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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Neodecanoic Acid, Ethenyl Ester, Polymer with 2-Butenoic Acid and Ethenyl Acetate

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 National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT**Neodecanoic Acid, Ethenyl Ester, Polymer with 2-Butenoic Acid and Ethenyl Acetate****1. APPLICANT**

BASF Australia Ltd of 500 Princess Highway NOBLE PARK VIC 3174 (ACN 008 437 876) has submitted a notification statement in support of their application for an assessment certificate for the synthetic polymer of low concern (PLC), "Neodecanoic acid, ethenyl ester, polymer with 2-butenic acid and ethenyl acetate".

2. IDENTITY OF THE CHEMICAL

Spectral data and details of the polymer composition have been exempted from publication in the Full Public Report.

Chemical name:

Neodecanoic acid, ethenyl ester, polymer with 2-butenic acid and ethenyl acetate.

CAS number:

58748-38-2

Other names:

2-Butenoic acid, polymer with and ethenyl acetate and ethenyl neodecanoate;

Acetic acid ethenyl ester, polymer with 2-butenic acid and ethenyl neodecanoate.

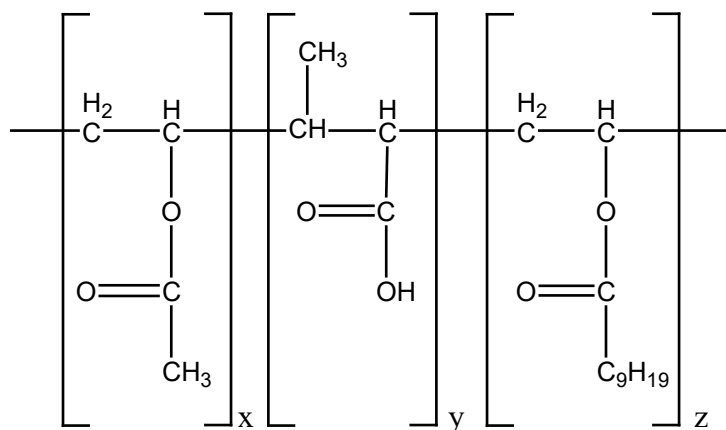
Trade names:

Luviset CAN

Molecular formula:

$(C_{12}H_{22}O_2 \cdot C_4H_6O_2 \cdot C_4H_6O_2)_x$

Structural formula:



Reactive functional groups:

Carboxyl group (low).

Functional group equivalent weight (FGEW):

107 000

Molecular weight (MW):

Number-average MW	Weight-average MW	% MW < 1000	% MW < 500	Method
10 700	64 000	1.9	0.76	GPC

3. POLYMER COMPOSITION AND PURITY

Details of the polymer composition have been exempted from publication in the Full Public Report.

Purity (%): 98-100.

Hazardous impurities (other than residual monomers and reactants): None.

Non-hazardous impurities at 1% by weight or more: None.

Additives/adjuvants: None.

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

Property	Result	Comments
Appearance	Odourless white powder.	
Melting point	40-50°C	
Density	750 kg/m ³	
Water solubility	<1 mg/L	
Particle size	Mean diameter approximately 250 µm	The fraction of particle size less than 30 µm is very low.
Flammability	Not flammable.	
Autoignition temperature	Not determined.	
Explosive properties	Not determined.	The structure does not indicate explosive properties.
Stability/reactivity	Stable under the conditions of use.	Will not hydrolyse, undergo photo- or thermal degradation or depolymerise.

5.1 Comments on physical and chemical properties

The water solubility of the notified polymer is stated as < 1ppm at 23°C though the presence of approximately 10% carboxylic acid functionality would help increase solubility. If the notified polymer is neutralised by AMP (2-amino-2-methylpropan-1-ol) the resulting polymer salt is expected to show significant water solubility.

Significant hydrolysis of the ester linkages within the polymer is unlikely at environmental pH 4-9, though the rate would increase in solution.

As imported, the polymer contains a free carboxylic acid functionality expected to have typical acidity.

The notified polymer contains only reactive functional groups of low concern.

6. USE, VOLUME AND FORMULATION

Use:

The notified polymer will be used in hair setting formulations, e.g. hair spray.

Manufacture/Import volume:

The notifier estimates that the import volume will be 1 to 10 tonnes per annum for the first 5 years.

Formulation details:

The notified polymer is imported in 100 kg polyethylene drums. It will be neutralised with AMP or DEPA (diethylaminopropylamine), TIPA (triisopropanolamine), sodium

hydroxide, or potassium hydroxide, and blended with other components such as alcohol, propane, butane and resin to form a 2-6% hair spray solution. The final hair spray products are packed into 200 g pressure pack cans.

7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier
<i>Formulation</i>		
<i>2 Process operators and 2 packaging operators.</i>		
Dermal, ocular and inhalation	Weighing and packaging (6-7 hours per day and 48 weeks per year). Connecting and disconnecting of hoses and cleaning equipment.	Local exhaust ventilation where natural ventilation is inadequate. Sealed processing vessel. Workers will wear industrial clothing, apron, protective footwear, safety glasses/chemical goggles/face shields and impervious gloves. Air-purifying respirator may be used if breathable dust is formed.
<i>2-4 Laboratory technicians.</i>		
Dermal, ocular and inhalation	Sampling and analysing small quantities (2-4 hours per week).	Exhaust fume hoods. Disposable rubber latex or vinyl gloves, laboratory coats, protective glasses and protective footwear. Dust mask are available.
<i>End use</i>		
<i>Hairdressers</i>		
Dermal, ocular and inhalation	Applying the hair spray.	Disposable rubber latex or vinyl gloves.
<i>Transport and storage</i>		
<i>2 Drivers and 1-2 Store persons</i>		
Dermal, ocular and inhalation	Only expected from accidental spillage.	No specific controls were described.

8. PUBLIC EXPOSURE

The potential for public exposure to the notified polymer during transport, use or disposal is assessed as negligible. The notified polymer will be used as an ingredient in hair spray

products. Therefore significant public exposure is expected. As a result of using hair spray products, members of the public may make dermal, ocular and respiratory contact with aerosols of products containing the notified polymer.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

During formulation, the notifier estimates that up to 0.2% or 20 kg/annum of notified polymer will be wasted as residues in the import containers. In addition, incidental spills will be swept up and disposed of to an approved industrial facility, at a maximum of 100 kg/annum, based on an estimated incidental spill rate of 1%.

The notifier intends to retain residues from the mixing vessel to reuse in the subsequent batch.

The remainder of the notified polymer, up to 9.9 tonnes/annum, will be incorporated into hair spray formulations for the domestic cosmetics market. It will be released either from the use of hair care products (up to 9.7 tonnes/annum) or from the disposal of pressurised cans containing hair care residues (up to 0.2 tonnes/annum), based on an estimated 2% residues in the pressurised cans.

9.2. Fate

Wastes generated during formulation will be swept up and disposed of to landfill as industrial waste or incinerated by a licensed waste contractor. Within landfill the polymer is likely to associate with the soil matrix and is not expected to leach into the aquatic environment. If incinerated, the notified polymer would be rapidly destroyed and converted to water vapour and oxides of carbon.

The majority of the notified polymer contained in hair care products will be deposited on hair, clothing, or immediate surroundings. It will end up in the water compartment as the result of washing, laundering and cleaning. Waste water will enter the domestic sewage system and ultimately the aquatic environment.

The remainder of the formulated notified polymer will be disposed of to domestic landfill as residues in the pressurised cans. Leaks within landfill are likely to associate with the soil matrix and are not expected to leach into the aquatic environment.

The notified polymer is not expected to cross biological membranes, due to its high molecular weight and predicted low water solubility, and should not bioaccumulate (Connell, 1990).

10. EVALUATION OF HEALTH EFFECTS DATA

No toxicological data were submitted. The Material Safety Data Sheet (MSDS) for Luviset CAN indicated that the notified polymer was of very low acute oral toxicity ($LD_{50} > 36.4$ g/kg) and low acute dermal toxicity ($LD_{50} > 10.2$ g/kg).

The health hazards of the constituents and hazardous impurities, additives and adjuvants are tabulated below.

Chemical	Health hazards	Regulatory controls
Constituents		
Vinyl acetate	Suspected carcinogen (Lewis, 1996)	TWA, 10 ppm or 35 mg/m ³ (NOHSC, 1995).
Hazardous impurities		
none	-	-
Additives/adjuvants		
none	-	-

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were submitted.

Anionic polymers containing polycarboxylic acid functionalities are of concern for toxicity to green algae. The 96 h EC₅₀ for algal growth inhibition is moderate, with toxicity values ranging from 1 to 100 ppm (Nabholz et al, 1993). The mode of toxic action of polycarboxylic acids appears to be over-chelation of nutrient elements needed by algae for growth. Maximum toxicity occurs when the carbon backbone contains a carboxylic acid group on every alternate carbon atom (Boethling et al, 1997), which is not the case with the notified polymer.

AMP may be used as a counter ion. It contains an amine group and is probably slightly toxic based on the toxicity data of ethanolamine, a structural analogue (Verschueren, 1996).

12. ENVIRONMENTAL RISK ASSESSMENT

The majority of imported polymer will ultimately be disposed of to the sewers from domestic use of the formulated hair care products. Assuming a worst case scenario, where there is no removal of the polymer in the sewage treatment plant, the resultant Predicted Environmental Concentration¹ (PEC) would be:

Import rate:	10 000 kg/annum
Release rate:	10 000 kg/annum
Population (national):	19×10^6
Volume of sewage per annum:	$19 \times 10^6 \times 365 \times 150 = 1.040 \times 10^{12}$ L/annum
Mean concentration in sewage:	9.6 µg/L (9.6 ppb)

On release to receiving waters (after treatment at the sewage treatment plant), it is usually assumed that the effluent is diluted by a factor of 10. This gives a final PEC in receiving

¹ These calculations assume that all the imported notified polymer will be used nationwide and that it is all released to the sewer system. It is also assumed that 150 L of sewage are generated per person each day.

waters of 0.96 µg/L (0.96 ppb).

It should be noted that no other removal mechanisms are considered in the above calculation. Biodegradation of the chemical or more likely adsorption to sediment will lower the above PEC estimates.

Therefore, considering a worst case scenario, the expected release rate of the notified polymer is several orders of magnitude below the expected algal toxicity. Hence the environmental hazard associated with the proposed use of the notified polymer in hair care products is expected to be low.

Minor quantities of the notified polymer will be released to landfill as residues and spills generated during formulation and residues in pressurised cans.

In the event of accidental release of the notified polymer into soils or waterways, the correct procedures identified in the MSDS should be followed.

Given the above considerations, the overall environmental hazard is expected to be low.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

No toxicological data were submitted. Since the notified polymer has NAMW >1 000, absorption across biological membranes will be restricted. The MSDS for the notified polymer indicated that it was of very low acute oral toxicity and low acute dermal toxicity. Based on the available information, the notified polymer would not be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

13.2. Occupational health and safety

There is little potential for significant occupational exposure to the notified polymer in the transport and storage of the polymer and the hair spray products containing the polymer, or during retail sale of these products.

During the reformulation and packaging processes, the main exposure routes for the notified polymer will be dermal and inhalation. The imported notified polymer is a powder, but the particle size is outside the inspiration range. The polymer is not expected to be hazardous by dermal exposure based on its molecular structure and the high molecular weight which will preclude absorption through the skin. The engineering controls such as local exhaust ventilation are installed at the workplace. Workers will wear personal protective equipment including industrial clothing, protective footwear, safety glasses/chemical goggles/face shields and protective gloves. If dust is formed, respirators may be used to provide protection against inhalation exposure to the notified polymer. Given the controlled exposure and anticipated low toxicity, the health risk at the reformulation and packaging sites is expected to be low.

Laboratory workers will be exposed to small quantities of the notified polymer for short periods. Suitable laboratory facilities such as exhaust ventilation and personal protective clothing should be used.

Occupational use of the finished products in the hairdressing industry may result in dermal and inhalation exposure to the notified polymer. A higher than normal incidence of respiratory complaints (lung disease and respiratory irritation and asthma) is found among workers in the hairdressing industry. The exact chemical cause cannot be determined in all cases, however the inhalation of aerosol droplets from hair sprays is believed to be a contributing factor. Hair dressing industry workers would be expected to have more frequent exposure than members of the general public using the same formulation. Employers in the hairdressing industry should take precautions to minimise inhalation of spray products, e.g. by providing adequate ventilation for workers and the public. The relevant State or Territory industry guidelines or codes of practice should be observed.

13.3. Public health

Products containing the notified polymer are available for sale to the general public. Members of the public may make dermal, ocular and respiratory contact with hair sprays containing the notified polymer. The risk to public health from exposure to the notified polymer in hair sprays will be low because the notified polymer is present in low concentrations and is unlikely to be bioavailable.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

14.2. Label

The label for the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

15. RECOMMENDATIONS

To minimise occupational exposure to ‘Neodecanoic acid, ethenyl ester, polymer with 2-butenic acid and ethenyl acetate’, the following guidelines and precautions should be observed:

- Protective eyewear, chemical resistant industrial clothing and footwear and impermeable gloves should be used during occupational use of the products

containing the notified polymer; where engineering controls and work practices do not reduce vapour and particulate exposure to safe levels, a dust mask or air fed respirator should be used;

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly by sweeping/vacuum and put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

National Occupational Health and Safety Commission has recommended an exposure standard of 10 mg/m³ for inspirable dust (NOHSC, 1995).

Guidance in selection of protective eyewear may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994a); for respirators, in AS/NZS 1715 (Standards Australia/ Standards New Zealand, 1994b) and AS/NZS 1716 (Standards Australia/ Standards New Zealand, 1994c).

16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Secondary notification may be required if:

- (i) any of the circumstances stipulated under subsection 64(2) of the Act arise. If any importer or manufacturer of (the notified chemical) becomes aware of any of these circumstances, they must notify the Director within 28 days; or
- (ii) the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

17. REFERENCES

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