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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Alcohols, C₁₂₋₁₅ ethoxylate, sulfonate, sodium salt (Avanel S-150)

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Director Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Alcohols, C12-15 ethoxylate, sulfonate, sodium salt (Avanel S-150)

1. APPLICANT

Johnson and Johnson Pacific Pty Ltd of Stephen Road, Botany NSW 2019 (ABN 73 01 121 446) has submitted a limited notification statement in support of their application for an assessment certificate for Alcohols, C12-15 ethoxylate, sulfonate, sodium salt (Avanel S-150).

No application was made by the notifier for any information regarding the notified chemical to be exempt from publication.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	Alcohols, C12-15 ethoxylate, sulfonate, sodium salt
Chemical Abstracts Service (CAS) Registry No.:	121546-77-8
Other Names:	Sodium C ₁₂₋₁₅ Pareth-15 Sulfonate
Marketing Name:	Component of Neutrogena Deep Clean Facial Wash Avanel S-150 Avanel S-150 CG N Sulfonate 300
Molecular Formula:	C ₁₂₋₁₅ H ₂₄₋₃₁ (OC ₂ H ₄) _n SO ₃ Na

Structural Formula:



Where n = 3 - 40, average = 15

Molecular Weight:

954 (range 405 – 2077)

Method of Detection and Determination:	The notified chemical was detected by Infrared (IR) spectroscopy.
Spectral Data:	An IR spectrum was supplied for the notified chemical.

3. PHYSICAL AND CHEMICAL PROPERTIES

Unless otherwise stated, the following data refer to a 35% aqueous solution of the notified chemical.

Appearance at 20°C & 101.3 kPa:	Clear yellowish liquid
Boiling Point:	> 300°C
Melting Point:	-18°C
Specific Gravity:	1.07 (approximately)
Vapour Pressure:	0.1 kPa at 25°C
Water Solubility:	Soluble
Partition Co-efficient (n-octanol/water):	Not determined. See comments below.
Hydrolysis as a Function of pH:	0.23% at pH 4.0 Not detectable at pH 7.0 Not detectable at pH 9.0
Adsorption/Desorption:	Not determined. See comments below.
Dissociation Constant:	$pK_a = 6.8 - 7.5$ (10% aqueous solution)
Flash Point:	>93°C (closed cup)
Flammability Limits:	Not determined
Autoignition Temperature:	Not determined
Explosive Properties:	Not explosive
Reactivity/Stability:	Stable

3.1 Comments on Physico-Chemical Properties

The notified chemical is a salt containing a considerable portion of a polyethoxylated chain,

leading to high solubility (at least 35%) in water.

The hydrolysis as a function of pH was not determined via OECD guidelines. On the basis that the notified chemical would produce free sulphate ions on hydrolysis, a HPLC procedure was used to determine the ratio of phosphate to the concentration of sulphate ions in solution (Flynn, 2001). It was found that there was 0.23% hydrolysis at pH 4 but the percentage hydrolysis at pH 7 and 9 was below the detection limit of 0.01%. Therefore, it is unlikely that the notified chemical will hydrolyse in the environmental pH range 4-9.

Since the notified chemical is surface active, determination of the partition coefficient is not required.

Due to its high water solubility the chemical's adsorption/desorption (K_{oc}) is expected to be low. However, as discussed in Section 8.2, similar surfactants have been found to readily adsorb to sludge. The notified chemical may therefore readily adsorb and have medium to low mobility in soil/sediments.

The parent acid of the notified chemical is a very strong acid (Morrison and Boyd, 1992) and is likely to require very low pH values to protonate. Therefore, in the environmental pH range 4-9 the notified chemical will remain dissociated.

4. PURITY OF THE CHEMICAL

Degree of Purity:	18 - 23%	
Hazardous Impurities:	None	
Non-hazardous Impurities (> 1% by weight):		
Chemical name:	Sodium chloride	
Weight percentage:	0.5 - 4%	
CAS No.:	7647-14-5	
Chemical name:	Sodium sulphate	
Weight percentage:	0.1 - 2%	
CAS No.:	7757-82-6	
Additives/Adjuvants:		

Chemical name:	Water
CAS No.:	7732-18-5
Weight percentage:	54-62%

CAS No.:	Not given
Weight percentage:	5-11%
Chemical name:	Ethanol
CAS No.:	64-17-5
Weight percentage:	9-11%

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as a cleaning agent in facial wash for topical rinse-off applications. The chemical will not be manufactured in Australia but imported in a formulated finished cleaning product in 200mL plastic packs at 1.6% w/w.

The notified chemical will be imported at a rate of 550kg/year for the first year and 600kg/year for the subsequent 4 years.

6. OCCUPATIONAL EXPOSURE

Import, Transport and Sales

The notified chemical will be imported in a finished product in 200mL plastic packs in cardboard boxes. No reformulation will occur. Exposure of workers including four warehouse staff involved in import, transport and storage will only occur as a result of inadvertent puncture of the import containers.

Workers in retail and wholesale outlets will also handle the notified chemical. Similarly, because containers should remain closed prior to end-use, exposure of these workers will only occur as a result of accidental puncture and spillage from import containers.

7. PUBLIC EXPOSURE

The notified chemical will be imported to Australia as a component of a finished cosmetic facial cleaner and sold to the public. Since its proposed use is as a facial cleaner, exposure to the public will be widespread. The facial cleanser will be dispensed through a pump, which supplies approximately 1.6mL of product (0.0256g of notified chemical), per pump. Given that normal usage is expected to be 2 pumps per application, approximately 0.0512g of notified chemical will be applied to the face per use, which will then be rinsed off.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

There will be no production, reformulation or repackaging involving the notified chemical.

The facial wash will be used in homes Australia wide. A small amount will be applied to the face and then washed off, so ultimately most of the notified chemical will be washed down the drain, ie. approximately 99% of the notified chemical will go to sewer (up to 594 kg annually). Less than 1% will remain in the empty container. Therefore, up to 6 kg annually may be disposed of to landfill in general domestic rubbish.

8.2 Fate

The notified chemical is not manufactured, reformulated or repackaged in Australia. There will be two sources of release: the disposal of the empty user container and release in household water to sewer.

Due to its high water solubility the notified chemical might be expected to remain in the sewage water and not be removed via adsorption on organic matter or the sludge. However, a Dutch study (Matthijs et al., 1999) found that the detergent surfactant (C_{12-15}) alcohol ethoxylated (EO_{8.2}) sulphate had a removal range of 99.3-99.9% in municipal sewage treatment plants. This indicates that the majority of the notified chemical will be removed in the sewage treatment plant.

Less than 1% (a maximum of 6 kg per annum) of the contents will remain in the user's container and go to landfill in domestic rubbish. Due to its water solubility, the notified chemical may leach, but this would be at very low concentration and in a very diffuse manner. It is not expected to be mobile in soil.

No degradation studies have been done on the notified chemical, however the notifier has provided information on the degradation rate for similar chemicals which indicate that the notified chemical is likely to degrade (65-100%) within 30 days (Swisher, 1987). It is likely that the notified chemical will be degraded by biotic and abiotic action in the water body.

Due to its water solubility and molecular weight, it is unlikely that the notified chemical will bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

The following data refer to a human patch cumulative irritation and contact dermatitis test of a 4% aqueous dilution of facial cleanser containing the notified chemical.

Test	Species	Outcome	Reference
skin irritation	human	mildly irritating	Rizer (1996)
skin sensitisation	human	not sensitising	Rizer (1996)

9.1.1 Skin Irritation (Rizer, 1996)

Twenty-eight subjects received skin patches of finished cleanser containing the notified chemical and were scored for irritation using a 7 grade scoring system over consecutive 13

days. Details on the type and positioning of patches and criteria for the assignment of scores were not provided.

Irritation increased gradually during the study and was most severe at the last observation (day 13). At day 13, grade 3 irritation was still observed in 7 subjects, grade 2 in 5 subjects and grade 1 in 9 subjects.

9.1.2 Skin Sensitisation (Rizer, 1996)

Following the cumulative irritation test and following a rest period (time unspecified), 26 subjects were patch challenged at naïve sites with the finished cleanser containing the notified chemical. At 48 and 96 hours after patch application, a total of 8 subjects showed irritation scores of 0.5. All other subjects show no responses.

9.2 Overall Assessment of Toxicological Data

The cumulative irritation and sensitisation study indicates that the product containing the notified chemical is mildly irritating and not sensitising in humans. Although irritation was observed, data are insufficient to classify the notified chemical as hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided.

Van de Plassche et al. (1999) discussed the predicted no-effect concentrations and risk characterisation of the alcohol ethoxylated sulphate. In summary, the findings from short-term data were:

- Algae LC₅₀ range 3.5-10 mg/L
- Daphnia LC₅₀ range 4.2-72 mg/L
- Fish LC₅₀ range 0.7-94.4 mg/L

Warne and Schifko (1999) found the EC_{50} values for ethoxylated $C_{12-15}EO_8$ alcohol and sodium $C_{12-16}EO_{2.7}$ alkyl ethoxy sulfate were 0.39 mg/L and 3.43 mg/L, respectively.

From this information it can be seen that these surfactants are moderately to highly toxic to aquatic organism. It is likely that the notified chemical may also be moderately to highly toxic to aquatic organisms. Pettersson et al. (2000) has indicated that this toxicity is due to the non-specific interaction of the surfactant with the cell membranes. This would result in the alteration in the permeability of the cell membrane. Surfactant toxicity is primarily determined both by the absorption tendency of the surfactant and ease of its penetration into the cell membrane and appears to be independent of the ionic nature of the surfactant (Rosen et al., 2001).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As a skin care product, almost all the notified chemical (approximately 99%) will be released

to the environment in sewage. This release will be nationwide, in a very diffuse manner, and at low levels. A predicted environmental concentration (PEC) can be estimated assuming an annual import of 600 kg and no biodegradation or adsorption in the sewage treatment plant:

594 kg
150 L
19 million
365
10
0.057 μg/L

No ecotoxicity data were provided for the notified chemical by the notifier. However, from comparison to data for similar surfactants in available literature, the PEC is 3 orders of magnitude below the lowest available EC50 value. If it is assumed that 99% of the notified chemical may be removed in the sewage treatment plant, then the estimated PEC is reduced by a further two orders of magnitude.

Due to the diffuse nature, low level of release and likely biodegradation rate of the notified chemical, the environmental hazard from the specified use is considered to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

A single cumulative human irritation and sensitisation study indicates that the product containing the notified chemical is mildly irritating and not sensitising. Although irritation was observed, data are insufficient to classify the notified chemical as hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b). The Material Safety Data Sheet (MSDS) for the product containing the notified chemical warns of skin irritation with normal use, discomfort to the skin with prolonged exposure and discomfort upon exposure to the eyes. Gastrointestinal discomfort may be experienced with ingestion of large quantities.

Occupational Health and Safety

Exposure to the notified chemical may occur to transport, warehouse and retail workers only following accidental puncture of import containers. If spillage occurs, exposure to the skin and eyes would be expected to produce irritation. Given the low likelihood of exposure, the health impact for workers from the notified chemical would be assessed as negligible.

Public Health

Given the low concentration of notified chemical contained in the facial cleanser, the risk to the public from the notified chemical is considered to be low.

13. RECOMMENDATIONS

To minimise occupational exposure to alcohols, C12-15 ethoxylate, sulfonate, sodium salt (Avanel S-150) the following guidelines and precautions should be observed:

Occupational Health and Safety

• Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the product:

Protective eyewear, chemical resistant industrial clothing and footwear and impermeable gloves should be used where frequent or prolonged occupational exposure to products containing the notified chemical is possible.

Guidance in selection of protective eyewear may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards Australia/ Standards New Zealand, 1994) or other internationally accepted standards.

- 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

• Consumer labels should warn of the possibility of skin and eye irritation for users of end-use products.

Emergency procedures

• Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

Secondary notification

The NICNAS Director must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) <u>Under Section 64(1) of the Act:</u>
 - if more than 1 tonne/year of the notified chemical is to be introduced;
- (2) <u>Under Section 64(2) of the Act:</u>
 if any of the circumstances listed in this subsection arise.

The Director will then decide whether secondary notification is required. A standard notification will require Parts A, B, and C of the schedule, in particular, tests for toxicity to fish, daphnia and algae.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a).

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.

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