-0410, primary dermal irritation study, Toxikon Woburn, MA, USA.

12. Draize, J. H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* **49**.

13. Fitzgerald G 1991, Toxikon Project Number 91G-0411, primary ocular irritation, Toxikon Woburn, MA, USA.

14. Prezibso J A, 1996. *Salmonella typhimurium* reverse mutation assay direct plate incorporation method. Toxikon Corporation, Bedford, MA, USA.

15. Standards Australia, 1987, *Australian Standard 2919 - 1987 Industrial Clothing,* Standards Association of Australia Publ., Sydney, Australia.

16. Standards Australia, Standards New Zealand 1994, *Australian/ New Zealand Standard 2210 - 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications,* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

17. National Occupational Health and Safety Commission 1994. *National Code of Practice for the Completion of Material Safety Data Sheets*, [NOHSC:2011(1994)], AGPS, Canberra.

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe