File No.:EX10(NA/604)

Date: November 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Akypo-Soft 45NV

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Family Services.

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Director
Chemicals Notification and Assessment

File No.:EX10(NA604)

MODIFICATIONS TO FULL PUBLIC REPORT

Akypo-Soft 45NV

1. APPLICANT

First Applicant (NA/604)

Schwarzkopf Pty Limited of Rodborough Road FRENCHS FOREST NSW 2086 has submitted a standard notification statement in support of their application for an assessment certificate for Akypo-Soft 45NV.

An assessment Certificate was granted to Schwarzkopf Pty Limited on 31 July 1998

Second Applicant (EX/10)

Asia Pacific Specialty Chemicals Limited of 15 Park Road SEVEN HILLS NSW 2147 has submitted a notification statement in support of their application for an Extension of the Original Assessment Certificate for Akypo-Soft 45NV.

The applicant has submitted supplementary information outlining occupational, environmental and public exposure. The notified chemical will be imported in solution and reformulated into finished products at one site in Australia. No new information was available to the applicant for extension regarding the health and environmental effects of the notified chemical.

5. USE, VOLUME AND FORMULATION

To be added as follows.

EX10:
The notified chemical will not be manufactured in Australia. It is a thickener for surfactant based formulations such as hair dyes and shampoos. It will be imported in solution at 22% concentration and the solution formulated at 22.5% into hair shampoos at a single site. The final concentration of the notified chemical in the shampoo products is 4.95%.

The import volume for Akypo-Soft 45NV for formulation into hair shampoos will be approximately 2 250 kg per annum over the first five years.

6. OCCUPATIONAL EXPOSURE

To be modified by addition of the following:

EX 10: Formulation of End-Use Products in Australia

Waterside Transport and Storage
The notified chemical will be imported into Australia in 150kg plastic drums. The total import volume will be transported by road to the APS Chemical warehouse at Seven Hills NSW for storage prior to transportation to the customer's site.

For waterside, transport and warehouse workers, there is not expected to be any exposure to the notified chemical during storage and distribution, except in the event of a spill.

Formulation
At the customer's site, drums containing the notified chemical will be stored on racks and, after quality control analysis by laboratory technicians, will be transferred via forklifts to the formulation area. The notified chemical is manually added to the blender with other ingredients and mechanically mixed under local exhaust ventilation. The end product is pumped into a sealed tank which is transferred by a pallet truck to the packaging floor. The final product containing the notified chemical is pumped via pipes from the sealed tank to 250 mL bottles. These are packed on site, and transported to retail outlets. The following categories and numbers of workers may be exposed to the notified chemical at the formulation site.

Category of workers	***Number***	***Hours/day***	***Days/year***
Storemen	1	0.5	12
Laboratory technicians	2	0.5	24
Compounders	3	2	24
Linesetters	1	0.5	24

Dermal and ocular exposure to the notified chemical is possible during manual dispensing and blending operations. Exposure by inhalation is expected to be minimal given the low vapour pressure of the notified chemical. Exposure resulting from escape of aerosols containing the notified chemical during blending is minimised by good general and local exhaust ventilation in the mixing and dispensing areas. The storage, sampling and packaging areas are provided with general ventilation and laboratories are equipped with fume hoods. During formulation operations, all plant workmen will be attired with safety glasses, protective clothing and gloves.

Linesetters who fill the final products into 250 mL bottles, may have contact with spills with end use product, containing the notified chemical at 4.95%. Some skin contact may occur if spillage occurs during the filling process. The final shampoo products will be transported to consumer outlets where it will be sold to the public.

End-use
If professional hairdressers use the shampoos, some dermal exposure to the notified chemical

may occur.

7. PUBLIC EXPOSURE

To be modified by addition after the last paragraph as follows

EX 10:Hair shampoo formulation and use
It is expected that during transport, reformulation and storage, exposure of the general public to the notified chemical will be low. There is the potential for widespread public exposure to the notified chemical in the shampoo products, limited only by the commercial success of the products containing it. Consumers will be exposed via the dermal route, with the possibility of accidental ocular exposure. The products are intended for regular use.

For the purpose of this evaluation, regular use suggests an application of around 3 to 4 times per week, and frequent use suggests daily application. For calculation of maximum consumer exposure, the amount of shampoo per application of 12 g is adopted from Risk Assessment of Existing Substances: Technical Guidance Document. European Commission, 1994.

The estimated maximum systemic dermal exposure for a shampoo containing 4.95% of the notified chemical or 22.5% of Akypo-Soft 45NV and assuming daily use and a 10% dermal absorption would be 1.98 and 9.0 mg/kg/day for a 60 kg adult.

$\frac{4.95 \times 12 \times 2 \times 1\,000}{100 \times 60} = 19.8 = 1.98$ mg/kg/day for the notified chemical (10% dermal absorption)

$\frac{22.5 \times 12 \times 2 \times 1\,000}{100 \times 60} = 90.0 = 9.0$ mg/kg/day for Akypo-Soft 45NV (10% dermal absorption)

8. ENVIRONMENTAL EXPOSURE

Release

To be modified by addition after the last paragraph as follows

EX 10: Formulation of end-use products in Australia
The notifier estimates that at worst, 675 kg per year (30%) of the notified chemical will be released during reformulation (spillage, equipment cleaning). However this amount is considered to be excessive and releases are likely to be approximately 5% (113 kg) of the import volume.

The notified chemical will be reformulated at one factory. The notified chemical acts as a surfactant and is mechanically mixed with other agents to produce the finished shampoo end use product. The concentration of the notified chemical in the end use product (shampoo) is 4.95% (imported solution at 22.5%). The end use product is transferred into 250 mL bottles. Empty bottles will contain approximately 2% (45 kg per year) of the notified chemical as residue. These bottles will be disposed of to landfill through domestic garbage services.

After each batch manufacture, the equipment is cleaned and up to 1.5 kg of the end use product may be released in a diluted form to the in-house effluent plant. The effluent treatment process is a batch process involving 10,000 L per treatment cycle. During this process the alkaline effluent is adjusted to pH 6-10 using 32% (v/v) hydrochloric acid. Ammonia stripping via aeration/evaporation is another feature of this process. The treated water is then released to a single waste water treatment plant.

All spills will be contained and removed by a registered authority.

Fate

To be modified by addition after the second paragraph as follows

EX 10:Formulation of end-use products in Australia
The shampoos containing the notified chemical would be expected to be released to the environment via consumer use through rinsing the chemical off the hair and into the sewerage system. Very little would be expected to adsorb to the skin. The fate of the notified chemical would be expected to be similar to that described in the original assessment. In the sewer, it is anticipated that some would adsorb to sewage sludge due to the expected surface active nature of the chemical. Sewage sludge will either be deposited to landfill or incinerated. The remainder of the notified chemical will remain in solution, where it is expected to be diluted and degraded.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

To be modified by addition after the last paragraph as follows

EX 10: Formulation of end-use products in Australia
The hazard will be similar to that of the original assessment. However, an additional 2 250 kg of waste will be entering the aquatic compartment.

As the product is likely to be used nationwide and sent to sewage treatment plants at both city and country locations, a combined PEC based on continental use has been calculated.

EX/10 import volume (after waste subtraction)	2205 kg
NA/604 import volume (after waste subtraction)	4850 kg
Total import volume	7055 kg
Amount discharged to sewer	100%
Volume discharged per day	19.33 kg
Sewer output per day*	1800 ML
Concentration in Sewage Treatment Plant	10.74 µg/L
Further diluted (1:10) in receiving waters	1.1 µg/L
Safety factor (Ide 96 h LC_{50} = 2.64)	2650

*Sewer output based on an Australian population of 18 million, each using 100 L water per day.

The PEC of the notified chemical in receiving waters indicates that the overall environmental hazard may be considered low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

To be modified as follows.

EX 10: Hazard Assessment
The notified chemical will be imported as an aqueous solution at approximately 22% concentration to be formulated into hair shampoo in Australia.

The notified chemical is determined to be hazardous substance in accordance with NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) in relation to irritant effects (eye). This requires the risk phrase, R36: Irritating to the eyes to be carried on the Material Safety Data Sheet (MSDS) and label. Akypo-Soft 45NV, the imported solution containing the notified chemical, is also a hazardous substance (R36) as the concentration of notified chemical is above the cut-off level of 20%.

Occupational health and safety
During importation and transportation of the notified chemical, there is unlikely to be any worker exposure, except in the event of a spill. Exposure after a spill can be minimised by the use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier.

Worker exposure may occur to the notified chemical during blending operations. There is potential for ocular and dermal contact and to a lesser extent inhalation exposure during dispensing the product containing the notified chemical to the blender and mixing. Should dermal or ocular, contact occur, the notified chemical is unlikely to cause systemic toxicity. Consequently, there is a risk of eye irritation and possibly slight skin irritation during the mixing operation. However, in combination with personal protective equipment (goggles, gloves and overalls), this risk is minimised by the presence of effective engineering controls, for example, closed mixer and local exhaust ventilation. In addition, the notifier stated that the workers involved will receive education and training on safe use of the notified chemical and preventive controls.

The presence of good general ventilation in the storage, sampling and packaging areas and local exhaust ventilation over the dispensing and mixing areas and a fume hood in the laboratories are employed to control exposure to the notified chemical and therefore minimise the risk of irritant effects.

If the end-use products containing the notified chemical are used by professionals such as hairdressers, the risk of skin irritation arising from exposure to the notified chemical is low due to its low skin irritancy and low concentration (< 5%) in finished products. Due to the low probability of ocular exposure by professional hairdressers, the risk of eye irritation arising from exposure to the notified chemical is low.

EX 10:Public health

Hair shampoo. There will be widespread public exposure to the notified chemical through its use in hair shampoos. The product label for Keratase Preventive Bath states that the product should be used regularly and that if the product enters the eyes, it should be rinsed out. The label for Keratase Dual Action Bath carries the same wording regarding eye contact and has been specifically formulated for frequent use. Based on daily use the estimated maximum systemic dermal exposure for a shampoo containing 4.95% of the notified chemical is 2 mg/kg/d for a 60 kg person. Of greater concern is the high concentration of a severe eye irritant and a slight skin irritant in these products. Consequently, sodium laureth-6-carboxylate will be proposed for scheduling by the National Drugs & Poisons Schedule Committee (NDPSC).

13. RECOMMENDATIONS

To be modified as follows.

EX 10:

1. It is recommended that the notified chemical be proposed for scheduling by NDPSC, Department of Health and Aged Care.

2. To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

   - Safety glasses should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);

   - Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990);

   - Impermeable gloves or mittens should conform to AS 2161.2 (Standards Australia/Standards New Zealand, 1998);

   - All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994c);

14. MATERIAL SAFETY DATA SHEET

To be modified as follows.

EX 10: The MSDS for Akypo soft 45NV was provided in a format consistent with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets*.

This MSDS was provided as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

16. REFERENCES

To be modified by the addition of the following:

EX 10: Standards Australia 1994, Australian Standard 1336-1994, Eye protection in the Industrial Environment, Standards Association of Australia Publ., Sydney.

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.

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

Standards Australia 1990, Australian Standard 3765.1-1990, Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals, Standards Association of Australia Publ., Sydney.

1998, Occupational protective gloves, Part 2: General requirements. Standards Association of Australia, Sydney. Standards Australia/Standards New Zealand (1998) Australian/New Zealand Standard 2161.2

Standards Australia/Standards New Zealand 1994, Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

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