

File No: PLC/182

July 2002

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

**Protein hydrolysates, wheat, [2-hydroxy-3-[3-(trimethoxysilyl)propoxy]propyl],
hydrolyzed**

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.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, National Occupational Health and Safety Commission, Plaza level, Alan Woods Building, 25 Constitution Avenue, Canberra ACT 2600 between 9am to 5pm Monday to Friday.

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

For enquiries please contact the Administration Section at:

Street Address: 334-336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA

Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA

Telephone: (61) (02) 8577 8816 FAX (61) (02) 8577 8888

Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT.....	3
2. IDENTITY OF POLYMER.....	3
3. POLYMER COMPOSITION AND PURITY	4
4. PLC JUSTIFICATION	4
5. PHYSICAL AND CHEMICAL PROPERTIES.....	5
6. USE, VOLUME AND FORMULATION	6
7. OCCUPATIONAL EXPOSURE.....	7
8. PUBLIC EXPOSURE.....	8
9. ENVIRONMENTAL EXPOSURE	8
9.1. Release	8
9.2. Fate.....	8
10. EVALUATION OF HEALTH EFFECTS DATA.....	8
11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA	9
12. ENVIRONMENTAL RISK ASSESSMENT	9
13. HEALTH AND SAFETY RISK ASSESSMENT	10
13.1. Hazard assessment	10
13.2. Occupational health and safety	10
13.3. Public health.....	10
14. MSDS AND LABEL ASSESSMENT.....	11
14.1. MSDS.....	11
14.2. Label	11
15. RECOMMENDATIONS	11
15.1 Secondary notification	12
16. REFERENCES	12

FULL PUBLIC REPORT

Protein hydrolysates, wheat, [2-hydroxy-3-[3-(trimethoxysilyl)propoxy]propyl], hydrolyzed

1. APPLICANT

Croda Surfactants of 23 McIlwraith Street, Wetherill Park NSW 2164 (ABN 34 088 345 457) has submitted a notification statement in support of their application for an assessment certificate for the synthetic polymer of low concern (PLC), Protein hydrolysates, wheat, [2-hydroxy-3-[3-(trimethoxysilyl)propoxy]propyl], hydrolyzed (Crodasone W). No details are claimed exempt from publication.

2. IDENTITY OF POLYMER

Chemical name: Protein hydrolysates, wheat, [2-hydroxy-3-[3-(trimethoxysilyl)propoxy]propyl], hydrolyzed

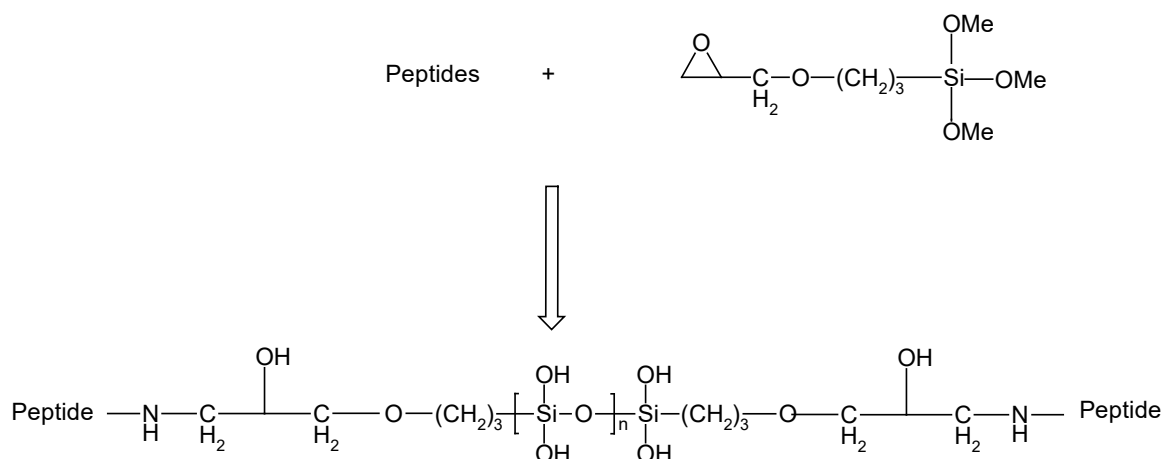
CAS number: 152887-30-4

Other names: Hydrolysed wheat protein hydroxy polysiloxane

Marketing names: Crodasone W (26-30 % active ingredient)

Molecular formula: The notified chemical is a UVCB compound and cannot be represented by a single molecular formula.

Structural formula:



Reactive functional groups:None

Molecular weight (MW):

Number-average MW	Weight-average MW	% MW < 1000	% MW < 500	Method
>1000	>200, 000	36.8*	nd	1000 Da cut off membrane

* - The majority of the low molecular weight species <1000 is due to unreacted hydrolysed wheat protein and not oligomers formed during polymer manufacture.
nd – not determined

Structural identification method:IR

Peaks at 1600 – 1700 and 3000 - 4000 cm⁻¹

3. POLYMER COMPOSITION AND PURITY

Polymer constituents

Constituent	Synonym	CAS no.	% weight	% residual
Protein hydrolyzates, wheat germ	Hydrolysed wheat protein	94350-06-8	71.4	*
Silane, trimethoxy[3-(oxiranylmethoxy)propyl]-	3-glycidoxypropyl trimethoxysilane	2530-83-8	28.6	*

*There are no residual monomers. The 3-glycidoxypropyl trimethoxysilane (GPTMS) reacts with the side chain or end terminal amino groups of the peptide chains obtained from hydrolysed wheat protein to produce the protein silicone polymer. Any residual GPTMS will readily hydrolyse to give 2,3-hydroxypropyl trihydroxysilane, which will then polymerise to form a polysilicone. Therefore, no residual GPTMS will remain.

Purity (%): >99

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

Non-hazardous impurities at 1% by weight or more:

Chemical name	Synonym	CAS no.	% weight
Sodium chloride*			8

* Ash in the form of sodium chloride resulted from neutralisation reactions with sodium hydroxide and hydrochloric acid during manufacturing process.

Additives/adjuvants: None

4. PLC JUSTIFICATION

The notified polymer does not meet the following PLC criteria:
Low Molecular Weight Species <1000, which is equivalent to <40%.

However, it is accepted for assessment as a PLC on the following grounds:
The majority of the low molecular weight species <1000 is due to unreacted hydrolysed wheat protein and not oligomers formed during polymer manufacture.

5. PHYSICAL AND CHEMICAL PROPERTIES

Property	Result	Comments
Appearance	Light amber liquid	
Boiling point	Not determined	
Density	1000 kg/m ³	
Water solubility	Not determined	On the basis that the notified polymer is imported as a 26% aqueous solution, the water solubility is at least 260 mg/L. The notifier indicates that the notified polymer is soluble in water above pH 5.5. However, below this pH the notified polymer exhibits limited solubility (Humpries M et al).
Flammability	Not flammable	
Autoignition temperature	Not determined	Not expected to auto-ignite.
Explosive properties	Not explosive	
Stability/reactivity	Not determined	The notified polymer does not contain any reactive functional groups. Under normal conditions, the notified polymer is stable.
Hydrolysis as function of pH	Not determined	The notified polymer contains peptides, which may hydrolyse but are expected to remain intact at environmental pH range.
Partition coefficient	Not determined	Due to the expected high water solubility of the notified polymer, it is likely to partition into the aqueous phase.
Particle size	Not applicable	The notified polymer will be imported in a liquid form.
Adsorption/desorption	Not determined	Based on the high water solubility, the notified polymer will have little affinity for organic matter in the soil and is expected to be mobile in both

terrestrial and aquatic compartments. It is not clear whether the notified polymer exhibits surface activity, which would cause stronger absorption to soil.

Dissociation constant	Not determined	The notified polymer does not contain functional groups capable of undergoing dissociation in the environmental pH range of 4-9.
------------------------------	----------------	--

6. USE, VOLUME AND FORMULATION

Use:

Crodasone W will function as a hair-conditioning agent. It will be used as an ingredient in the formulation of hair care products, such as shampoos and conditioners.

Manufacture/Import volume:

The notified polymer will not be manufactured or repackaged in Australia. It will be imported by Croda Surfactants and will be sold to Goldwell Cosmetics (Australia) Pty Ltd, who will distribute the finished hair shampoos and conditioners for the hair dressing salon market. Rauxel Pty Ltd of Mt Kuringai, NSW will manufacture the hair care products for Goldwell Cosmetics (Australia) Pty Ltd. Between 260-300 kg of the notified polymer will be imported per annum as a component of aqueous preparation at 26-30% concentration, during the first five years.

Formulation details:

The notified polymer will be imported in 25 kg plastic drums. The polymer will be transported from the dockside to the manufacturing site at Mt Kuringai, NSW, where it will be stored and formulated into hair care products.

The hair care products are formulated in batch sizes of 2000 kg. The notified polymer is poured manually into a stainless steel container filled with solvent for dissolution. The resulting mixture is transferred under vacuum into a second sealed blending vessel where other components of the hair care products are added. Prior to packaging, sampling and quality testing of the preparation is carried out in the laboratory. The formulated hair care products will then be transferred to a hopper with a multiple head filler machine and automatically poured into 0.3, 1.0 or 2.0L plastic bottles. The finished hair care products will contain 0.15% notified polymer.

The bottled products will be packed in cardboard cartons and will be sent to Goldwell Cosmetics (Australia) Pty Ltd warehouse for storage until distribution to hairdressing salons.

End use

Hairdressers will apply the hair care products containing the notified polymer. The product will be applied to hair for less than 15 min and then completely washed off after application. A customer will go to the hairdresser at a maximum of twice a month.

7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier
<i>Manufacture of hair care products</i>		
<i>Formulation, filling containers, cleaning and maintenance (6 workers, 8 hours/day, 20 days/year)</i>		
Dermal and ocular	Dermal and limited ocular exposure when opening and closing drums, adding the notified polymer manually into mixing vessel, and connecting and disconnecting transfer and filling lines. Dermal exposure due to drips and spills and if containers are overfilled at the filling station can also occur. Skin contamination of maintenance workers when cleaning equipment and during routine maintenance.	Mixing vessels are enclosed. Filling machines are automated and fitted with local exhaust ventilation to capture any volatile or aerosol materials at the source. PPE: overalls, safety glasses and/or safety shoes, PVC or disposable latex gloves and head cover.
<i>Quality control (1 worker, 4 hours/day, 20 days/year)</i>		
Dermal	Limited dermal exposure to small quantities during sampling and testing.	PPE: laboratory coats and safety glasses.
<i>End use</i>		
<i>Product application by hairdressers (Approximately 1000 workers)</i>		
Dermal	Limited dermal exposure when applying hair care products.	PPE: The notifier indicated that impermeable gloves are worn; however, this is not a general practice.
<i>Transport and storage</i>		
<i>Transport and storage of the notified polymer (2-4 workers, 1-2 hours/day, 2 days/year)</i>		
None	No exposure is expected except in the case of an accident	PPE – not specified
<i>Transport and storage of formulated hair care products (2-4 workers, 1-2 hours/day, 2 days/year)</i>		

None	No exposure is expected except in the case of an accident	PPE – not specified
------	---	---------------------

8. PUBLIC EXPOSURE

Public exposure through importation, transportation or storage is negligible. The notified polymer will be a component of hair care products, which is intended for professional hair salon market. However, the products will also be available to the public from hair salons, hence public exposure of the notified polymer is expected.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

During formulation of the hair care products the notifier estimates that up to 20 kg per annum of notified polymer will be released into the environment as a result of spills and equipment cleaning. Subsequent water washes will pass to interceptor pits where the settled material will be collected and disposed of to landfill. Wastewater will be used for gardening or recycled in the plant for other processing activities.

The plastic import drums containing residual notified polymer (up to 10 kg per annum) will be disposed of to landfill. The bottles in which the hair product will be sold to consumers and the residues they contain (up to 20 kg per annum) will be disposed of in domestic landfill.

The majority of the notified polymer will be incorporated into hair products and as such will almost completely be released to the environment.

9.2. Fate

The notifier indicates that empty drums and their residues will be disposed of to landfill. Wastes from the cleaning of equipment and spills will pass to interceptor pits where the settled material will be collected and disposed of to landfill. The notifier indicates that the notified polymer is highly soluble in water. However, its solubility decreases rapidly under acidic conditions. Therefore in landfill, the notified polymer has the potential to be mobile in both terrestrial and aquatic compartments. However, overtime the notified polymer is expected to adsorb to soil and sediments and degrade slowly through biotic and abiotic processes.

The majority of the notified polymer will be released into the sewer following washing of hair. However, this will be in dilute manner, as the notified polymer contained within these products will be released from domestic use at low concentrations. Over time, the notified polymer is expected to adsorb to soil and sediments and degrade slowly by the processes described above.

10. EVALUATION OF HEALTH EFFECTS DATA

The notifier provided skin irritation and skin sensitisation studies for the aqueous preparation containing the notified polymer. The test material did not show evidence of skin irritation

using the TESTSKINTM in vitro toxicity testing system and skin sensitisation based on human repeat insult patch test.

The Material Safety Data Sheet (MSDS) for the aqueous solution of the notified polymer indicates that the polymer may be a slight irritant.

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were submitted.

12. ENVIRONMENTAL RISK ASSESSMENT

The intended use pattern of the notified polymer is expected to result in the majority of the polymer being eventually released to the environment. However, this will be in dilute manner, as the notified polymer contained within the hair care products will be released from domestic use at low concentrations.

The Predicted Environment Concentration (PEC) in sewage effluent on a nationwide basis is estimated as 0.96 µg/L based on the following assumptions:

- A worst case scenario of a maximum annual import of 1 tonne per annum, all of which is released to sewer and assuming that none is removed during sewage treatment processes; and
- A national population of 19,000,000 where each person contributes an average 150 L/day to overall sewage flows.

Amount of Crodasone entering sewer annually	1000kg
Population of Australia	19 million
Amount of water used per person per day	150 L
Number of days in a year	365
Estimated PEC	0.96µg/L (0.96ppb)

When released to receiving waters the concentration is reduced by a further factor of at least 10, and so the PEC is approximately 0.096 µg/L. Over time, the notified polymer is expected to adsorb to soil and sediments and degrade slowly through biotic and abiotic processes.

In landfill, the notified polymer has the potential to be mobile in both terrestrial and aquatic compartments. However, over time it is expected to adsorb to soil and sediments and degrade slowly through biotic and abiotic processes.

Therefore, the environmental exposure and overall environment hazard from the notified chemical is expected to be acceptable.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

The notified polymer is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). It is neither a skin irritant nor a skin sensitiser based on skin irritation and sensitisation studies provided. The MSDS for the aqueous solution of the notified polymer indicates that the polymer may be a slight irritant.

The notified polymer has high molecular weight, and is not expected to be absorbed across the skin or other biological membranes, and therefore, systemic toxicity would be limited. No hazardous impurities, additives and adjuvants are present.

13.2. Occupational health and safety

Except in the event of accident, exposure during transport and storage is limited, since workers are only expected to handle sealed containers.

Reformulation will be carried out predominantly in closed systems, however addition of the polymer solution involves manual operations. Limited dermal and ocular exposure to the notified chemical is possible when opening and closing drums, connecting and disconnecting transfer and filling lines, and cleaning and maintenance of equipment. Limited dermal exposure to small quantities of the notified polymer during quality control testing can also occur. The use of ventilation systems and personal protective equipment such as overalls, gloves, protective foot wear and protective glasses would limit exposure to the notified polymer during the above activities.

Intermittent dermal exposure can occur when applying the hair care products to the hair. The notifier indicates that hairdressers will wear impermeable gloves when applying hair care products; however, it is not a general practice. The low concentration of the notified chemical in the hair care products (maximum 0.15%) and the use of gloves would ensure low occupational risk.

Precautions should be taken to avoid ocular contact with the hair care preparations, as slight eye irritation may occur.

Conclusion

The notified polymer is of low concern to human health and safety. The control measures in place during hair care product manufacture and the use of protective equipment when handling the notified polymer will minimise the risk of adverse health effects. No specific risk reduction measures are necessary.

13.3. Public health

In home use, typical shampoo use is expected to be 12 grams per application, 2 to 7 times per week. The expected absorption is <10%. At 0.15% notified polymer, the consumer would be exposed to 18 mg of notified polymer (expected to be 0.3 mg/kg bw for a 60 kg female). Although the notified polymer may be a slight eye irritant, it is present at a very low concentration in the formulated product, and it is normal practice to minimise eye contact

with shampoos. Therefore, the notified polymer is not expected to pose a health risk to the public.

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 and products containing the polymer provided by the notifier were 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

Control Measures

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Exhaust ventilation during hair care product manufacture and filling operations
 - Enclosed and automated mixing and bottle filling operations
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid spills and splashes during manual transfer of the polymer into the mixing vessel and during cleaning operations
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Overalls (or similar protective apparel)
 - Safety glasses
 - Safety footwear
 - Impervious gloves

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.

15.1 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 Section 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 Section 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.

16. REFERENCES

Humphries M et al. Protein-silicone copolymers. Croda Colloids Ltd, UK (unpublished report submitted by Croda Australia).

National Occupational Health and Safety Commission (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1994b) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Australian Government Publishing Service, Canberra.