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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

AMIDO POLYETHER MODIFIED SILICONE FLUID

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

AMIDO POLYETHER MODIFIED SILICONE FLUID

1. APPLICANT

Dow Corning Australia Pty Ltd, 21 Tattersall Rd, Blacktown, NSW 2148

2. IDENTITY OF THE CHEMICAL

Chemical name: Siloxanes and silicones, Dimethyl, methyl 3-[(2-lauroxy polyethyleneglycol acetamido ethyl) amino] propyl, trimethyl endblocked

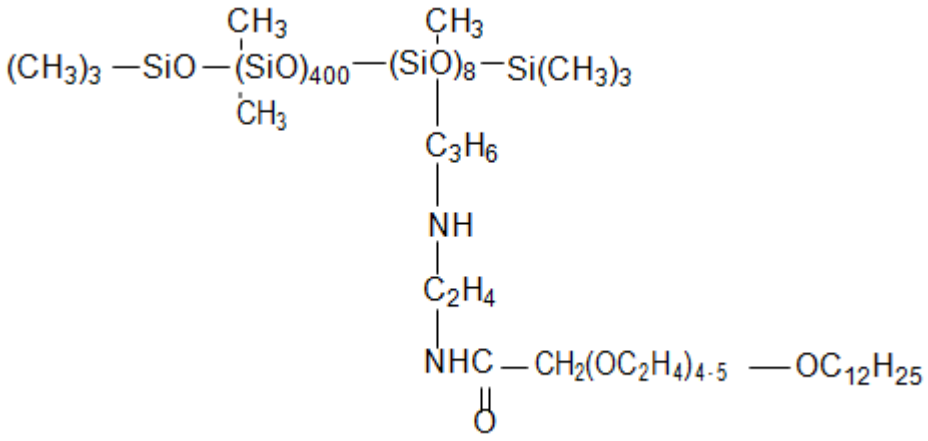
Chemical Abstracts Service (CAS) Registry No.: none

Other names: Amido polyether modified silicone fluid, APMS fluid, BY16-878

Trade names: Dow Corning Toray Silicone BY16-878 amido type silicone fluid

Molecular formula: $C_3H_9SiO[C_2H_6SiO]_{400}\ [C_{29}H_{59}O_3N_2]_8\ SiC_3H_9$

Structural formula:



Notes on chemical identity

The molecular weight has been calculated directly from the structural formula. The polymer is stated to contain between 3-4% of dimethyl cyclosiloxanes (4-10 siloxane units) as volatile impurities.

Molecular weight:	34400
Maximum percentage of low molecular weight species <1000	5%

Method of detection and determination: The notified chemical may be detected by infra-red spectroscopy.

Spectral data:

IR Spectrum: Major absorption peaks are 800, 1260, 1095, 1020, 1390, 1690, 1100, 2970 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Pale yellow coloured liquid
Odour:	amine odour
Melting Point	< - 30°C. The chemical will decompose or gel at temperatures above 200°C.
Specific Gravity:	0.98
Vapour Pressure:	Not determined
Water Solubility:	below 0.1% w/w
Hydrolysis as a function of pH:	Not determined
Partition Co-efficient: (n-octanol/water)	Not determined

Adsorption/Desorption: Not determined

Dissociation Constant: Not determined

Flash Point: 197°C

Flammability Limits: Not determined

Autoignition Temperature: None

Explosive Properties: Not explosive

Reactivity/Stability: the notified chemical may react with strong acids and bases and with epoxy compounds

Degradation Products: organic amines and $HOOCCH_2(C_2H_4O)_{4.5}C_{12}H_{25}$

The environmental properties of polydimethylsiloxane fluids have been well reviewed by Hamelink (1). 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 the non-polar mediium 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.

Data such as solubility and partition coefficient are not particularly interface between polar and apolar media, rather than partitioning between them. Polydimethylsiloxanes are extremely hydrophobic, but according to the submission, modification as in the present case favours formation of stable emulsions. It also increases the hydrophilicity, but the magnitude of this increase is unclear as a relatively insensitive detection limit of 1000 ppm was used in solubility tests.

The structure provided contains eight amide linkages, and the notifier lists the corresponding amine and carboxylic acid derivatives as possible degradation products. Prolonged storage is said to give rise to ammoniacal odours. The extent to which hydrolysis would occur in the environment is unclear, given that

silicones are insoluble and adsorb strongly to surfaces. However, the hydrophilic substituents can be expected to project into the aqueous phase where they may be available for microbial attack.

4. PURITY OF THE CHEMICAL

Degree of purity: 95%

Toxic or hazardous impurities: None

Non-hazardous impurities: (> 1% by weight)

. **Chemical name:** cyclosiloxanes,di-me(4-10 siloxane units)

Weight percentage: 5%

Additives/Adjuvants: None

5. INDUSTRIAL USES

Amido polyether modified silicone fluid (APMS fluid) is to be used as a fabric softener in the textile industry. The chemical is to be imported into Australia in quantities of less than 10 tonnes/year for the first five years.

6. OCCUPATIONAL EXPOSURE

APMS fluid will be transported in steel pails/drums containing 20 or 200 litres of the notified chemical.

The notified chemical will be reformulated, generally into an emulsion containing surfactants, before treating the fabric. The emulsion is diluted to give a silicone concentration 1-2%. Fabrics are dipped into the bath and subsequently passed over or through squeeze rollers. At the end of this process it is expected that the treated fabric or other material will have "picked up" between 50 -100% of its own weight of bath material. The fabric will then be dried at 105-120^{O}C for five minutes.

It is expected that between 20 and 100 process workers in the textile industry will have an exposure to the notified chemical.

Maximum exposure will be eight hours per day five days per week. Processes and machinery and therefore type of exposure will vary according to the individual plant. However workers will be exposed at room temperatures mixing the chemical and handling wet or dry textiles. Workers will be instructed to wear gloves and goggles.

Additional workers may be exposed at formulators of textile chemicals who will buy the notified chemical for reformulation and further sale.

7. PUBLIC EXPOSURE

APMS fluid will be manufactured in Japan and imported into Australia, where it will be transported in steel drums or pails, at a rate of about 10 tonnes/year. APMS fluid is a polymeric fabric softener for use by the textile industry. Discharge into the sewage system at textile mills will be low and in dilute form. Waste disposal will be by landfill and treated fabric may be incinerated. Public exposure to the raw material is expected to be low. However, significant exposure via treated fabric is possible. The polymer is likely to be bound to the fabric but no information on this was included in the submission.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The substance is likely to be used by textile mills situated in coastal and inland cities throughout Australia (eg Sydney, Melbourne, Wangaratta, Maitland and Wagga Wagga).

Fabric is passed through the treatment bath, an emulsion containing around 1-2% of the silicone, nipped through two or more squeeze rollers, and dried at 105-120^{o}C for 5 min. The amount of emulsion absorbed by the fabric after nipping is known as the pick-up, and is expressed as a percentage based on the weight of the fabric. Pick-up varies depending on the fabric. The recommended maximum level of application is 1% silicone based on the weight of the fabric.

The notifier states that accidental discharge from the application bath may enter sewers, but has been unable to provide estimates of likely amounts and concentrations, other than a worst case concentration of 1% from accidental spillage. Treatment baths presumably need to be emptied and refilled as the emulsions they contain become spent or contaminated, but the frequency with which this may occur is not apparent in the submission. However, high molecular weight silicone fluids are removed during sewage treatment, with little, if any, discharged in waste waters.

Another possible route for environmental exposure to the modified silicone is wash off from treated fabric, but this is not expected to occur at a significant rate because of the strong affinity of silicones for textile surfaces.

. Formulation, handling and disposal

The notified substance is imported from Japan, presumably without formulation as the local Material Safety Data Sheet refers to 100% amide modified silicone fluid. The product is sold to customers as a 30-40% oil-in-water emulsion containing around 5% of nonionic surfactants. The extent of environmental release arising from formulation is unclear as details of the process were not made available.

8.2 Fate

As noted above, amounts and concentrations of the notified substance likely to enter sewers are unclear. The notified substance is hydrophobic but carries hydrophilic substituents. However, the length of the hydrophobic backbone and the relatively low number of hydrophilic substituents suggest that this modified silicone will be promptly removed from solution by adsorption onto sludge with little, if any, likely to be contained in treated waste waters. Sludge containing the notified substance may then be incinerated or landfilled. Incineration would destroy the substance and liberate oxides of carbon, nitrogen 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 (1).

As noted above, the hydrolytic stability of this modified silicone is unclear. However, hydrolysis products do not appear to be of significant ecological concern. The amine hydrolysate is listed on Australian Inventory of Chemical Substances (AICS) and would remain as a biocompatible component of the sediment. The corresponding carboxylated lauroxyethoxylate is similar to other surfactants listed on AICS and would partition to the aqueous phase where biodegradation can be expected to follow, based on its structure.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological testing is not a requirement under the *Industrial Chemicals (Notification and Assessment) Act, 1989* (the Act) for polymers with an average number molecular weight greater than 1000. However, a skin irritation study on the notified chemical was carried out with a patch test in humans. Additionally, an *in vitro* test for mutagenicity and a skin sensitisation study in guinea pigs (both tests using one of the reaction ingredients as the test substance) were carried out and included in the submission.

9.1.1 Skin Irritation patch test in humans (2)

The data included results of a patch test to the skin of the back in humans. Details of methodology, including the method of application, were not available. Twenty test subjects were evaluated, both macroscopically and microscopically, after 24 hours application of the test compound. Microscopical examination showed that 2 subjects had some deep furrows on examination. Macroscopically there were no signs of erythema, oedema or papules. The notified chemical would appear to have negligible irritant potential in humans.

9.1.2 Skin Sensitisation (3)

T-19, an ingredient in the reaction mixture producing the notified chemical was assessed for skin sensitisation potential in guinea pigs by the maximisation method.

Groups of ten female Hartley guinea pigs received six, separate injections into a shaved scapular area: two injections of each of the following:

. Freund's complete adjuvant 0.05 ml;
. APMS fluid (0.05 ml 100% undiluted) or 0.05 ml 2,4-dinitrochlorobenzene (DNCB) at a concentration of 1% (W/V) in olive oil ;
. 0.05 ml of APMS fluid or DNCB, emulsified in Freund's complete adjuvant.

DNCB served as positive control. Two negative control groups of ten animals were untreated until challenge.

On day six, the scapular area of treated rats was shaved again and 10% lauryl sodium sulfate was applied to the site. Next day, filter paper moistened with either 0.3 g T-19 in oil or 0.3 ml DNCB, as appropriate, was applied to the site and covered with an occlusive dressing for 48 hours.

On day 20, a new site on the back was shaved and, on day twenty-one, 0.3g of either T-19 or 0.3 ml DNCB 1% was applied under an occlusive dressing for 24 hours. Although this procedure was described in the test report as 'induction' it appears to have been the challenge procedure.

The negative control groups underwent this challenge procedure and received either T-19 or DNCB without prior induction and sensitisation.

Challenge sites were observed 24 and 48 hours after removal of the occlusive dressing. No animals in either negative control group showed any redness or reaction to the challenge substances. DNCB produced mild to severe erythema 24 hours after induction which was increased at the 48 hour interval. Seven animals had crusts on the reaction sites. Four of the animals receiving T-19 exhibited slight erythema 24 hours after challenge. At 48 hours six animals showed moderate erythema.

The test substance T-19, an ingredient in the reaction mixture producing APMS fluid, was found to be a mild sensitiser. The significance of this result is questionable.

9.2 Genotoxicity

9.2.1 Reverse Mutagenicity Study (4)

The mutagenic potential of T-19 in dimethylsulfoxide (DMSO) was determined using *Salmonella typhimurium* strains TA 100, TA 1535, TA 98, TA 1537 and *Eschericia coli* WP2uvrA. S-9 mix was used as the metabolic activator.

The test compound was dissolved after heating at 85°C in DMSO. Positive controls were also dissolved in DMSO. Controls were chosen as follows:

with S9 mix: 2-aminoanthracene (2-AA)

without S9 mix: N-ethyl-N'-nitro-N-nitrosoguanidine (ENNG);
2-nitrofluorene (2-NF): and
9-aminoacridine hydrochloride (ACR).

Bacteria were incubated with T-19 in concentrations ranging from 156-5000 ug/plate at 37°C for a period of 48 hours. DMSO was used as the vehicle control.

Concentrations of 5000 ug/plate T-19 were found to inhibit growth of *S. typhimurium* TA 100, TA 1535, TA 98, TA 1537 in the absence of S-9 mix and of strain TA 1535 and TA 1537 in the presence of S-9 mix. Growth of the *E. coli* strain was not affected.

There was no increase in the number of revertant strains with any concentration of T-19 in any of the tested strains of bacteria, with or without S9 mix. All positive controls produced marked increases in the number of revertant colonies.

T-19 was found not to be mutagenic against *S typhimurium or E coli* in vitro.

9.3 Overall Assessment of Toxicological Data

A patch test in humans found the notified chemical to have negligible skin irritant potential.

Two toxicology tests - a skin sensitisation study and a genotoxicity study, were submitted on one of the ingredients in the reaction mixture which produces APMS fluid. The ingredient

in the reaction mixture (T-19) was not found to be mutagenic in vitro but was found to be a weak sensitiser in guinea pigs. The tested compound has a molecular weight of approximately 15000 compared to the molecular weight of 34400 for the notified chemical. The relevance of the submitted data is therefore difficult to assess.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of NAMW > 1000 according to the Act. The high molecular weight and low solubility of the substance suggest that it will not cross biological membranes, and will therefore be of low toxicity. It is well accepted that polydimethylsiloxane fluids become permanent residents of sediment but should not exert adverse environmental effects. Physical effects such as surface entrapment have been observed when testing aquatic invertebrates in clean laboratory water, but similar effects are not expected in natural environments where a large variety of other surfaces provide opportunities for deposition (1).

While the polymer contains secondary amine functionalities, which when quaternised are known to interact with gill membranes, environmental behaviour of this modified silicone is expected to be dominated by the siloxane backbone, which will rapidly align itself at or on surfaces. The toxicity of quaternary ammonium compounds is known to be greatly reduced in the environment because of preferential binding to dissolved organics in surface water (5), and the hydrophobic properties of the polydimethylsiloxane chain will further moderate any toxicity which may arise through quaternisation of its amino substituents.

11. ASSESSMENT OF ENVIRONMENTAL HAZARDS

As noted above, the notifier has been unable to provide estimates of typical amounts and concentrations of this modified silicone likely to be discharged from textile factories. In the worst case situation of accidental discharge of the bath to the sewer, the daily budget of fabric conditioner may be released all at once, at a concentration in the order of 1%. Assuming 10% of total use at an inland location where production occurs on 300 days each year, the worst case daily discharge would be

around 3.3 kg. Passage through sewage treatment works, assuming daily flow of 5 ML, would dilute this discharge to below 1 ppm.

Calculations such as the above indicating the degree of dilution of textile waste streams before they reach the environment are not particularly meaningful for strongly surface active compounds, which tend to undergo essentially complete removal through sorptive processes during waste water treatment. However, the above exercise confirms that unacceptable concentrations of the new modified silicone fluid should not enter the environment.

Water soluble, polyether substituted polydimethylsiloxane fluids are widely used as home laundry fabric softeners and personal hair care products, applications which involve potential aquatic exposure. The introduction of a more hydrophobic but otherwise similar compound for industrial use is not expected to lead to a significant increase in environmental hazard, given the biocompatible nature of these substances.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY

The notifier has stated that exposure to the chemical will be at room temperature during the processing of textiles. During the process of weighing and mixing chemicals, exposure by skin contact or eye contact with the notified chemical in its pure form may occur. Good housekeeping procedures and personal protective equipment will be recommended. Workers handling wet fabrics should also wear personal protective equipment to minimise skin contact although the irritant potential of the chemical is expected to be low.

Vapour pressure for a polymer of molecular weight 34000 is expected to be minimal at room temperature, however, there is no precise information on vapour pressure and there may be some inhalational exposure, particularly to volatile impurities, during the drying process at 105^{O}C which takes place at the end of the treatment.

13. RECOMMENDATIONS

The following guidelines and precautions should be observed when using APMS fluid:

. Good housekeeping procedures should be observed to avoid splashes and exposure to the chemical by skin or eye contact.

. Areas in which APMS fluid is to be used should have local exhaust ventilation or good general ventilation. Where possible, fabrics treated with products containing APMS fluid should be dried within a space which does not vent to the workplace.

. Material safety data sheets (MSDS) for APMS fluid and products containing it should be freely available to workers handling these chemicals.

  Workers using APMS fluid or products containing it should wear protective clothing conforming to AS 3756.1 (6), goggles conforming to AS 1337-1984 (7) and impervious gloves conforming to AS 2161-1978 (8).

14. MATERIAL SAFETY DATA SHEET(S)

The Material Safety Data Sheet (MSDS) for Amido polyether modified silicone fluid (Attachment 1) was provided in Worksafe Australia format (9).This MSDS was provided by Dow Corning Australia Pty Ltd as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Dow Corning Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of APMS fluid 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) Hamelink, J.L (1992), Silicones in The Handbook of Environmental Chemistry, Vol 3: Detergents, N.T.de Oude (ed).

(2) Result of Skin Patch Test. Japanese Society for Cutaneous Health. KAWAI Medical Laboratory for Cutaneous Health, 60 Hinaminishino-Cho, Nishinanajyo, Shimogyo,

(3) Test report: Skin Sensitisation Test of T-19 in guinea pigs (maximisation method), Life Science Laboratory 5-19, 2 chome Nishihonmachi. Nishi-Ku. Osaka, Japan.

(4) Reverse Mutagenicity Study using microorganisms of T-19. Life Science Laboratory 5-19, 2 chome Nishihonmachi. Nishi-Ku Osaka, Japan.

(5) Goodrich M S, Dulak H L, Friedman M A and Lech J J. Environmental Toxicology and Chemistry 10, 509-515, 1991.

(6) Australian Standard 3765.1-1990. Clothing for Protection against Hazardous Chemicals. Part 1: Protection against General or Specific Chemicals. Standards Association of Australia Pub, Sydney 1990.

(7) Australian Standard 1337-1984. Eye Protectors for Industrial Applications. Standards Association of Australia Publ, Sydney 1984.

(8) Australian Standard 2161-1978. Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves). Standards Association of Australia Publ, Sydney 1978.

(9) Guidance Note for Completion of a Material Safety Data Sheet [NOHSC: 3001 (1991)], 3rd Edition, October 1991.