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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Waxes and Waxy substances, shellac (INCI Name: Shellac Wax)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
NICNAS**

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FULL PUBLIC REPORT**Waxes and Waxy substances, shellac (INCI Name: Shellac Wax)****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Avon Products Pty Ltd (ABN: 48 008 428 457)
120 Old Pittwater Road
Brookvale, NSW 2100

NOTIFICATION CATEGORY

Limited-small volume: Chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for physico-chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Shellac Wax 7302L

CAS NUMBER

97766-50-2

CHEMICAL NAME

Waxes and Waxy substances, shellac

OTHER NAME(S)

Shellac Wax (INCI Name)

MOLECULAR AND STRUCTURAL FORMULA

Unspecified (UVCB substance)

Shellac wax is the waxy fraction (*ca.* 5%) of shellac. It is mainly comprised of fatty esters and/or fatty acids and alcohols, with the specific composition varying depending on the source. A typical distribution of the components of hydrolysed shellac wax is fatty alcohols (77%), fatty acids (21%) and hydrocarbons (2%) [CIR (1986)]. The breakdown is shown in the following table:

Substance group and approximate percentage of hydrolysed waxy fraction		Identified components				Distribution of components within each group
		Molecular formula	CAS number	Chemical name	Approximate molecular weight	
Fatty Alcohols	77	C ₂₈ H ₅₈ O	557-61-9	1-Octacosanol	410	66.6%
		C ₃₀ H ₆₂ O	593-50-0	1-Triacontanol	438	21.0%
		C ₃₂ H ₆₆ O	6624-79-9	1-Dotriacontanol	466	9.0%
		C ₃₄ H ₇₀ O	28484-70-0	1-Tetratriacontanol	494	2.8%
		C ₂₆ H ₅₄ O	506-52-5	1-Hexacosanol	382	<u>0.6%</u>
						100%
Fatty Acids	21	C ₃₂ H ₆₄ O ₂	3625-52-3	Dotriacontanoic acid	480	27.2%
		C ₃₀ H ₆₀ O ₂	506-50-3	Triacontanoic acid	452	25.1%
		C ₂₈ H ₅₆ O ₂	506-48-89	Octacosanoic acid	424	18.9%
		C ₃₄ H ₆₈ O ₂	38232-04-1	Tetratriacontanoic acid	508	17.6%
		other				<u>11.2%</u>
						100%
Hydrocarbons	2	C ₂₇ H ₅₆	593-49-7	Heptacosane	380	42.0%
		C ₂₉ H ₆₀	630-03-5	Nonacosane	408	35.1%
		C ₃₁ H ₆₄	630-04-6	Hentriacontane	436	13.4%
		other				<u>9.5%</u>
						100%

MOLECULAR WEIGHT
>380 Da

ANALYTICAL DATA
Saponification value 45-65 mg KOH/g (MSDS)
Acid value 5-15 mg KOH/g (MSDS)

3. COMPOSITION

DEGREE OF PURITY UVCB Substance

IMPURITIES/RESIDUAL MONOMERS None identified

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: yellow solid pellets

Property	Value	Data Source/Justification
Melting Point	78-84 °C	MSDS
Density	950-1000 kg/m ³	MSDS
Vapour Pressure	5.35 x 10 ⁻⁵ kPa at 25 °C	Estimated by Modified Grain method (US EPA, 2009) for the predominant component of the hydrolysed notified chemical, 1-octacosanol.
Water Solubility	1.4 × 10 ⁻¹⁰ g/L at 25 °C	Estimated by WSKOW (v1.41) (US EPA, 2009) for the predominant component of the hydrolysed notified chemical, 1-octacosanol.
Hydrolysis as a Function of pH	Not determined	Contains components with hydrolysable functionality. However, due to their low expected water

Partition Coefficient (n-octanol/water)	log K _{OW} = 12.63	solubility, they are expected to hydrolyse very slowly in the environmental pH range (4-9) at ambient temperature Estimated by KOWWIN (v1.67) (US EPA, 2009) for the predominant component of the hydrolysed notified chemical, 1-octacosanol.
Adsorption/Desorption	log K _{OC} ≥ 6.79	Estimated using KOCWIN (v2.00) (US EPA, 2009) for the predominant component of the hydrolysed notified chemical, 1-octacosanol.
Dissociation Constant	Not determined	A typical dissociation constant for aliphatic carboxylic acids (pK _a ~4-5) is expected for the fatty acid components of the notified chemical
Particle Size	Not determined	Waxy solid pellets
Flash Point	>149 °C	MSDS
Autoignition Temperature	Not determined	Not expected to autoignite based on melting point.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.

DISCUSSION OF PROPERTIES

Reactivity

Stable under normal conditions of use. The notified chemical is incompatible with strong acids, alkalis and oxidising agents and may burn if involved in a fire. Combustion products include carbon monoxide and carbon dioxide.

Dangerous Goods classification

Based on the limited submitted physical-chemical data in the above table the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be introduced as a component (≤5%) of finished cosmetic products.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	1	1	1	1	1

PORT OF ENTRY

Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

Avon Products Pty Ltd

TRANSPORTATION AND PACKAGING

The products containing the notified chemical (≤5%) will be imported in tubes/containers suitable for retail sale. These will be packaged in cardboard cartons. The cartons will be distributed within Australia by road.

USE

The notified chemical will be used as a binder and film former in cosmetic and personal care products at up to 5% concentration. The notified chemical may be used in a broad spectrum of rinse-off and leave-on products (for example, in mascara at 5%).

OPERATION DESCRIPTION

The notified chemical will be imported as a component of finished cosmetic products. Reformulation will not take-place in Australia.

The finished products containing the notified chemical will be used by consumers and professionals (such as workers in beauty salons). Depending on the nature of the product, application could be by hand or through the use of an applicator.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	10	4	12
Store persons	2	4	12
Salon workers	unspecified	unspecified	unspecified

EXPOSURE DETAILS

Transport and storage workers may come into contact with the notified chemical as a component of end-use products (at $\leq 5\%$) only in the event of accidental rupture of containers.

Exposure to the notified chemical in end-use products may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hair dressers, workers in beauty salons). Such professionals may use some personal protective equipment (PPE) to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

6.1.2. Public exposure

There will be widespread and repeated exposure of the public to the notified chemical through the use of the rinse-off and leave-on cosmetic and personal care products. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray.

6.2. Human health effects assessment

No toxicity data were submitted.

The notified chemical contains aliphatic acids and aliphatic monoalcohols which are structural alerts for corrosion and eye irritation (Hulzebos *et al.*, 2005; Tsakovska *et al.*, 2007). However, the potential for corrosion is only expected for chemicals with < 8 carbons and slight eye irritation is only expected for chemical with > 15 carbons in the aliphatic chain. Given that the notified chemical contains > 27 carbons in the aliphatic chain, the potential for corrosion and eye irritation is not expected.

The notified chemical is also comprised of esters that are a structural alert for skin irritation, particularly those with a MW < 200 Da (Hulzebos *et al.*, 2005). Given the molecular weight of the esters in the notified chemical are > 700 Da, the potential for skin irritation is not expected.

The notified chemical does not contain structural alerts for sensitisation, hence it is not expected to be a sensitiser.

The notified chemical was determined to be of low acute oral toxicity in rats ($LD_{50} > 5000$ mg/kg) and was not mutagenic in bacterial reverse mutation studies with and without metabolic activation (CIR, 1986). In a reproduction and subchronic feeding study, rats (25 per sex) were fed with up to 10,000 ppm of Regular Bleached Shellac containing $\sim 5\%$ of the notified chemical in commercial feed for 28 consecutive days. Animals from these respective groups were mated after this period. The weaned offspring (25 per sex) were then fed with

the same diet as for the parents for an additional 90 days. The study concluded that there was no evidence of treatment-related toxic or pathological effects in both the parent and offspring fed with the Regular Bleached Shellac containing ~5% of the notified chemical (CIR, 1986). Fertility, reproductive performance and pup development were similar to the control.

In 1989, the (United States) Food and Drug Administration published a proposed rule for affirming that shellac and shellac wax were generally recognised as safe (GRAS) with specific limitations for use as direct human food ingredients (FDA, 1989).

In summary, based on the available toxicity information, physico-chemical properties and structure, the notified chemical is of low acute oral toxicity and is not expected to present other health hazards, such as irritation, sensitisation or mutagenicity.

Health hazard classification

Based on the information provided, the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Beauty care professionals will handle the notified chemical at up to 5% concentration, similar to public use. Therefore, the risk for beauty care professionals who regularly use products containing the notified chemical is expected to be of a similar or lesser extent than that experienced by members of the public who use such products on a regular basis.

Based on the information available, the risk to workers associated with use of the notified chemical at up to 5% concentration in rinse-off and leave-on cosmetic products is not considered to be unacceptable.

6.3.2. Public health

At the proposed use concentration of up to 5% notified chemical in rinse-off and leave-on cosmetic products, acute toxicity effects are not expected. Although repeat dose toxicity data is not available for the notified chemical, no systemic toxicity was reported in a reproductive and chronic study in rats fed with Regular Bleached Shellac containing ~5% of the notified chemical. In addition, it is noted that shellac wax has GRAS status with specific limitations for use as a food ingredient, hence systemic toxicity is not expected from use of the notified chemical at concentrations up to 5% in cosmetic products.

Therefore, based on the information available, the risk to the public associated with the use of the notified chemical at up to 5% concentration in rinse-off and leave-on cosmetic products is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured or reformulated in Australia. It will be imported as a component of finished cosmetics and personal care products. There is unlikely to be any significant release to the environment from storage and transport, except in the case of accidental spills. Accidental spills are unlikely, given the imported product will be containerised. If spills do occur, the product containing the notified chemical is expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified chemical is a component in rinse-off and leave-on cosmetic products (e.g. mascara). The formulated product will be applied to body parts and will either be removed with tissues and disposed of to domestic garbage, or washed off the body with ultimate release to the sewer.

RELEASE OF CHEMICAL FROM DISPOSAL

Expired waste and residue of the notified chemical in the empty containers (3%) is likely either to share the fate of the container and be disposed of to landfill, or to be washed to sewer when containers are rinsed before recycling.

7.1.2 Environmental fate

No environmental fate data were submitted. Some notified chemical will be disposed of to landfill, although the majority of the imported quantity of notified chemical is expected to be released to the sewer as solubilised material or in the form of particulate matter. It is estimated that greater than 80% of the notified chemical in influent is likely to adsorb to sediment and sludge in sewage treatment plants, based on the predicted physico-chemical properties of the predominant component of the notified chemical, 1-octacosanol (Simple Treat; European Commission, 2003). Although it has a moderate molecular weight and a high calculated partition coefficient ($\log K_{ow} = 12.63$), calculations with BCFBAF (v3.00) (US EPA, 2009) indicate that 1-octacosanol, and therefore the notified chemical, is not likely to bioaccumulate, based on the low bioconcentration factor ($\log BCF = 1.36$) predicted by a regression-based method (BCFBAF v3.00; US EPA, 2009). Sewage sludge containing the notified chemical may be disposed of to landfill or used for soil remediation. In sludge, soil or landfill, the notified chemical is expected to be immobile, due to its predicted low water solubility and high soil adsorption coefficient. It is not predicted to be readily biodegradable but is expected to slowly degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3 Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) for a worst case scenario has been determined with the assumptions that 100% of the annual import volume will be released to sewer nationwide and that none of the notified polymer will be removed by sewage treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.65	µg/L
PEC - Ocean:	0.06	µg/L

The PEC calculation for surface waters tabulated above represents a conservative worst case whereby the total import volume of the notified chemical is assumed to be released in effluent. Sewage treatment plant (STP) effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 0.647 µg/L may potentially result in a soil concentration of approximately 4.316 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 21.58 µg/kg and 43.16 µg/kg, respectively. However, as the notified chemical is expected to be removed from STP influent due to its absorptive characteristics, these calculated values represent maximum concentrations only.

The notified chemical is expected to partition to sludge, and the removal of >80% of the notified chemical from influent by STP processes is predicted, based on the estimated physico-chemical properties of 1-octacosanol (Simple Treat; European Commission, 2003). Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 5.179 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m³ and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 35 µg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids

application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 175 µg/kg and 350 µg/kg, respectively.

7.2. Environmental effects assessment

No experimental data were submitted. The notified chemical is not expected to be bioavailable based on the very high predicted partition coefficient for the predominant component of the notified chemical, 1-octacosanol (log K_{ow} = 12.63). No effects on aquatic biota are predicted for 1-octacosanol, and therefore the notified chemical, at its water saturation concentration (ECOSAR (v1.00), US EPA, 2009). Classification should only be based on toxic responses observed in the soluble range and, therefore, the notified chemical cannot be formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

7.2.1 Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) has not been calculated as 1-octacosanol, and therefore the notified chemical, is predicted to have no effect on aquatic biota at its water saturation concentration and is not expected to be bioavailable, based on the estimated log K_{ow} of 12.63 (ECOSAR (v1.00), US EPA, 2009).

7.3. Environmental risk assessment

A risk quotient (PEC/PNEC) for the notified chemical was not calculated as a PNEC was not derived. However, the notified chemical is anticipated to have very limited aquatic exposure based on the expected efficient removal of the chemical from waste water by sorption to sewage sludge. The notified chemical is also not expected to be bioavailable to aquatic organisms in surface waters based on its intrinsic hydrophobicity. Therefore, when used as proposed the notified chemical is not expected to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the information provided, the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment

On the basis of the reported use pattern, the notified chemical is not expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified chemical itself. However, these should be selected on the basis of all ingredients in the formulation.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS 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 importation volume exceeds one tonne per annum notified chemical;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a component of rinse-off and leave-on cosmetic and personal care products at $\leq 5\%$ concentration, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 1 tonne per annum, or is likely to increase, significantly;
 - the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the notified chemical (and a product containing the notified chemical) provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

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