File No SANHP/3

March 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Parsol SLX

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
DSM Nutritional Products Australia Pty Ltd (ABN 36 000 991 793) of Level 2 , Building 8, 49 Frenchs Forest Rd, Frenchs Forest, NSW, 2086.

NOTIFICATION CATEGORY
Self-Assessment: Non-hazardous Synthetic Polymer with NAMW ≥ 1000

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name
Other Names
Molecular Formula
Structural Formula
Polymer Constituents
Use
Molecular weight

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
France 1996
Switzerland 1998

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Polysilicone-15

MARKETING NAME(S)
Parsol SLX

3. COMPOSITION

DEGREE OF PURITY
> 99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All residual monomers and hazardous impurities are present below the relevant cut-offs for classification of the notified polymer as a hazardous substance.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The polymer will be imported as a viscous liquid substance and then formulated in Australia into the cosmetic end-use products for skin and hair care.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.2	0.3	0.4	0.6	0.65

USE
The polymer will be used in skin and hair care end-use products up to a maximum concentration of 10%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Formulation sites will be located in NSW, South Australia and Queensland

TRANSPORTATION AND PACKAGING
Transportation: Sea, land and air transportation within Australia.
Packaging: Industrial packaging: steel drums (20 kg, 200kg)
Packaging of end-products: plastic and glass containers (up to 200mL), or aluminium containers (up to 100 mL).

5.2. Operation Description

The notified polymer will not be manufactured in Australia. The notified polymer will be formulated into end-use products by manufacturers for cosmetic products in Australia. Typically operational procedures are described as follows:

Transfer of the notified polymer from drums into the formulation process: Depending on the site of formulation, the notified polymer may be transferred manually, semi-automatically, e.g. by dip-pipe or automatically by dedicated pipe work. Smaller quantities may be pre-weighed into smaller drums or buck lets before addition to the blending vessel.

Formulation: Depending on the site of formulation, blending vessels may be open or closed.

Filling: Typically, the bottle filling process will be automated; however, some manual input may be involved such as capping.

5.3. Disposal

Packaging of industrial use: The steel drums will be handed over to drum re-conditioners or professional waste contractors.

Packaging of end-products may be disposed of via the local domestic waste to a land-fill or incineration.

6. EXPOSURE INFORMATION

6.1. Summary of Occupational Exposure

During the following steps occupational exposure may occur:
1. Transport and warehouse: Dermal and ocular contact with the notified polymer may only occur through accidental leaks and spillages of containers.

2. Typical operations:
- e.g. Laboratory/quality control personal: weighing, sampling for analysis
- e.g. workers in formulation: may manually empty the import containers or connect/disconnect the dip tube and pump to the drums.

Workers involved in direct handling of the polymer during typical operations as described above and formulation may become incidentally exposed to the polymer on the skin of their hands or arms when spilling or dripping the polymer. Workers exposure will be minimised by use of protective clothes, coats, shoes, gloves and safety glasses. Incidental exposure is expected to occur only approximately during 15 days a year.

Potential exposure to the notified polymer via inhalation is negligible, due to its very low vapour pressure.

Exposure during filling of the formulated product may occur only incidentally when spilling. Exposure is expected to be low since the final formulation contains only a maximum of 10% of the notified polymer. While filling the formulation, workers will wear personal protective equipment as described above.

6.2. Summary of Public Exposure

The public comes into contact with the notified polymer when using skin and hair care products on a domestic basis. The exposure level will depend on the use pattern of the end-product for skin or hair.

Skin application: The daily applied cosmetic end-products e.g. creams and lotions will be applied to the skin of the consumers. These products are expected to stay on the skin for a short duration until they will be rinsed-off during daily washing or showering or bathing in public swimming pools.

Hair: The notified polymer may be applied daily to hair by using spray-on end-products and also rinse-off products. The notified polymer will stay on the hair until it will be washed off as described above for skin application.

An estimate of exposure when using different cosmetic products is calculated as follows:

Type of cosmetic product	Application quantity * (g/application)	Application frequency per day *	Retention factor *	% notified polymer in product	Daily exposure to the notified polymer (g/day)
Body lotion	8.0	1	1	10	0.8
Creams	1.2	2	1	10	0.24
Hair Styling Products **	5.0	2	0.1	10	0.1

* values taken from SCCNFP document:
** the polymer will be used in rinse-off (hair conditioner) and leave-on products (hair-styling). For calculation of the margin of safety in section 10.3 the higher value for daily exposure (= hair styling products) is being used as a worst case.

6.3. Summary of Environmental Exposure

6.3.1. Environmental Release

The notified polymer will be imported in drums of 20 and 200 kg into Australia at Sydney from where

it will be transported to local manufacturers of skin and hair care products. It will be formulated with other ingredients into the cosmetic end-use product.

Release to the environment at the manufacturing site may occur mainly via three routes:

1. Formulation: Accidental spills during manufacturing of end-use products may occur and are estimated to be about 1% or 0.018 kg/day based on the maximum 12-month import volume (650 kg). For cleaning appropriate adsorbent material will be used. Release into the environment is avoided or minimised when adsorbent is disposed of to waste landfill and/or by incineration.
2. Disposal of empty drums with residuals of the polymer: The drums may contain estimated residues of 1% of the total amount of the polymer and will be handed over to drum re-conditioners or professional waste contractors. Residues of the polymer are estimated to be about 1% or 0.018 kg/ day based on the maximum 12-month import volume and assuming a continuous process. Residues will either be thermally decomposed by incineration or eliminated by secure landfill.
3. Cleaning of equipment will be performed by using organic solvents, release into the environment can be minimised by incineration of solvents. An amount of 1% or 0.018 kg/day based on a maximum 12-month import volume is expected to be released during cleaning of equipment.

Release of chemical during domestic use:
The end-use cosmetic products containing low concentrations (up to 10%) of the notified polymer are applied to skin as a lotion or cream and to hair as a styling (leave-on) or conditioner (rinse-off) product (see also 6.2).

Based on the results in the skin penetration absorption study a major part of the polymer will presumably remain on the skin surface or hair. Thus it is expected to be washed off into the waste water or by swimming in public pools or natural waterways. The waste water will be treated in public sewage treatment plants before being released into the environment. A calculation of the PEC is given in section 10.1.

In the sewage treatment plants, the notified polymer is expected to be mainly eliminated by adsorption to the sewage sludge which may be incinerated or securely land filled.
The minimal residues remaining in consumer packages are estimated to be about 1% and will be disposed of by domestic waste to landfill or incineration. The total amount disposed by domestic waste can be estimated to be 6.5 kg/year based on the maximum yearly amount imported.

6.3.2. Environmental Fate

The notified polymer is expected to be hydrolytically stable. As the notified polymer was shown as not being readily biodegradable it is expected that it will not be degraded in waste water treatment plants. Due to its hydrophobic properties, the notified polymer will be mainly associated with the anaerobic sewage sludge phase, sediment or soil organic matter. Thus, it is expected to be mainly eliminated by adsorption to the sewage sludge and only a minor portion may reach the environment through effluent water. The notified polymer can be expected to be bound strongly to the soil or sediment organic matter due to its low water solubility. Thus in landfill, leaching of the polymer is not expected. Biodegradation is anticipated to occur slowly in the environment.

7. ESTABLISHMENT OF LOW PHYSICAL AND CHEMICAL HAZARD

Appearance at 20°C and 101.3 kPa	Colourless to slightly yellow liquid
Melting Point	< -50°C
Boiling Point	Decomposes before boiling at 100kPa @ 223°C
Density	1.023 kg/m^3 at 20°C
Vapour Pressure	< 20Pa at 20°C
Water Solubility	< 0.0001 g/L at 20°C
Hydrolysis as a Function of pH	data not available, no hydrolysis expected
Partition Coefficient (n-octanol/water)	Log Pow = 6 at 30°C

Absorption/Desorption	Not available. The mobility is estimated to be very low due the high MW and low water solubility of the notified polymer
Dissociation Constant	Not applicable
Particle Size	Not applicable (liquid)
Flash Point	> 100 ^{o}C at 1013Pa
Flammability	No (430^{o}C)
Explosive properties	No
Reactivity	Stable under normal environmental conditions

8. ESTABLISHMENT OF LOW HUMAN HAZARD

Endpoint	*Result*	*Classified?*	*Effects Observed?* *	*Test Guideline*
1. Rat, acute oral	LD50 >2000 mg/kg bw	no	no	OECD TG 401
2. Rat, acute dermal	LD50 >2000 mg/kg bw	no	no	OECD TG 402
3. Rat, acute inhalation	Not performed	no	no	OECD TG 403
4. Rabbit, skin irritation	slightly irritating	no	yes	OECD TG 404
5. Rabbit, eye irritation	slightly irritating	no	yes	OECD TG 405
6. Skin sensitisation - adjuvant test	no evidence of sensitisation.	no	no	OECD TG 406 Maximisation test
7. Rat, oral route (gavage) repeat dose toxicity – 90 days.	NOAEL: 1000 mg/kg/d /LOAEL	no	no	OECD TG 408
8. Genotoxicity - bacterial reverse mutation	non mutagenic	no	no	OECD TG 471
9. Genotoxicity – in vitro				
9.1 Chromosomal aberration test	non genotoxic	no	no	OECD TG 473
9.2 Photoclastogenicity evaluation (V79 chinese hamster cells)	non photoclastogenic	no	no	Modified OECD TG 473
10. Genotoxicity – in vivo	Not performed	-	-	OECD TG 474, 475, 486
11. Developmental and reproductive effects	Not performed	-	-	
12. Carcinogenicity	Not performed	-	-	

13.1 Pharmacokinetic study with radiolabeled polymer following oral administration to rats	The results obtained in the study suggest that the polymer is poorly adsorbed following oral administration.	-	-
13.2 Pharmacokinetic study with radiolabeled polymer following dermal administration	The results obtained suggest that the polymer is poorly adsorbed following dermal administration.	-	-
14. Percutaneous absorption study in vitro (skin):	Penetration of polymer is minimal; from a standard O/W emulsion the penetration into epidermis and dermis is < 0.5**%** , 16 hours after application on domestic pig skin.	-	-

8.1. Discussion of Observed Effects

Irritation and Sensitisation

Skin irritation: Slight erythema in one animal after 24 hours only.

Eye irritation: Mild early –onset and transient ocular changes, such as reddening of the conjunctivae and sclerae. This effect was reversible and no longer evident after 72 hours after treatment .No corrosion was observed at any of the measuring intervals.

Sensitisation test: no effects observed

Repeated Dose Toxicity (oral route- gavage)

Mortality and Time to Death: No

Clinical Observations: No

Laboratory findings: Clinical Chemistry: Minor differences in some clinical chemistry parameters (slight decrease in serum concentrations of total bilirubin, serum aspartate aminotransferase and serum alkaline phosphatase) were considered to be a hepatic adaptation to the test substance.

Haematology, Urinalysis: No findings

Pathology (Organ weight): Minor differences in liver weight (16% in male high dose group only) see conclusion below

Gross Pathology, Histopathology): No

Conclusion: Because none of the individual values of the liver weight or above mentioned biochemical parameters were regarded as pathological and all differences were absent following treatment-free period, the above mentioned differences were considered to be of no toxicological importance.

Skin Irritation Scores

Lesion	*Maximum Score**	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	1	1	0
Oedema	0	0	0

Eye Irritation Scores

Lesion	*Maximum Score*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	1	2	0
Conjunctiva: chemosis	1	1	0
Conjunctiva:discharge	0	0	0
Corneal opacity	0	0	0
Iridial inflammation	0	0	0

Skin Sensitisation Scores

Group	*Challenge Concentration*	*Number of Animals Showing Any Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	0/20	0/20		
	10%	0/20	0/20		
Control Group	100%	0/10	0/10		
	10%	0/10	0/10		

8.2. Human Health Hazard Assessment

Based on the toxicological data, the notified polymer is expected to be of no concern for human health. The notified polymer is considered to be of low acute oral and dermal toxicity. It is slightly irritating to skin and eyes and did not show any potential for skin sensitisation. There is no toxicological significance for chronic toxicity. The notified polymer is considered to be non-mutagenic, non-photomutagenic and non- photoclastogenic.

9. ESTABLISHMENT OF LOW ENVIRONMENTAL HAZARD

Endpoint	*Result*	*Criterion met?*	*Effects Observed?**	*Test Guideline*
1. Ready Biodegradability	not biodegradable	no	no	OECD TG 301 F
2. Bioaccumulation	not bioaccumulative	no	no	-

9.1.1 Discussion of Observed Effects

Ready Biodegradability: The notified polymer is not readily biodegradable (no biodegradation when tested to OECD TG 301F - Manometric Respirometry Test). Due to its poor water solubility a low microbial bioavailability is anticipated.

Bioaccumulation: No study was performed. Bioaccumulation potential is expected to be very low since the high molecular weight of the notified polymer would preclude the notified polymer from crossing biological membranes.

9.2. Ecotoxicological investigations

Endpoint	*Result*	*Criterion met?*	*Effects Observed?**	*Test Guideline*
1. Fish Toxicity	EL50 > 10000 mg/L	yes	no	OECD TG 203
2. Daphnia Toxicity	EL50 > 10000 mg/L	yes	no	OECD TG 202
3. Algal Toxicity	EL50 > 530 mg/L	yes	yes	OECD TG 201

4. Inhibition of Bacterial Respiration	EL50 > 100 mg/L	yes	no	Derived from OECD TG 301 F

Note: concerning all acute toxicity tests to aquatic organisms as mentioned above: Due to the poor water solubility of the notified polymer, water accommodated fractions (WAF) of the polymer were prepared by weighing amounts of 10, 100, 1000 and 10000 mg test substance per litre water. The suspensions were stirred for about 20 hours in closed vessels in the dark. Then, the dispersions were allowed to settle for some hours in a separation vessel until a stable separation of liquid phases was reached. The water phases containing the water soluble fraction of the notified polymer were carefully removed from the vessels. The water soluble fraction (WAF) of the polymer was used for testing.

All results were indicative of low hazard.

9.2.1. Discussion of Observed Effects

Fish Toxicity: No effects were observed

Daphnia Toxicity: No effects were observed

Algal Toxicity: a growth rate reduction (EL50) was observed for WAF prepared at an initial loading of 530 mg/L.

Cell growth inhibition (EL 50) corresponded with a WAF prepared at 920 mg/L.
A NOEC for cell growth inhibition corresponded with a WAF prepared at 100 mg/L.

Inhibition of Bacterial Respiration: No; No toxic or inhibitory effects to the micro-organisms were observed for the positive control aniline compared with a combination of test item and aniline in the Manometric Respiratory test (OECD TG 301F)

9.3. Environmental Hazard Assessment

The notified polymer is not acute toxic to the tested aquatic organism. For this reason, there is no concern for the aquatic environment.

The PNEC for aquatic organism can be derived from EL50 obtained for the most sensitive aquatic species algae at the loading of 530 mg/L by applying an assessment factor of 100:
PNEC: 53 µg/L

10. RISK ASSESSMENT

10.1. Environment – risk characterisation

Environmental exposure and risk due to private use

The end-use product containing a maximum of 10% of the notified polymer will be applied daily to skin or hair of the consumer. It is expected that the polymer will be washed off partially during daily washing or showering. As a worst case, it is assumed for the following calculations that 100 % of the total amount of the end-use product will be washed off into the waste water. It was also assumed that the polymer is not being eliminated either by biodegradation or adsorption to the sewage sludge in the water treatment plant. Thus it will be passed through to the effluent water into the environment.

Based on this, a worst case very simplified model calculation of the PEC of the polymer for Australia has been done by using the following parameters:

Maximum 12-month volume of the polymer placed on the Australian market over next 5 years (A): 650 kg or A* 10^9 = 6.5*10^{11} µg = assumed to be released into the environment

Assumed fraction of the polymer released into the sewage effluent (E): 1 (= 100%)
Population in Australia (P_{AUS}): 20'000'000
Applications of the end-use product per year (C): 365
Amount of water used per person per day (V): 200 L/day

The predicted environmental concentration (PEC) of the polymer in the effluent water is:

$$PEC = \frac{A * 10^9 * E}{P_{AUS} * V * C}$$

Dilution factor for inland: 1
Dilution factor for ocean: 10

The PEC were calculated to be:
PEC inland = 0.445 µg/L
PEC ocean = 0.0445 µg/L

PNEC aquatic organism (EL algal= 530 mg/L/ assessment factor 100) = 53 µg/L

PECinland /PNEC = 0.445 µg/L/53 µg/L= 0.008

The PEC/PNEC ratio for fresh water (inland) and ocean is considerably less than 1. Thus there should be no significant risk neither for the fresh water nor for marine aquatic organism.

The potential for bioaccumulation of the notified polymer is regarded as very low as its high molecular weight precludes it from crossing biological membranes.

10.2. Occupational health and safety – risk characterisation

Available toxicological data indicate a low risk for a serious health or safety hazard. Occupational exposure is anticipated to be low or may occur only incidentally since recommended personal safety and hygienic measures are in place. Therefore, the health and safety risk for worker can be regarded as low. Due to the very low vapour pressure no risk for human health by inhalation is expected.

The notified polymer is a slight skin and eye irritant. Therefore, the following personal protective equipment should be worn during the weighing and transfer of the notified polymer: Protective eyewear, protective clothing and impermeable gloves.

10.3. Public health – risk characterisation

The public will be dermally exposed to the notified polymer present in skin and hair personal care products.

Calculation of margin of safety for the notified polymer assuming the use of cream, body lotion and hair styling product (I = sum of daily exposure values for body lotion, cream and hair styling product as outlined in section 6.2):

Daily Exposure to notified polymer	**I** = 1100 mg
Percutaneous absorption of notified polymer	**A** = < 0.5 %
Total amount absorbed	**I x A**= 5.5 mg
Typical body weight of human	**bw** = 60 kg
Systemic Exposure Dose	**SED** = IxA/bw= 0.09 mg/kg/bw

NOAEL: 1000 mg/kg/day
Margin of Safety (MOS): **= NOAEL/SED > 10000**

The high margin of safety for the notified polymer indicates a negligible risk will be posed to the public health.

11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

11.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

11.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the chemical is not considered to pose a risk to the environment based on its reported use pattern.

11.3. Human health risk assessment

11.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

11.3.2. Public health

There is negligible concern for human health based on its reported use pattern. A Margin of safety of > 10000 was calculated indicating a negligible risk.

12. MATERIAL SAFETY DATA SHEET

12.1. Material Safety Data Sheet

The notifier has provided MSDS in accordance with the schedule item B 12 of the *ICNA Act*. It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

13. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced:
  - Handling of the notified polymer in closed systems and under inter gas (eg. Nitrogen) is recommended. Electrostatic charge of equipment should be avoided.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Chemical resistant gloves
  - Protective clothing
  - Safety goggles

  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.

Environment

- The following control measures should be implemented by the employer to minimise environmental exposure during (manufacture, formulation, use) of the notified polymer:
  - The notified polymer should be kept in a closed or semi-closed system during processing and transportation etc where possible. An appropriate organic solvent (eg. ethanol) should be used for cleaning of the processing equipment. The organic solvent containing residues of the notified polymer should be submitted preferably to incineration.
  - In case of an accidental spill, an appropriate inert adsorbent should be used for decontamination. The adsorbent should be disposed of to a professional waste removal or incineration.

Disposal

- The notified polymer should be disposed of by incineration with flue gas scrubbing or secure land-fill.

Storage

- The following precautions should be taken by the cosmetic producer regarding storage of the notified polymer:
  - Storage in tightly closed containers of coated steel (protective lacquer) or polyethylene at room temperature (20-25 °C)

Emergency procedures

- Accidental spills/release of the notified polymer should be handled by trained service personal
- In case of fire use foam powder or carbon dioxide for extinguishing.
- Rinse eyes with water for 10 minutes, open eyelids forcibly
- Take off contaminated cloths and wash skin with water and soap, do not use solvents.
- Treat symptomatically

Transport and Packaging
See under storage for containers to be used.

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
  - additional information has become available so that the notified polymer does not meet the definition of a non-hazardous chemical.

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.