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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Dow Corning® 2501 Cosmetic Wax

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Dow Corning® 2501 Cosmetic Wax

1. APPLICANT

Dow Corning Australia Pty Ltd of 21 Tattersall Road BLACKTOWN NSW 2148 has submitted a limited notification statement in support of their application for an assessment certificate for Dow Corning® 2501 Cosmetic Wax.

2. IDENTITY OF THE CHEMICAL

Dow Corning® 2501 Cosmetic Wax 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 and details of the polymer composition have been exempted from publication in the Full Public Report and the Summary Report.

Other names:	Dimethicone Copolyol Silicone Copolyol
Trade name:	Dow Corning® 2501 Cosmetic Wax
Number-average molecular weight (NAMW):	> 1000
Maximum percentage of low molecular weight species (molecular weight < 1000):	< 10%
Method of detection and determination:	infrared spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white to light yellow soft wax
Melting Point:	28-34°C (at 760 mm Hg)
Specific Gravity:	1.04 at 25°C

Vapour Pressure:	not applicable - notified chemical is a solid
Water Solubility:	1000 g/L at 25°C
Partition Co-efficient (n-octanol/water):	not determined
Hydrolysis as a Function of pH:	increases as pH decreases from neutral increases as pH increases from neutral
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined
Flash Point:	> 100°C
Flammability Limits:	not determined
Autoignition Temperature:	not determined
Explosive Properties:	none
Reactivity/Stability:	hydrolyses in water

Comments on Physico-Chemical Properties

The notifier describes the notified chemical as very water soluble. This was determined through "Haze by Visual Observation" Corporate Test Method 0283. Because of the length of the two soluble polyethylene glycol chains on the molecule, and relatively small hydrophilic end, high solubility would be expected.

The notifier states the notified product is hydrolytically unstable and readily forms free methoxy-polyethylene-glycol (MPEG); low MW OH-endblocked polydimethyl siloxanes (PDMS) and traces of cyclic dimethyl siloxanes.

No partition coefficient, adsorption/desorption coefficient or dissociation constant have been provided by the notifier. Due to the low percentage of hydrophobic groups on the polymer, it would not be expected to partition in the organic phase or to adsorb to sediments or organic matter while in its complete form. Dissociation is not expected.

The notifier states the product is not a surfactant in the true sense, and acts as a profoamer. Due to the chemical structure, a degree of surface activity would be expected, but because of the high potential for hydrolysis under normal environmental conditions, the chemical would be expected to degrade relatively quickly, thereby mitigating any impact resulting from surface activity.

4. PURITY OF THE CHEMICAL

Degree of purity: 84%

Toxic or hazardous impurities: none

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

Chemical name:	poly (oxy-1,2-ethanediyl), alpha-methyl-omega-hydroxy-
Synonyms:	polyethylene glycol monoethyl ether
Weight percentage:	16%
CAS No.:	9004-74-4

Maximum content of residual monomers: none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will be imported into Australia for formulation into aqueous cosmetic cleaning systems such as shampoos, shower gels and liquid soaps. The chemical may also be used in skin care products. The notified chemical will be imported at a rate of 10 tonnes per year for the next five years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in 200 L steel drums and 20 L pails. There is not anticipated to be any exposure to transport workers, except in the event of an accident or damage to packaging.

The notified chemical will be transported to the site of reformulation into cosmetic products. Reformulation will involve the manual addition of the wax, using a scoop or similar implement, to mixers into which other cosmetic chemicals will be added. These mixers will be both open and closed, depending on the formulation being prepared. These formulations will be mixed at about 50°C to formulate a range of different personal cosmetic cleaning products for dermal application. There may be between twenty and one hundred personal care industry workers involved in the reformulation of the notified chemical. This may entail potential exposure to the notified chemical for 8 hours per day, 5 days per week.

The notified chemical will exist in cosmetic preparations at between 0.1 and 20%. These cosmetic preparations will then be packaged in plastic and glass containers and distributed for sale. There may exist some dermal occupational exposure to sales staff who may be exposed to the notified chemical when demonstrating the use of a product, however the number of workers who will be exposed to the notified

chemical through sales cannot be accurately estimated.

7. PUBLIC EXPOSURE

The notified polymer will be used in skin care cosmetic products including shampoos, shower gels, liquid soaps and skin moisturisers such as creams, lotions, toners and gels at levels of 0.1-20%. Skin contact with cosmetic products will be the main route of public exposure to the notified polymer.

The notified polymer is hydrolytically unstable and readily forms methoxy-polyethylene-glycol, low molecular weight polydimethyl siloxanes and traces of cyclic dimethylsiloxanes. Therefore, users of the cosmetic products containing the notified polymer will also be exposed to these hydrolysis products.

8. ENVIRONMENTAL EXPOSURE

Release

The polymer will be compounded into cosmetics by an estimated 10 cosmetics manufacturing companies in at least 3 major cities. It is expected to be sold Australia wide providing a wide environmental exposure of the substance. Given that cosmetics formulation involves use of a maximum estimated import quantity of 10 tonnes per annum of the notified substance, average substance usage per site is expected to be 1000 kg per annum.

Release during reformulation of the cosmetic wax into various cosmetic products will result from unused residues in the polymer containers, equipment washings and batch residues. There is no indication from the notifier as to how much chemical will be released through reformulation, but it is not likely to be significant. Previous experience indicates an expected total polymer wastage factor of 0.5%. The notifier indicates a maximum of 260 days worked per year which gives an average daily release at each plant of around 20 g.

The major release to the environment is from end use where residues of the notified chemical would be washed or wiped off the face, hands and body and residues in used "empty" containers would be disposed of with the containers. The volume released to the waste stream has not been estimated by the notifier. For hazard calculations in this assessment, it will be assumed that 95% of the notified chemical consumed will eventually be released to sewer with the remaining chemical being left as residues in empty containers, and consigned with the household garbage to landfill or incineration.

Fate

Precise details of the fate of the notified chemical in the environment are not known. Biodegradation tests are not required for polymers with NAMW > 1000. Hydrolysis could provide a major route of breakdown, and the product has been stated as hydrolytically unstable, and to readily form free methoxy-polyethylene-glycol, (MPEG) which would be expected to remain in solution, and low molecular weight hydroxy endblocked polydimethyl siloxanes (PDMS) and traces of cyclic dimethylsiloxanes, both of which would be expected to bind to sediments.

The free MPEG will have a distribution of molecular weights ranging from about 300 to 1300 (as shown by the GPC trace). Due to the very small hydrophobic part of the chain (one methoxy group), the MPEG is likely to remain in solution (1), and would not be expected to hydrolyse further under normal environmental conditions.

Bioaccumulation of MPEG would not be expected due to the relatively high average molecular weight (shown by the GPC trace to be between NAMW = 550 and 950), and high water solubility.

9. EVALUATION OF TOXICOLOGICAL DATA

According to the Act, toxicological data is not required for polymers with NAMW > 1000 although the data summarised below were submitted by the notifier for Dow Corning® 2501 Cosmetic Wax.

9.1 Acute Toxicity

Summary of the acute toxicity of Dow Corning® 2501 Cosmetic Wax

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	> 5000 mg/kg	2
acute dermal toxicity	rabbit	> 2000 mg/kg	3
skin irritation	rabbit	non-irritant	4
eye irritation	rabbit	non-irritant	5

9.1.1 Oral Toxicity (2)

Species/strain:	Sprague-Dawley rats
Number/sex of animals:	5 males/5 females
Observation period:	14 days
Method of administration:	gavage; 50% (w/v) suspension in distilled water at a concentration of 5000 mg/kg
Clinical observations:	no clinical signs of toxicity were noted

Mortality:	none
Morphological findings:	no treatment-related effects were observed
Test method:	according to US Federal Hazardous Substances Act (FHSA) (6)
LD_{50}:	> 5000 mg/kg
Result:	the notified chemical was of low oral toxicity in rats

9.1.2 Dermal Toxicity (3)

Species/strain:	New Zealand White rabbits
Number/sex of animals:	5 males/5 females
Observation period:	14 days
Method of administration:	a single dose of 2000 mg/kg of the test material was applied to the shaved dorsal body surface; occlusive dressing applied; after 24 hours the bandage was removed and residual test material wiped away; rabbits were observed for 14 days after which they were sacrificed for necropsy
Clinical observations:	no clinical observations were noted
Mortality:	none
Morphological findings:	no treatment related effects were observed
Test method:	according to (US) Federal Hazardous Substances Act (FHSA) (6)
LD_{50}:	> 2000 mg/kg
Result:	the notified chemical was of low dermal toxicity in rabbits

9.1.3 Skin Irritation (4)

Species/strain:	New Zealand White rabbits
Number/sex of animals:	6 animals
Observation period:	72 hours
Method of administration:	a single dose of 0.5 mL of undiluted test material applied to intact and abraded sites on shaved dorsal section of skin; surgical gauze patch applied for 24 hours; after 24 hours the bandages were removed and the animals observed for up to 72 hours, the dermal region scored according to Draize (7)
Test method:	according to (US) Federal Hazardous Substances Act (FHSA) (6)
Result:	there were no scores greater than 0; the notified chemical was not found to be a skin irritant in rabbits

9.1.4 Eye Irritation (5)

Species/strain:	New Zealand White rabbits
Number of animals:	6 animals
Observation period:	7 days
Method of administration:	a dose of 0.1 mL of the test material was facilitated into the right bottom lid of each rabbit; the eyes were not washed following instillation except at the 72 hour and 7 day readings; the left eye remained untreated and served as a control; eyes examined at 24, 48, 72 hours and 7 days and scored according to Draize (7)
Test method:	according to (US) Federal Hazardous Substances Act (FHSA) (6)
Result:	there were no scores greater than 0; the notified chemical was not found to be an eye irritant in rabbits

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (8,9)

experiment 1 (8)

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 98, TA 100; *Escherichia coli* WP2 *uvrA*
Concentration range:	312.5-10 000 µg/plate with or without S9 rat liver metabolic activation
Test method:	according to Maron and Ames (10)
Result:	dose-related increase in number of revertant colonies noted for TA1535 strain at doses above 5000 µg/plate; the test material is considered mutagenic in bacteria

experiment 2 (9)

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 1538, TA 98, TA 100; *Escherichia coli* WP2 *uvrA*
Concentration range:	10-5000 µg/plate with or without S9 rat liver metabolic activation
Test method:	according to Maron and Ames (10)
Result:	the test substance is not considered mutagenic in bacteria

9.3 Overall Assessment of Toxicological Data

The notified chemical exhibited low acute oral toxicity in rats (LD_{50} > 5000 mg/kg) and low acute dermal toxicity in rabbits (LD_{50} > 2000 mg/kg). It was found not to be a skin or eye irritant in rabbits. One mutagenicity study showed a dose-dependent increase in revertant bacterial colonies in one bacterial strain at high doses of the substance. However, the chemical was not mutagenic in a second Ames test. These results suggest that the chemical is weakly mutagenic in bacteria.

Based on the toxicological data provided, the notified chemical would not be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data are required for polymers of NAMW > 1000 according to the Act.

Data has been generated using the ASTER database (12), to obtain an indication of toxicity values of the breakdown product, methoxy-polyethylene-glycol. The MPEG used for the results had a molecular weight of 869 g/mol. This indicates toxicity to 4 fish species and *Daphnia magna* to be > 8000 mg/L.

These results can be used as guides only, but indicate that free MPEG resulting from hydrolysis of the notified chemical will be practically non-toxic to aquatic species.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The polymer is unlikely to present a hazard to the environment either during reformulation into cosmetic products (resulting in an estimated 5 kg per annum per site of reformulation waste disposed of to landfill), or end use when consumers wash the polymer residue to sewer after use.

For the purpose of a worst case predicted environmental concentration (PEC) it will be assumed that 95% (9.5 tonnes per annum) of the notified product is washed to sewer. This gives a daily release of 26 kg Australia wide. With an Australian population of 18 million, and a daily per capita water usage volume of 150 L the daily sewer output is 2 700 ML. This provides a PEC in the order of 10 µg/L in sewage water which would be further diluted in receiving waters. This supports the conclusion of a low hazard.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on the animal data provided by the notifier, the notified chemical would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (11). However, a positive result in one of two bacterial mutagenicity studies suggests that the notified chemical may be genotoxic at high doses.

Dermal exposure to the notified chemical may occur during reformulation, when workers transfer the wax from the drums and pails in which it is imported to the mixing vessel. The risk of irritant effects or acute toxicity is expected to be minimal, based on the results of animal tests supplied by the notifier. However, as the notified chemical may be genotoxic at high doses and reformulators may be exposed to the notified chemical for up to 8 hours/day, 5 days/week, protective clothing (as suggested in the recommendations section) should be worn when exposure to the pure wax occurs.

Sales workers potentially exposed during the use and demonstration of products

containing the notified chemical are unlikely to suffer any acute adverse health effects due to the relatively low concentration of the notified chemical in cosmetic formulations (0.1 to 20%) and the non-irritating nature of the chemical. The risk of genotoxic effects is minimal, due to the expected intermittent exposure to the chemical and the fact that effects in bacteria were seen only at high doses in one study.

Public exposure to the notified chemical will be largely through skin contact. As discussed above, the risk of experiencing adverse health effects when using formulations containing the notified chemical is low, due to the low acute toxicity and non-irritating nature of the substance. In addition the concentration of the notified chemical in commercial cosmetic preparations is relatively low.

The major constituent of the notified polymer molecule is MPEG and less than 5% of the molecule is dimethyl siloxane. Thus hydrolysis of the notified polymer in cosmetic products should not produce more than 5% low molecular weight polydimethyl siloxanes. At the maximum concentration of 20% notified polymer in cosmetic formulations, the highest possible level of low molecular polydimethyl siloxanes resulting from hydrolysis is about 1%. This low concentration is not expected to cause significant adverse health effects.

13. RECOMMENDATIONS

To minimise occupational exposure to Dow Corning® 2501 Cosmetic Wax the following guidelines and precautions should be observed when exposure to the pure chemical may occur:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (13) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (14),

- Industrial clothing should conform to the specifications detailed in AS 2919 (15),

- Impermeable gloves or mittens should conform to AS 2161 (16),

In addition, the following recommendations should be applied whenever workplace exposure to the notified chemical (in either pure form or within formulations) may occur:

- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;

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

- A copy of the Material Safety Data Sheet (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

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3. Stanton, E, Siddiqui, W, and Sibert, GJ, 1991, *An Acute Dermal Toxicity Study of Dow Corning® X2-5428 in Albino Rabbits*, Report No. 1991-I0000-36482, data on file, Dow Corning Corporation, Michigan.

4. Stanton, E and Siddiqui, W, 1991, *An Acute Skin Irritation Study of Dow Corning® X2-5428 in Rabbits*, Report Number 1991-I0000-36381, data on file, Dow Corning Corporation, Michigan.

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6. (US) Federal Hazardous Substances Act (FHSA), 1990.

7. Draize, JH, 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics", *Association of Food and Drug Officials of the US,* **49**.

8. Henrich, RT, Isquith, AJ and McMahon, JM, 1991, *Genetic Evaluation of Dow Corning® X2-5428 in Bacterial Reverse Mutation Assay*, Report Number 1991-I0000-36586, data on file, Dow Corning Corporation, Michigan.

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10. Maron, DM and Ames, BN, 1983, 'Revised Methods for the *Salmonella* Mutagenicity Test', *Mutation Research,* **38**: 3-32.

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

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

16. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves),* Standards Association of Australia Publ., Sydney.

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