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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

NECON LO-80

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

NECON LO-80

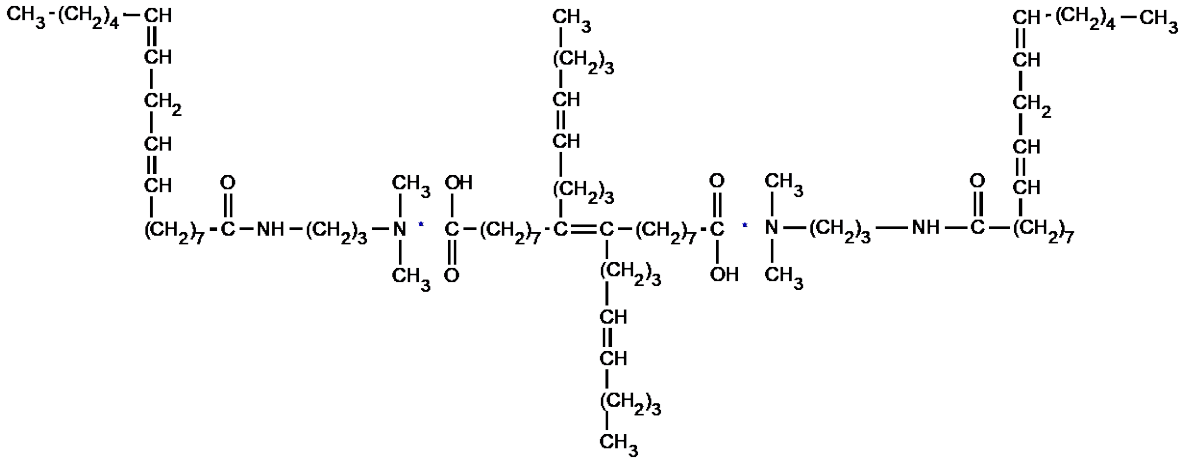
1. APPLICANT

Bristol-Myers Company Pty Ltd of 320 Victoria Road, Rydalmere NSW 2116 has applied for an assessment certificate and submitted a limited notification statement for Necon LO-80. The notified chemical will be used as a cationic, antistatic, hair conditioning agent with cosmetics.

2. IDENTITY OF THE CHEMICAL

Chemical name:	Linoleamidopropyldimethylamine Dimer Dilinoleate; Bis (linoleamidopropyl Dimethyl Amine) Dimer Dilinoleate
Chemical Abstracts Service (CAS) Registry No.:	125804-10-6
Other names:	Necon LO-80
Molecular formula:	$(C_{23}H_{44}N_2O)_2.C_{36}H_{64}O_4$

Structural formula:



Molecular weight: 1228

Method of detection and determination: Infrared Spectrum

Spectral data:

functional group	peaks (cm^{-1})
cis carbon-carbon bonds	725, 3010
carboxylic acid and carboxylic ion	1260, 1400, 1550, 2930
tertiary amine	1180
secondary amine	1650, 3070, 3300

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: clear, amber viscous liquid

Odour: amine-fishy odour

Boiling Point: >188°C

Density: 0.940 x 10^3 kg/m^3

Vapour Pressure: not determined. The vapour pressure was calculated to be 7.4 X 10^{-2} Pa.

Water Solubility: 40 mcg/L at 20°C

Fat Solubility: not provided

Partition Co-efficient (n-octanol/water) log P_{ow}: not available

Hydrolysis as a function of pH: not determined. Notified chemical is virtually insoluble in water

Adsorption/Desorption: not available

Dissociation Constant pK_a**:** not available

Flash Point: 160°C

Flammability Limits: is combustible

Combustion Products: ammonia, carbon monoxide and/or carbon dioxide, nitrogen oxides

Decomposition Temperature: not provided

Decomposition Products:	not provided
Autoignition Temperature:	not available
Explosive Properties:	not explosive
Reactivity/Stability:	based on structure low probability of reactivity

Comments on Physico-Chemical Properties

The substance contains amide functionalities which could hydrolyse, however, this is not expected to occur under environmental conditions due to the low solubility in water.

As a result of the low solubility in water, the P_{ow} is expected to be high.

As a result of the expected high P_{ow}, strong adsorption is expected.

The notified substance contains carboxylic acid and tertiary amine functionalities as an ionic complex, without any readily ionisable groups. As the complex is not expected to dissociate in water and has low solubility, measurement of the dissociation constant would be difficult.

4. PURITY OF THE CHEMICAL

Degree of purity

The notified chemical is a reaction product. Material is predominantly Linoleamidopropyl Dimethylamine Dimer Dilinoleate ~80%; Oleamidopropyl Dimethylamine Dimer Linoleate ~ 10%; salts of palmitic and stearic acid ~10% and glycerine as a reaction by-product.

Additives/Adjuvants: none

5. INDUSTRIAL USE

The notified chemical will be imported as a clear amber viscous liquid for incorporation into formulated hair care products. The hair care products are intended to be manufactured in Australia. The initial import volume is approximately 200 kg rising to 400-500 kg per year.

6. OCCUPATIONAL EXPOSURE

Necon LO-80 will be imported by air or sea freight and stored in closed mild steel, epoxy phenolic lined drums of 200 L capacity at below 30ºC. Upon importation the notified chemical will be transported by road to the formulation facility. All transport of the notified chemical inside and outside the formulation facility will be in these unbreakable containers. Up to 10 handling/formulation workers may come into possible contact with the notified chemical via the oral/dermal route during the handling, transportation, storage and preparation of mixtures containing the Necon LO-80. All workers handling the chemical are expected to be wearing impervious gloves and safety goggles complying to the Australian Standard. The exposure is expected to be for 3 hours/day, 4 days/year.

Up to 4 quality control operators are also expected to come into contact with the notified chemical during the sampling and testing of the mixtures containing the notified chemical. There is potential here for exposure to the oral or dermal route by splashing of the notified chemical. The exposure is expected to be for 2 hours/day, 4 days/year.

Approximately 20 manufacturing operators are responsible for the dispensing of the chemical and the compounding of the product containing the chemical. Dispensing the chemical is expected to involve exposure to the chemical for 1 hour/day 12 days/year, the compounding taking 8 hours/day, 24 days/year.

The exposure to the notified chemical during the dispensing and formulation stages is expected to be minimal as the majority of the process takes place within a closed system thereby reducing occupational exposure.

It is expected that there may also be dermal exposure of the notified chemical to hairdressers in the hair conditioning agent. Exposure would be limited to a 2% solution within the hair conditioner.

7. PUBLIC EXPOSURE

Necon LO-80 can be incorporated into various cosmetic formulations but the notifier states that the substance will only be used in hair conditioning products in amounts up to 2% w/w, generally as a liquid formulation. Consequently there will be significant public exposure to the notified chemical in this diluted form. Minor public exposure to the undiluted notified chemical may result from accidental spillage during transport and storage, and during reformulation. Disposal of the chemical after accidental spillage will be carried out by a licensed waste disposal contractor to approved landfills.

8. ENVIRONMENTAL EXPOSURE

Release

Releases to the environment should be limited to those that occur during formulation and use. The formulation and packaging of the hair care products are to be performed in a closed system. During formulation and packaging of the hair care products the equipment used is expected to be washed and cleaned occasionally. The company has not indicated where these washings will be disposed of but they are expected to be by discharge to the sewer.

The hair care products containing the notified chemical are expected to be used in bathrooms and other wet areas throughout Australia. All of the product is expected to enter the sewers from these wet areas and to be treated with the sewage before being released to the environment.

Fate

Most of the imported chemical will be discharged to the sewer and is expected to be trapped with the solids in the sludge, due to the low solubility in water. The sludge from sewage treatment works is normally landfilled or incinerated.

As the notified chemical is derived from natural fatty acids, it has a number of functional groups that are expected to undergo biodegradation. However, due to the low water solubility biodegradation is likely to be slow.

9. EVALUATION OF TOXICOLOGICAL DATA

Under the conditions for a limited notification toxicological data is not required. The notifier however has provided some summary toxicological data for assessment.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Necon LO-80

Test	Species	Outcome
Acute oral toxicity	Rat	LD_{50} > 5.0 g/kg
Skin Irritation	Rabbit	irritant
Eye irritation	Rabbit	non irritant

9.1.1 Oral Toxicity

Result: there were no significant toxicological observations.

LD_{50}: > 5.0 g/kg

Species/strain: Albino Rats

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration (vehicle): notified chemical in safflower oil (2 %) administered by gavage .

Clinical observations: no significant observations

Mortality: no deaths *Morphological findings:* no significant observations

Test Method: According to US Codes of Federal Regulations 16 (16 CFR 1500.3)

9.1.2 Skin Irritation

Result: produced well defined to moderate erythema and slight to well-defined edema. Mean erythema formation score of 2 indicates that notified chemical is classed as a hazardous substance.

Species/strain: New Zealand White rabbit

Number of animals: 6

Method of administration: single dermal application (0.5ml of a 2.0% v/v solution in safflower oil) onto an abraded and intact test site.

Draize (1) scores[1]

	intact skin		abraded skin	
rabbit number	**24 hours**	**72 hours**	**24 hours**	**72 hours**
Erythema and Eschar formation				
1	2	3	2	2
2	2	3	2	3
3	2	2	2	2
4	2	3	2	3
5	2	2	2	2
6	2	2	2	2
Oedema formation				
1	2	1	2	1
2	2	2	2	2
3	2	1	2	1
4	2	1	2	1
5	2	0	2	1
6	2	1	2	1

[1] see attachment 1

Test Method: According to US Codes of Federal Regulations 16 (16 CFR 1500.41)

9.1.3 Eye Irritation

Result: not an eye irritant

Species/strain: New Zealand White rabbits *Number of animals:* 6

Method of administration: a single intraocular application of 0.1 ml of test sample (2%) in one eye. The contralateral eye was untreated and served as a control.

Test Method: According to US Codes of Federal Regulations 16 (16 CFR 1500.42)

Draize (1) Scores [2]

Animal	**Time after instillation**														
	1 day			**2 days**			**3 days**			**4 days**			**7 days**		
CORNEA:	opacity area			opacity area			opacity area			opacity area			opacity area		
1	0		0	0		0	0		0	0		0	0		0
2	0		0	0		0	0		0	0		0	0		0
3	0		0	0		0	0		0	0		0	0		0
4	0		0	0		0	0		0	0		0	0		0
5	0		0	0		0	0		0	0		0	0		0
6	0		0	0		0	0		0	0		0	0		0
IRIS															
1		0			0			0			0			0	
2		0			0			0			0			0	
3		0			0			0			0			0	
4		1			1			0			0			0	
5		0			0			0			0			0	
6		0			0			0			0			0	
CONJUNCTIVA	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]
1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

[2] see attachment 1
[a] redness [b] chemosis [c] discharge

9.4 Overall Assessment of Toxicological Data

From the limited data provided the notified chemical was found to have a low oral toxicity and not to be an eye irritant. According to Worksafe Approved Criteria For Classifying Hazardous Substances (2), Necon LO-80 is classed as hazardous due to its skin irritancy.

Although the criteria do not require the chemical to be classed as hazardous on the basis of eye irritation, the chemical has been classified in the MSDS. This is

acceptable since precautions suitable for eye irritants should be observed for skin irritants.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicity data was presented by the applicant. This is acceptable according to the *Act* for small volume chemicals.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified chemical (approximately 400 kg per annum) is expected to be disposed of via the sewer. When the sewage is treated it is expected to become part of the sludge due to the low solubility in water or to be degraded. The sludge from the sewage treatment works is normally incinerated or landfilled. Incineration of the notified chemical will produce water together with the oxides of carbon and nitrogen. When landfilled, the notified chemical is not expected to leach from landfill due to the low solubility in water.

The predicted environmental exposure has been calculated as 2 ppb per day in the effluent, based on all of the notified chemical entering Australia being used in Melbourne (720 ML of effluent per day) and none removed during treatment of the sewage. These assumptions are extreme and the actual exposure is expected to be significantly less.

Accidental releases due to spills and transport accidents is, according to the MSDS, adsorbed and disposed of according to Federal, State and Local regulations. In most cases this is expected to be by secure landfill.

The overall environmental hazard can be rated as negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Necon LO-80 was found to have low oral toxicity (LD_{50} > 5.0 g/kg), was a skin irritant but was not an eye irritant. Due to the skin irritancy the notified chemical is classed as hazardous according to Worksafe Approved Criteria For Classifying Hazardous Substances (2).

The levels of exposure to Necon LO-80 during shipping and transport are expected to be negligible as the notified chemical will be in strong sealed containment. Significant exposure to the notified chemical via the dermal route is only likely to occur in the event of a spill.

There may be some exposure to the notified chemical during the handling of the chemical for preparation of mixtures or during quality control sampling via the dermal or oral route by splashing or spillage. This however should be minimised by the utilisation of personal protective equipment such as safety goggles and impervious

gloves. In the interests of safe handling it is also recommended that appropriate industrial clothing be worn to reduce the risk of dermal exposure.

There is not expected to be any significant exposure to the notified chemical during dispensing or reformulation as the majority of the processes take place within a closed system, thereby reducing the risk of major occupational exposure.

The chemical will be incorporated at a maximum concentration of 2% w/w in hair conditioning products and therefore public exposure will be significant. The notified substance may be a slight skin irritant to humans, but given the normal manner of using hair conditioner where exposure is only brief and generally followed by thorough rinsing, the substance is unlikely to pose a significant health risk. The potential for minor public exposure to the undiluted chemical exists during reformulation, transport and disposal of the chemical if accidentally spilt. This is minimised by the recommended practices during reformulation and transportation. The same level of risk also applies to hairdressers utilising the conditioning agent, however the frequency of exposure to the notified chemical will be greater than the general public. This may result in dermal irritancy in which case appropriate hand protection (plastic gloves) should be employed.

The overall risk from Necon LO-80 is considered to be minor due to the reduced risk of any significant occupational exposure and the relatively low levels of toxicity. There is a however the potential for skin irritancy and any dermal exposure to the notified chemical should be minimised if not through normal usage as a conditioning agent.

13. RECOMMENDATIONS

To minimise occupational exposure to Necon LO-80 the following guidelines and precautions should be observed:

- if engineering controls and work practices are insufficient to reduce exposure to Necon LO-80 to a safe level, then:
    - eye protection should be selected and fitted in accordance to AS 1336 (3)and used in accordance to AS/NZS 1337 (4).
    - industrial clothing must conform to AS 2919 (5) and AS 3765.1 (6)
    - industrial gloves should conform to AS 2161 (7) and AS 3765.1 (6).
    - all occupational footwear should be selected in accordance and conform to AS/NZS 2210 (8).
- particular care should be taken to avoid spillage or splashing of the notified chemical.
- good personal hygiene should be practised to minimise the potential for ingestion.

- a copy of the Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Necon LO-80 was provided in an acceptable format (9).

This MSDS was provided by Bristol-Myers Company Pty Ltd as part of their notification statement. The accuracy of this information remains the responsibility of Bristol-Myers Company Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Necon LO-80 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. Draize, JH, 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* **49.**

2. National Occupational Health and Safety Commission, 1994, *Approved Criteria For Classifiying Hazardous Substances [NOHSC:1008 (1994)],* AGPS, Canberra.

3. Standards Australia , 1994, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment.*, Standards Association of Australia Publ. Sydney, Australia.

4. Standards Australia, Standards New Zealand 1992, *Australian/ New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

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

6. Standards Australia, 1990, *Australian Standard 3765-1990 Clothing for Protection Against Chemical Hazards, Part 1 Protection Against General or Specific Chemicals, Part 2 Limited Protection Against Specific Chemicals,* Standards Association of Australia Publ., Sydney, Australia.

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

8. Standards Australia, Standards New Zealand 1994, *Australian/ New Zealand Standard 2210 - 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications,* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

9. National Occupational Health and Safety Commission, *Guidance Note for the Completion of a Material Safety Data Sheet,* 2nd. edition, AGPS, Canberra, 1990.

Attachment 1

[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. 1mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

[2] 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 translu cent 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.	Disharge 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