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

FULL PUBLIC REPORT

Kester Wax K80P

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

Director

Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Kester Wax K80P

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Beiersdorf Australia Ltd of 4 Khartoum Road NORTH RYDE NSW 2113 (ABN 98 000 025 623).

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 as follows: water solubility, vapour pressure, adsorption/desorption and flammability.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Low Volume Permit No. 502.

NOTIFICATION IN OTHER COUNTRIES

None.

2. IDENTITY OF CHEMICAL

CHEMICAL NAME

C₂₀₋₄₀ Fatty alcohols, reaction products with 12-hydroxy octadecanoic acid.

C₂₀₋₄₀ Fatty alcohols, reaction products with 12-hydroxystearic acid.

OTHER NAME(S)

C18-38 Alkyl hydroxystearoyl stearate

MARKETING NAME(S)

Kester Wax K80P (100% notified chemical)

Nivea Lip Care Vitamin Power (imported finished product containing 20% notified chemical)

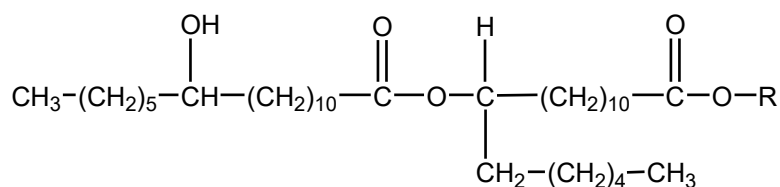
CAS NUMBER

Not available

MOLECULAR FORMULA

(C₁₈H₃₅O₂)₂ C₁₈₋₃₀H₃₇₋₆₁

STRUCTURAL FORMULA



R represents the C₁₈₋₃₈ alkyl moiety.

MOLECULAR WEIGHT
799 g/mol (minimum)

SPECTRAL DATA

ANALYTICAL METHOD	FT IR Spectrum (KBr disk)
Remarks	3367.73, 2917.46, 2849.19, 2849.19, 2332.25, 1737.07, 1463.43, 1415.12, 1377.61, 1173.52, 1113.39, 1080.12, 919.26, 861.77, 835.67, 729.79, 720.24, 584.17 cm ⁻¹ .
TEST FACILITY	Not stated.

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	IR spectroscopy.
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Comments:

The notified chemical is a synthetic version of the polyester fraction of beeswax and constitutes about 25% of natural beeswax. The chain length of synthetic beeswax is generally taken to be approximately C34-C62, whereas the chain length of the notified chemical is approximately C56-C76.

3. COMPOSITION

DEGREE OF PURITY
90% (approx.)

HAZARDOUS IMPURITIES
None.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

Stearic acid comprises approximately 10% of the 12-hydroxystearic acid component used to manufacture the notified chemical.

<i>Chemical Name</i>	Stearate esters		
<i>CAS No.</i>	-	<i>Weight %</i>	10

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported as a component in the finished product.

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>	0.6	0.6	0.6	0.6	0.6

USE

The notified chemical will be used in lip moisturiser called Nivea Lip Care Vitamin Power. The concentration of the notified chemical in the finished products will be 20%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS

Beiersdorf Australia Ltd.

TRANSPORTATION AND PACKAGING

The notified chemical will be imported in a lip stick (5 mL) which will be in a plastic dispenser and packed in a blister pack. These will be packed in outer packaging, which are in turn packed in cardboard shipping cartons. The products are not Dangerous Goods and no special transport containers are required.

5.2. Operation Description

The products containing the notified chemical will be imported as fully finished consumer products and will be transported and stored in the original containers. The main operations will be warehousing and transport. The products will be sold to retail outlets such as department stores and pharmacies.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Transport and Storage	2-4	1-2 hour/day	50 day/year
Retail	>5000	0.5 – 1 hour/day	200 day/year

Exposure Details

Transport workers will unload shipping containers and load them onto trucks for road transport from the dockside in Sydney to the Beiersdorf warehouse and distribution centre at Huntingwood NSW. The products will be stored and distributed to either other warehouses interstate belonging to the applicant or directly to customer warehouse facilities. At the warehouses, forklift drivers will move pallets of product to and from storage shelving. Workers (pickers) may also open shipping cartons and re-pack them with other goods to fill smaller orders. Exposure will only occur in the event of an accident where the containers are damaged and product is spilt. The notified chemical will be present in the products at 20%. However, the product is in a waxy solid form.

At the retail outlets, workers will remove the products from shipping cartons and place the products on shelves for sale. There may also be some demonstration of the products to retail customers.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured or reformulated in Australia.

RELEASE OF CHEMICAL FROM USE

The lipstick will be applied to the lips and washed off or wiped off at various times, thus, approximately 80% of the imported notified chemical will enter the sewer. When the lipstick

container is disposed of, usually to the general rubbish, there will be a 'stump' of lipstick left. This, along with lipstick on tissues etc, is equivalent to approximately 20% of the imported notified chemical and is likely to be disposed of to landfill.

5.5. Disposal

Since the notified chemical will not be manufactured or reformulated in Australia, there will be no wastes (including containers) that need disposal.

The majority (approximately 80%) of the total imported notified chemical will be disposed of via the sewer. The remainder (approximately 20%) will go to landfill in the empty user containers.

5.6. Public exposure

The notified chemical will be imported in cosmetic products in a lip stick form. The products will be used by the public and will be applied to the lips. The notified chemical will be used at a concentration of 20%. If 0.2 g of product is applied to the lips with each application, the dosage is approximately 0.67 mg/kg body weight (assuming 60 kg bw). The products are likely to be used once per day.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Light yellow slabs.
Melting Point/Freezing Point	> 85°C
Boiling Point	Not determined.
Density	880 kg/m ³ at 20°C
Vapour Pressure	Not determined.
Water Solubility	Not determined. The notified chemical is a high molecular weight fatty ester and is chemically similar to beeswax. It is expected to be very insoluble in water.
Hydrolysis as a Function of pH	Not attempted due to the chemical's likely low water solubility. The notified chemical contains ester groups, which are not likely to hydrolyse under ambient environmental conditions.
Partition Coefficient (n-octanol/water)	Not attempted due to the chemical's likely low water solubility. It is expected that the chemical will partition into n-octanol.
Adsorption/Desorption	Not attempted due to the chemical's likely low water solubility. It is expected that the chemical will be immobile and partition on to the organic matter in soil.
Dissociation Constant	Not attempted. The notified chemical does not contain any groups that can undergo dissociation.
Particle Size	Not applicable. The notified chemical is a waxy material.
Flash Point	> 275°C
Flammability Limits	Not determined. Not expected to be flammable.
Autoignition Temperature	Decomposes at > 160°C

Explosive Properties

Not predicted to be explosive.

Reactivity

Emits irritating gases when overheated. Avoid contact with oxidising agents.

7. TOXICOLOGICAL INVESTIGATIONS

The only toxicological study provided for the notified chemical (Kester Wax K80P) was a repeat insult patch test. A summary of toxicological information for Kester Wax K80P was also provided.

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Skin sensitisation – human volunteers	no evidence of sensitisation.

7.1 Skin sensitisation – human volunteers

TEST SUBSTANCE	Notified chemical.
METHOD	In house method.
Study Design	The study consisted of an induction procedure and a challenge procedure.
Study Group	107 male and female subjects aged 18 to 74 years completed the study.
Vehicle	None.
Induction Procedure	0.1 g was applied to the upper back between the scapulae under occluded gauze dressings for a total of 10 applications on Monday, Wednesday and Friday. The dressings were removed after 24 hours.
Rest Period	Approximately 2 weeks.
Challenge Procedure	A challenge patch was applied to a virgin site and the original site and evaluated at 24 and 48 hours after application.
RESULTS	
Remarks – Results	No details of the study results were provided in the report.
CONCLUSION	A repeat insult patch test was conducted using undiluted notified chemical under occlusive dressing. The notified chemical was non-irritating and non-sensitising under the conditions of the test.
TEST FACILITY	Consumer Product Testing Co (1996).

7.2 Summary of Toxicological Data for Analogues and Constituents

Some toxicological and safety data on analogues and constituents of Kester Wax K80P from the manufacturer were provided in the notification. Kester Wax K80P is the result of the esterification of synthetic long chain fatty alcohols and 12-hydroxystearic acid. On the basis of this similarity with the Beeswax polyester fraction and with other analogues and constituents, the notified chemical is expected to have low acute and subchronic toxicity and is not a skin irritant, eye irritant, or a skin sensitiser. It is not expected to be mutagenic, carcinogenic, teratogenic or embryotoxic.

An EU MSDS provided by the notifier stated that the Kester Wax K80P was of low acute oral toxicity, and was not irritating to eyes or skin.

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Usage patterns indicate that ultimately, approximately 80% of the notified chemical will be released into the aquatic environment at end use via sewage treatment facilities. The notified chemical is expected to be water insoluble and hence, in sewage treatment plants, is expected to partition mainly into the sediment.

A worst case scenario daily PEC for the aquatic environment resulting from release at end use of products containing the notified chemical is provided. In calculating the PEC, it is assumed that release of the notified chemical to sewage systems occurs on a nationwide basis, is continuous throughout the year with no removal by adsorption. While it is recognised that larger releases of the chemical are likely to occur in higher population areas where usage rates would be higher, it was not considered practical to determine such releases for end use. Thus, a worst case nationwide Predicted Environmental Concentration (PEC) can be estimated as follows:

Maximum amount released	480 kg
Number of days	365 days
Population	19 million
Amount of water used per person	150 L
Daily water usage	$19\,000\,000 \times 150 = 2850\,000\,000\text{ L}$
Nationwide daily PEC	$480\,000\,000 / (365 \times 2850\,000\,000)$ $= 0.5\text{ }\mu\text{g/L}$

It is likely that the notified chemical will be removed in the sewage treatment facilities via adsorption to organic matter in the sludge. Thus, the PEC would be reduced significantly.

Any of the notified chemical disposed of to landfill in lipstick wastes, will become associated to the organic matter in the soil and will not be mobile. Over time it will degrade due to biotic and abiotic processes to release water and oxides of carbon.

9.1.2. Environment – effects assessment

Since no ecotoxicity data were available, a PNEC cannot be determined.

9.1.3. Environment – risk characterisation

The PEC/PNEC ratio for the local aquatic environment cannot be calculated. However, the estimated PEC is very low.

In soil or sediment environments, the notified chemical is expected to be immobile. While it is not known if the chemical will be biodegradable, it is expected to undergo slow degradation through biotic and abiotic processes.

Due to its molecular size and likely water insolubility, the notified chemical is not expected to cross biological membranes and bioaccumulate (Connell 1989).

Given the above considerations, the notified chemical is not expected to pose any significant hazard to the environment. The anticipated nationwide use of the product indicates that the levels of release of the chemical to the environment will be low and widespread.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported in pre-packed cosmetic products. No formulation or repackaging will occur in Australia. The products containing the notified chemical will be sold as is on the retail market. Therefore, the potential for worker exposure is low.

During transport and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

9.2.2. Public health – exposure assessment

Cosmetic products containing the notified chemical are for sale to the general public. Members of the public will apply the lipstick products containing the notified chemical on their lips. The following estimation is basically based on the scenario provided by the notifier:

Amount of each application to the lips:	0.2 g (product)
Frequency of application:	Once per day.
Concentration of the notified chemical in the lipstick:	20%
Assuming absorption rate on lips:	100%
Average human body weight:	60 kg
The daily dose for a human being:	200 mg/day (product) or 40 mg/day (notified chemical) 0.67 mg/kg/day (notified chemical)

The public exposure to the notified chemical is considered to be low.

9.2.3. Human health - effects assessment

Based on the toxicological profile of the notified chemical and its analogues, the notified chemical is expected to have low acute and subchronic toxicity. It is not irritating to eyes or skin, or sensitising to skin. The notified chemical is not expected to be genotoxic.

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low due to its low toxicity and low potential for occupational exposure.

9.2.5. Public health – risk characterisation

Members of the public may apply lipstick products containing the notified chemical on daily basis. How the estimated public exposure (0.67 mg/kg/day) as a worst-case scenario is considered to be low. In addition, the notified chemical is of low toxicity. Thus, the health risk for public members using lipstick products containing the notified chemical is expected to be low.

Consumers will be advised to stop application of the product if any skin reactions occur.

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (1999).

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern, widespread release and expected low PEC.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is No Significant Concern to public health based on its reported use pattern.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and product containing the chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). The MSDS for the product is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the product containing the chemical 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.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- 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 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.

Public Health

- The following measures should be taken to minimise public exposure to the notified chemical:
 - Consumers should be advised to stop application of the product containing the notified chemical if any skin reactions occur.

Environment

- The following control measures should be implemented by user to minimise environmental exposure during use of the notified chemical:
 - Use only as directed and dispose of container in a responsible manner.

Disposal

- The notified chemical should be disposed of by landfill or incineration.

Emergency procedures

- Spills/release of the notified chemical should be prevented from entering drains and water bodies and then manual collected and disposal of to landfill.

12.1. 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(2) of the Act:

- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Connell DW (1989) General characteristics of organic compounds which exhibit bioaccumulation. In: Connell DW ed. Bioaccumulation of xenobiotic compounds. Boca Raton, USA, CRC Press, pp 47-57.

Consumer Product Testing Co (1996) Repeated insult patch test, Study No. C96-0437-1, Consumer Product Testing Co. USA (unpublished report, provided by the notifier).

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