File No: EX/4 (NA/460)

February 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION

AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Abil EM90

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Abil EM90

1. APPLICANT

Amway of Australia of 46 Carrington Road CASTLE HILL NSW 2154 has submitted a notification statement in support of their application for an extension of the original assessment certificate for Abil EM90.

The original assessment certificate (Certificate No. 000599, File No. NA/460) was issued on 14 March 1997 and is held by Salkat Australia Pty Ltd of 262 Highett Road HIGHETT VIC 3190. Salkat Australia Pty Ltd has agreed to this extension.

There has been no significant variation in matters affecting occupational, environmental or public exposure as set out in the notification statement that accompanied the application for extension of the original certificate. There has been no new information available to the applicant for extension of the original assessment certificate regarding the health and environmental effects of the notified polymer.

2. IDENTITY OF THE CHEMICAL

Other Names:	modified polyether-polysiloxane/dimethicone copolyol
Trade Name:	Abil EM90, CL 530

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	clear colourless and nearly odourless viscous liquid
Boiling Point:	not available
Specific Gravity:	0.941 at 25°C (estimated)
Vapour Pressure:	not available
Water Solubility:	8 $mg.L^{-1}$ at 25°C
Partition Co-efficient (n-octanol/water):	not available

Hydrolysis as a Function of pH:	not available
Adsorption/Desorption:	not available
Dissociation Constant:	not applicable, Abil EM90 is nonionic
Flash Point:	> 120°C
Flammability Limits:	not available
Autoignition Temperature:	not available
Explosive Properties:	not available
Reactivity/Stability:	relatively stable

Comments on Physico-Chemical Properties

The vapour pressure of the notified polymer was not determined because of its high molecular weight. Related chemicals such as dimethicone have a relatively high vapour pressure and evaporate readily (1).

Data such as solubility and partition coefficient are not particularly relevant to surface active compounds, which prefer to reside at or on the interface between polar and apolar media, rather than partitioning between them. This type of molecule is generally extremely hydrophobic. The structure of the notified polymer would increase this hydrophobicity.

The siloxane and ether linkages of the polymer are not expected to hydrolyse in the pH range 4-9. At pH values below 2 and above 11 and temperatures above 90°C cleavage of the Si-O-Si bonds in the chemical will occur. The extent to which hydrolysis would occur in the environment is unclear, given that silicones adsorb strongly to surfaces.

The notified chemical contains no dissociable hydrogens or basic functionalities.

Low flammability indicates that the autoignition temperature will be high.

4. PURITY OF THE CHEMICAL

Degree of Purity:	high
Toxic or Hazardous Impurities:	none

Non-hazardous Impurities

None of the non-hazardous impurities are listed on the National Occupational Health and Safety Commission's (NOHSC) *List of Designated Hazardous Substances* (2). One is listed as a possible sensitiser in Sax and Lewis (3) and on Toxline (4) use of the chemical in dental fittings and jewellery can result in a sensitised state in some individuals. None of the other impurities are listed on Toxline as having significant toxicological effects (4).

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as an emulsifier in cosmetic preparations. The original import quantity notified was in excess of 1 tonne per annum. An additional volume of 100 kg per annum will be imported as a component of finished cosmetic product, during each of the first five years. The cosmetic product will be imported in pack sizes ranging from 25 to 250 mL.

Abil EM90 is already in the USA and Europe for the same use as is intended for Australia.

6. OCCUPATIONAL EXPOSURE

Abil EM90 will not be manufactured or reformulated in Australia. It will be imported as a component of finished cosmetic products at a concentration of 5%. The cosmetic products will be imported in pack sizes ranging from 25 to 250 mL bottles or tubes which are themselves housed in unit cartons. Occupational exposure during transport and warehousing is unlikely and will only occur in the event of accidental release.

The main routes of occupational exposure to the notified polymer will be via dermal contact with the possibility of eye contact through splashing if the package is unintentionally broken.

7. PUBLIC EXPOSURE

The public will be exposed to the notified polymer through use of the cosmetic formulations and skin care products that contain concentrations of the notified polymer up to a maximum concentration of 5%.

While public exposure to the cosmetic products containing the notified chemical is possible following accidental ingestion or eye contact, it is a standard practice of the company to provide detailed information of the product to all Poisons Information Centres, prior to cosmetic availability for sale.

8. ENVIRONMENTAL EXPOSURE

Release

The use of cosmetic products containing the polymer would be widespread but diffuse as it is applied in small quantities to the skin. The majority of the product will be rubbed off ie, onto clothing, etc or washed off while users are swimming or paddling. This will occur in either pools or natural waterways. Cosmetic remaining on users after swimming or paddling will be removed through washing resulting in its release to the sewer.

Fate

The environmental properties of polydimethylsiloxane fluids have been well reviewed in the literature (5).

Silicone fluids are very surface active because the flexible siloxane linkages permit alignment of the hydrophobic methyl substituents towards the non-polar phase, and of the polysiloxane backbone towards the polar phase.

The polar medium is generally water, and apolar media to which polydimethylsiloxanes become attached may be textiles, sewage sludge, algae, sediment, etc. In aqueous environments, strong, complete and permanent adsorption of high molecular weight silicone fluids to sediment may be assumed. Hence, this modified silicone will be removed from solution by adsorption onto sediment or sludge with little, if any, likely to be contained in natural or treated waste waters. Sludge containing the notified substance may then be incinerated or landfilled. Incineration would destroy the substance and liberate water and oxides of carbon and silicon, while disposal to landfill would immobilise it.

Polydimethylsiloxanes are thought to be unstable in terrestrial environments, where clays can catalyse cleavage of the siloxane linkage, but are probably more permanent in aquatic sediment as the catalytic action of clays is inversely related to their degree of hydration (5).

As noted above, the hydrolytic stability of this modified silicone in the environment is unclear. However, hydrolysis products do not appear to be of significant ecological concern.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Abil EM90

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 $mg.kg^{-1}$	6
skin irritation	rabbit	* irritant potential	7
eye irritation	rabbit	* irritant potential	8
skin sensitisation	guinea pig	not a sensitiser	9

* not classified as an irritant according to NOHSC's *Approved Criteria for Classifying Hazardous Substances* (10)

9.1.1 Oral Toxicity (6)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage, single dose 5 000 $mg.kg^{-1}$
Clinical observations:	one animal had ano-genital staining at day 1
Mortality:	nil
Morphological findings:	nil
Test method:	according to US Federal Hazardous Substances Control Act (FHSA) Guidelines (11)
LD_{50}:	> 5 000 $mg.kg^{-1}$
Result:	low acute oral toxicity

9.1.2 Skin Irritation (7)

Species/strain:	rabbit/ New Zealand White
Number/sex of animals:	6/not specified
Observation period:	72 hours
Method of administration:	0.5 ml of test chemical applied to clipped test site (2.5 cm^2) and occluded for 24 hours; test

site then wiped clean

Draize scores (12): intact skin

Time after treatment (days)	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
1	[a]2	2	2	2	1	2
3	1	0	1	1	0	2
Oedema						
1	1	1	1	1	1	1
3	0	0	0	1	0	1

[a] see Attachment 1 for Draize scales

Test method: according to US Federal Hazardous Substances Control Act (FHSA) Guidelines (11)

Result: some irritant effects, however below threshold for classification as hazardous (irritant) according to NOHSC's criteria (10)

9.1.3 Eye Irritation (8)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 6/female

Observation period: 72 hours

Method of administration: 0.1 ml in one eye

Draize scores (12) of unirrigated eyes: no corneal opacity or iritis in any test animal

	Time after instillation								
Animal	***1 day***			***2 days***			***3 days***		
Conjunctiva	***r[a]***	***c[b]***	***d[c]***	***r[a]***	***c[b]***	***d[c]***	***r[a]***	***c[b]***	***d[c]***
1	[1]2	1	2	2	1	2	1	0	0
2	2	1	2	1	1	1	1	0	0
3	2	1	2	2	1	2	1	0	0
4	1	1	2	1	1	2	0	0	0
5	2	1	2	2	1	2	0	0	0

6		2	1	2		2	2	2		2	0	0

[1] see Attachment 1 for Draize scales
[a] redness [b] chemosis [c] discharge

Test method: according to US Federal Hazardous Substances Control Act (FHSA) Guidelines (11)

Result: conjunctival effects only; with the exception of redness, all absent at 72 hours; not classified as an eye irritant according to NOHSC's criteria (10)

9.1.4 Skin Sensitisation (9)

Species/strain: guinea-pig/Dunkin Hartley

Number of animals: 20 test animals, 10 naive control, 10 naive rechallenge, 10 positive control, 5 positive naive control, 5 positive naive control rechallenge

Induction procedure: **intradermal induction**: 50% Freund's complete adjuvant (FCA) solution in distilled water; test substance at 100% (determined to be non-irritating in preliminary screen); 10% test substance in distilled water mixed in 1:1 with 50% FCA solution; control - 50% mixture of water in 50 % FCA solution; positive control - mercaptobenzothiazole (60% w/w in ethanol), 95% ethanol, 10% mercaptobenzothiazole in 95% ethanol 1:1 FCA 50% in distilled water, 95% ethanol 1:1 FCA 50% in distilled water

topical induction: test substance (100%), dry Hilltop chamber applied at dose site, mercaptobenzothiazole (60% w/w in ethanol), 95% ethanol

Challenge procedure: 24 hours before challenge, the site was treated with 10% sodium lauryl sulfate test substance (100%), mercaptobenzothiazole (60% w/w in ethanol),

Rechallenge procedure: test substance (100%), mercaptobenzothiazole (60% w/w in ethanol),

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	24 hours*	48 hours*	24 hours	48 hours
100%	**0/20	0/20	0/20	0/20

* time after patch removal
** number of animals exhibiting positive response

Test method: in accordance with OECD guidelines (13) with minor deviations

Result: not a skin sensitiser in guinea-pigs; controls gave appropriate responses

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (14)

Strains: TA 98, TA 100, TA 1535, TA 1537 and *Escherichia coli* strain WP2*uvrA*

Concentration range: 250, 500, 1 000, 5 000 μg.plate^{-1} with or without S9 activation

Test method: similar to OECD guidelines (13)

Result: not mutagenic in this system; controls gave appropriate response

9.4 Other Toxicological Data

A review of dimethicone copolyols (a component of the notified chemical) was provided by the notifier (1). It refers to a number of toxicology studies that support the data described above. In addition the tests which are absent from the above suite (dermal toxicity, inhalational toxicity and repeat dose studies) are described for various dimethicone copolyols. A dermal 28-day percutaneous toxicity study using dimethicone copolyol "A" 190 at 200 mg.kg^{-1}.day^{-1} resulted in nil mortality or behavioural effects. Slight to moderate erythema and oedema were found at the application sites after day 2. There was no weight loss in test animals and the only histopathological result of significance was a depression in spermatogenesis in one of the 10 test rabbits (all males). Inhalation toxicity studies in rats are described for a range of dimethicone copolyols. Mortality only occurred at elevated temperatures to concentrations of dimethicone copolyol "B" 7500 of 23.47 mg.L^{-1} (33% of test animals after 4 hours) and at an unspecified concentration (100% mortality after 8 hours). The same dimethicone copolyol produced nil mortality at lower temperature and/or for shorter time periods.

When rats were fed dimethicone copolyol "B" at a dose rate of 640 and 2 880 mg.kg^{-1}.day^{-1} for 89 days there were no mortalities or any deleterious effects

9.5 Overall Assessment of Toxicological Data

There is only a limited toxicological data set available for the notified polymer which is acceptable for a limited notification. It has a low oral toxicity in rats with an LD_{50} in excess of 5 000 $mg.kg^{-1}$. There is no dermal or inhalational toxicity data available for the notified polymer. In a rabbit skin irritation study, although there was some evidence of irritation (erythema) it was minimal and below the level requiring a hazardous classification (10). It should also be noted that the test protocol differed from the OECD (13) method as the notified chemical was in contact with the skin for 24 hours rather than the 4 hours recommended in the OECD protocol. An eye irritation study in rabbits produced conjunctival effects but these were below the threshold requiring a hazardous classification. The notified polymer was not a sensitiser in a guinea pig sensitisation study. It was not mutagenic in a *Salmonella typhimurium* reverse mutation assay with or without S9 activation.

A summary of toxicological information on dimethicone copolyols, a group that includes a component of the notified chemical, indicated a similar level of toxic response to those described for the notified polymer. A dermal 28-day percutaneous toxicity study using dimethicone copolyol "A" 190 at 200 $mg.kg^{-1}.day^{-1}$ produced only slight to moderate erythema and oedema at the application sites and a depression in spermatogenesis in one of the 10 test rabbits (all males). Inhalation toxicity studies in rats are described for a range of dimethicone copolyols. Mortality only occurred at elevated temperatures, nil mortality occurring at lower temperature and/or for shorter time periods at elevated temperatures. A repeat dose study using dimethicone copolyol "B" for a duration of 89 days resulted in no mortalities or deleterious effects at a dose of 2 880 $mg.kg^{-1}.day^{-1}$.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of number average molecular weight (NAMW) of greater than 1 000 according to the Act. The high molecular weight of the substance suggests that it will not cross biological membranes, and will therefore be of low toxicity and not bioaccumulate. It is well accepted that polydimethylsiloxane fluids become permanently adsorbed to sediment and should not exert adverse environmental effects. Physical effects such as surface entrapment has been observed when testing aquatic invertebrates in clean laboratory water. Similar effects are not expected in natural environments where a large variety of other surfaces provide opportunities for deposition (5).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified polymer is a minor component of cosmetic products and as such will be released to the environment in small amounts through washing from the skin. The expected additional import volume of 100 kg for this extension will not significantly increase the environmental exposure of the polymer. Based on the import volume originally notified, a worst case environmental concentration of 15 ppb is predicted if all the imported polymer remains suspended in sewage waters (assuming: approximately 15 000 kg are discharged annually to the sewer, by an Australian population of 18 million with a daily per capita waste water discharge of 150 L). However, most is expected to adsorb to sediment or sewerage sludge that will be landfilled or incinerated. In landfill the substance is not expected to be mobile or degrade due to its low water solubility. Hence, the overall environmental hazard of the chemical can be rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Abil EM90 is a high molecular weight (NAMW in excess of 1 000) modified polyether polysiloxane. It contains a significant level of low molecular weight species below 1 000 (< 9%) and below 500 (< 5%). The high molecular weight of the polymer precludes transmission across biological membranes although the low molecular weight species which the notifier indicates are largely paraffins are not so limited. None of these paraffins or the other impurities listed with the exception of one are listed as having significant toxicological attributes. The latter is a residue of the catalyst used in the production of the polymer, is at such low levels that it is unlikely to be of significance. It can result in a sensitised state in some individuals. The bioaccumulative capacity of the notified polymer is unknown as an octanol water partition coefficient was not provided. However, the inability to cross biological membranes reduces any concerns regarding bioaccumulative potential or possible systemic effects through gross exposure to the polymer.

The toxicological data submitted was limited but confirms the notified polymer as having a low oral toxicity with no indications of systemic effects in an acute study. It was not a classifiable eye or skin irritant according to NOHSC's *Approved Criteria for the Classification of Hazardous Substances* (10) although there were some minor indications of irritant potential. A guinea pig sensitisation study was negative as was an Ames test for mutagenicity. The dermal toxicity, inhalational toxicity and sub-chronic effects of Abil EM90 are unknown, however a summary provided by the notifier for dimethicone copolyols, one of which is a component of the notified polymer, indicate that they are of limited toxicological significance in these test systems.

Since Abil EM90 will be imported as a component of a finished cosmetic product, occupational exposure is only possible in the event of accidental release during transport and warehousing. The main routes of occupational exposure will be via dermal contact , or possible eye contact, through splashing, if the package is unintentionally damaged or broken. While occupational exposure is possible in the event of accident, the exposure will be limited and the risk through such exposure

will be low.

There will be widespread public contact with the notified polymer from use of cosmetic formulations and skin care products. Skin and eye irritation are slight in animals and products containing up to 5% of the notified polymer are likely to have negligible irritant potential. While public exposure to the cosmetic products containing the notified chemical is possible following accidental ingestion or eye contact, a detailed information of the product is provided to all Poisons Information Centres to protect the public prior to cosmetic availability for sale.

13. RECOMMENDATIONS

To minimise occupational exposure to Abil EM90 the following guidelines and precautions should be observed:

- Spillage of the product containing the notified polymer should be avoided. Spillages should be cleaned up promptly with absorbents which should then be placed in containers for disposal to landfill or by incineration;
- 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* (21).

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

1. Anonymous 1982. Final report of the safety assessment of dimethicone copolyol. *Journal of the American College of Toxicology* **1**, 4, p 33-54.

2. National Occupational Health and Safety Commission 1994, *List of Designated Hazardous Substances* [NOHSC:10005(1994)], Australian Government Publishing Service Publ., Canberra.

3. Sax, N. I. & Lewis, R. J. 1989, *Dangerous Properties of Industrial Materials*, Van Nostrand Reinhold, New York.

4. Toxline Silver Platter 1995, *Toxline SilverPlatter CD-ROM database, January 1994-June 1996*, Silver Platter International N.V.

5. Hamelink, J. L. 1992. Silicones. In: N T de Oude (ed), *The Handbook of Environmental Chemistry*, Volume 3 Part F, Anthropogenic Compounds: Detergents. Springer-Verlag, p 383-394.

6. Shapiro, R. 1990, FHSA acute oral toxicity limit test- Abil EM-90. Report No. T-102, Product Safety Labs, East Brunswick, New Jersey, U S A.

7. Shapiro, R. 1990, FHSA dermal irritation test- Abil EM-90. Report No. T-104, Product Safety Labs, East Brunswick, New Jersey, U S A.

8. Shapiro, R. 1990, FHSA primary eye irritation test- Abil EM-90. Report No. T-103, Product Safety Labs, East Brunswick, New Jersey, U S A.

9. Shapiro, R. 1995, Dermal sensitisation test - Magnusson-Kligman method- Abil EM 90. Report No. E50516-1R, Product Safety Labs, East Brunswick, New Jersey, U S A.

10. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)], Australian Government Publishing Service, Canberra.

11. Federal Hazardous Substances Act (FHSA) Regulations, guidelines.

12. Draize, J. H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* 49.

13. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris.

14. Pant, K. J. 1995, Evaluation of a test article in the *Salmonella typhimurium/ Escherichia coli* plate incorporation/preincubation mutation assay in the presence and absence of aroclor-induced rat liver S-9 with a confirmatory study. Report No. 0358-2140, Sitek Research laboratories, Rockville, Maryland, USA.

15. Standards Australia 1994, *Australian Standard 1336-1994*, *Eye protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney.

16. 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.

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

18. 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.

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

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

21. 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.

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe