File No.: NA/562

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

ASSESSMENT REPORT
(Full Public Report)

NECON LO-80

Under subsection 38(5) of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act), the Director of Chemicals Notification and Assessment publishes this assessment report by giving a copy of it to:

- the Chief Executive Officer of the National Occupational Health and Safety Commission (Worksafe Australia);
- the Secretary of the Department of the Environment, Sport, and Territories;
- the Secretary of the Department of Health and Family Services; and
- the Department of Occupational Health, Safety and Welfare (Western Australia).

This assessment report will be available for inspection by the public.

Director
Chemicals Notification and Assessment

October 1997

NECON LO-80

1. APPLICANT

Bristol-Myers Squibb Australia Pty Ltd of 320 Victoria Road RYDALMERE NSW 2116 has applied for an assessment certificate and submitted a standard notification statement for 'NECON LO-80'. This chemical has previously been notified as NA/316 by the aforementioned applicant. No application for exempt information was made by the notifier, and the Assessment report is published here in its entirety.

2. IDENTITY OF THE CHEMICAL

Chemical Name: 9,12-octadecanoic acid (Z,Z)-, dimer, compound with (Z,Z)-N-[3-(dimethylamino)propyl]-9, 12-octadecadienamide (1:1)

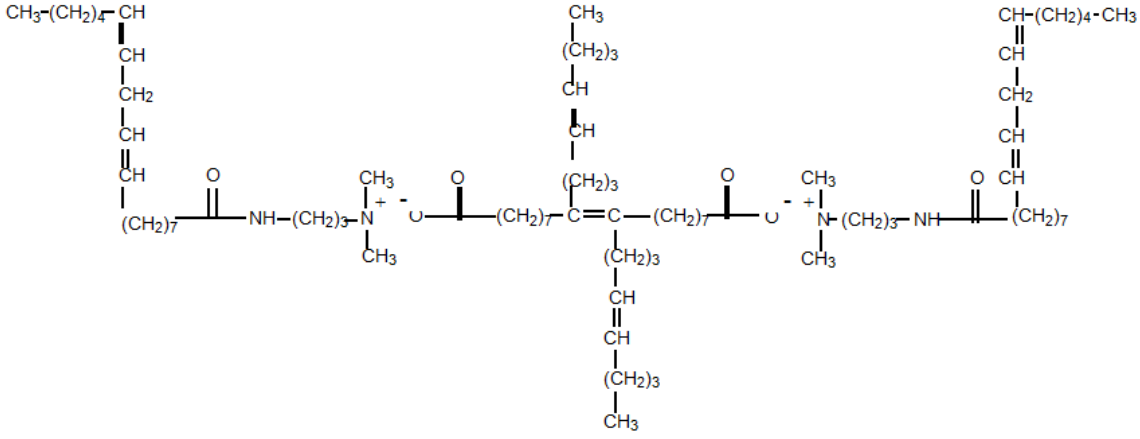
Chemical Abstracts Service (CAS) Registry No.: 125804-10-6

Other Names: linoleamidopropyl dimethylamine dimer dilinoleate
bis (linoleamidopropyl dimethyl amine) dimer dilinoleate

Trade Name: NECON LO-80

Molecular Formula: $(C_{23}H_{44}N_2O)_2.C_{36}H_{64}O_4$

Structural Formula:



Molecular Weight:	1 290
Method of Detection and Determination:	infrared (IR) spectroscopy
Spectral Data:	major IR peaks in the IR spectrum found at 725, 1 180, 1 260, 1 400, 1 550, 1 650, 2 930, 3 010, 3 070, 3 300 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	amber viscous liquid, with mild amine odour
Boiling Point:	> 188°C
Specific Gravity:	0.940 at 20^0C
Vapour Pressure:	7.4 x 10^{-2} kPa (calculated by Environment Australia)
Water Solubility:	40 $\mu g.L^{-1}$ at 20^oC (Nephelometric technique)
Partition Co-efficient (n-octanol/water):	not determined
Hydrolysis as a Function of pH:	not determined
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined
Flash Point:	160°C (Cleveland cup - open)
Flammability Limits:	not determined; combustible
Autoignition Temperature:	not determined
Explosive Properties:	not explosive
Reactivity/Stability:	not very reactive

Comments on Physico-Chemical Properties

The boiling point, density, vapour pressure and solubility reported are for NECON LO-80 which contains 80% of the notified chemical, the other 20% being similar compounds but with slightly different fatty acids and glycerine.

The solubility of 40 $\mu g.L^{-1}$ at 20°C is an estimate for NECON LO-80 using a Nephelometric technique. The product contains up to 5% glycerol, a substance soluble in water. Hence the actual solubility of the notified chemical may be even lower than 40 $\mu g.L^{-1}$.

The notified chemical contains amide functionalities that could undergo hydrolysis. However, this is not expected to occur in the environmental pH range (4-9) due to the low solubility in water.

Due to its very low solubility the chemical is likely to have a high octanol/water partition coefficient (Log P_{ow}).

Due to the expected high Log P_{ow}, the chemical will bind strongly to the organic matter in the soil and be immobile. The chemical is an organic salt with carboxylic acid and tertiary amine functionalities which are fully dissociated in water. However the extremely low water solubility would make the measurement of dissociation constant difficult. The chemical is likely to have some surface activity and due to the presence of amine and carboxylic acid functionalities it is likely to show some properties of surfactants.

4. PURITY OF THE CHEMICAL

Degree of Purity: 80%

Toxic or Hazardous Impurities: none

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

Chemical name:	glycerine
Weight percentage:	5%
CAS No.:	56-81-5
Chemical name:	oleamidopropyl dimethylamine dimer dilinoleate
Weight percentage:	10%
CAS No.:	not available
Chemical name (a):	stearamidopropyl dimethylamine dimer dilinoleate

Chemical name (b):	palmitamidopropyl dimethylamine dimer dilinoleate
Weight percentage (a)+(b):	5%
CAS No's.:	not available

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported into Australia in liquid form at a concentration of approximately 80%. Import volumes for the notified chemical are expected to be 4 to 5 tonnes per annum over the next five years.

The notified chemical will be used in four different hair care products that will be sold into the consumer market. One of these, Hydrience hair dye kit, containing a colourant tube and a conditioner sachet will be formulated in Australia. The increased import volume from the previous notification is for the manufacture of the colourant in this kit, the conditioner having being covered in the previous submission. Conditioner for three other hair dye kits (Nice'n Easy, Ultress, and Natural Instincts) also containing the notified chemical are imported as ready to sell sachets. The products Ultress and Natural Instincts were covered in the previous submission. Nice'n Easy conditioner is a new addition to the range of products with the notified chemical. Details of the four products containing the notified chemical are tabulated below.

Product	Formulation in Australia	Pack	% of notified chemical
Hydrience Hair Dye			
Colourant	Yes	60 g tube	4%
Conditioner	Yes	15 g sachet	2%
Nice'n Easy Hair Dye			
Conditioner	No	12.5 g sachet	2%
Ultress Hair Dye			
Conditioner	No	15 g sachet	2%
Natural Instincts Hair Dye			
Conditioner	No	15 g sachet	2%

The notified chemical will be imported in 200 L epoxy phenolic resin-lined steel drums. These will be transported by road to the notifier's warehousing and manufacturing site in Rydalmere, NSW. During the manufacture of the Hydrience hair care product, the drums are opened and required amount per batch [typically 7 kg (for conditioner) or 14 kg (for colourant)] is manually poured into buckets and

weighed. These are taken by trolley to 360 kg mobile mixing tanks and mixed with other ingredients, while stirring with an overhead stirrer. After mixing to required standard, the stirrer is removed and the tank connected to a filling machine. The formulated product is filled into 60 g laminated plastic tubes with screw tops.

The conditioner product (about 10% of the total production) is filled into 14 g laminated paper sachets by a contractor, Hallpack Pty Ltd, Gladesville, NSW. For this, the formulated product is transported by road, in 200 L drums from the notifier's site to the contractor's. There the contents are pumped directly from the drum into the sachets using a filling machine. Filled sachets taken back to the notifier's site are packed with the colourant into boxes as hair care kits and marketed.

6. OCCUPATIONAL EXPOSURE

All transport of the notified chemical inside and outside the formulation facility will be in these unbreakable 200 L containers. Up to 10 handling/formulation workers may come into possible contact with the notified chemical via the dermal route during the handling, transportation, storage and preparation of mixtures containing the Necon LO-80. The exposure is expected to be for 3 hours/day, 10 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 at this phase of operations for exposure to the oral, ocular or dermal routes by splashing of the notified chemical. The maximum potential for exposure is expected to be for 2 hours/day, 60 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 30 days/year, the compounding taking 8 hours/day 60 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.

7. PUBLIC EXPOSURE

NECON LO-80 will be incorporated into a hair dye colourant at 4% and hair conditioners at 2%. Thus there may be significant public exposure to the notified chemical in this diluted form by dermal contact. The colourant containing the notified chemical will be diluted 1:1 with a developer before being applied to the hair. Minor public exposure to the undiluted notified chemical may result from accidental spillage during transport and storage.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier has provided the following worst case estimates for the annual waste of the chemical in various aspects of formulating and handling; dispensing, 50 kg; mixing, 20 kg; filling (notifier), 20 kg; filling (contract manufacturer), 5 kg; washing equipment, 80 kg; residue in drums, 125 kg and spills and leaks, 30 kg. These wastes add up to a total of 330 kg per annum which is approximately 10% of the import volume.

Small spills are absorbed into absorbent material that will be disposed of to landfill. Larger spills are recovered as much as possible and placed in 200 L drums. These wastes as well as empty drum residues are disposed of by a licensed waste contractor. Mixing tank, stirrer, transfer lines and the filling machine are cleaned with water. These washings are passed through an on-site waste water treatment system before discharge to the sewer. At the contractor filling the conditioner sachets for the Hydrience hair kit, it is estimated that about 0.6 kg of the chemical (30 kg of conditioner) per annum would be washed into the waste water during the cleaning of the filling machine. This waste water is passed through a settling tank on site, the sludge from which is removed by a waste disposal contractor as required.

The hair care products containing the notified chemical are expected to be used in bathrooms and other wet areas throughout Australia. More than 95 % of the import volume is therefore expected to enter the sewer.

Fate

The bulk of the notified chemical discharged to the sewer is expected to be trapped within the solids of the sludge, due to the low water solubility. The sludge from the sewage treatment plants will be either landfilled or incinerated. Part of the waste from formulation and handling will also be landfilled or incinerated the rest being sent to the sewer after passing through the treatment plants of the two companies involved.

Ready biodegradability investigated in a Closed Bottle Test (1) with sodium benzoate as a control showed after 28 days, the biodegradation to be 46% at a concentration of 0.8 $mg.L^{-1}$. Hence the notified chemical does not qualify as readily biodegradable. However, up to 39% biodegradation occurred within the first 10 days and more extensive biodegradation may be indicated in inherent biodegradability tests given the natural fatty acid composition of the chemical.

Low solubility, expected high Log P_{ow}, and the lack of ready biodegradability all suggest a potential for bioaccumulation. However, the high molecular weight of the chemical is likely to make it too large to be absorbed across biological membranes and thereby limit the bioaccumulation potential (2,3)

In landfill, the chemical will remain bound to or associated with the soil. Incineration will destroy the chemical by converting it to water and oxides of carbon

and nitrogen.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of NECON LO-80

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg.kg^{-1}	(4)
acute dermal toxicity	rat	LD_{50} > 2 000 mg.kg^{-1}	(5)
skin irritation	rabbit	strong irritant	(6)
eye irritation	rabbit	non-irritant	(7)
skin sensitisation	guinea pig	sensitiser	(8)

9.1.1 Oral Toxicity (4)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	oral (gavage); vehicle was safflower oil
Clinical observations:	slight depression immediately after treatment, but animals returned to normal after a period of three hours
Mortality:	none
Morphological findings:	no abnormalities
Test method:	similar to OECD guidelines (1)
LD_{50}:	> 2 000 mg.kg^{-1}
Result:	the notified chemical was of low oral toxicity to rats

9.1.2 Dermal Toxicity (5)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	a single dose of the notified chemical (as a 10% w/w safflower oil solution) was spread evenly over the shaved dorsal area of each rat, covered with a gauze patch, and left for 24 hours
Clinical observations:	no abnormalities
Mortality:	nil
Morphological findings:	no abnormalities
Test method:	similar to OECD guidelines (1)
LD_{50}*:*	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low dermal toxicity to rats

9.1.3 Inhalation Toxicity

not determined

9.1.4 Skin Irritation (6)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	one male, 2 females
Observation period:	21 days; all signs of skin irritation had disappeared after this time.
Method of administration:	the notified chemical was used undiluted; 0.5 mL of the notified chemical was applied to the shaved dorsal area of each animal and covered with a semi-occlusive dressing for four hours

Draize scores (9):

Time after treatment	Animal # 1 hr	24 hr	48 hr	72 hr	7 days	14 days
Erythema						
1	2	2	2	4	4	3
2	2	2	2	4	4	3
3	2	2	2	4	4	3
Oedema						
1	0	4	4[b]	4	4[c]	3
2	0	4	4[b]	4	4[c]	3
3	0	4	4[b]	4	4[c]	3

[a] see Attachment 1 for Draize scales, [b] skin thickened, c skin thickened and very dry, eschar healing

Test method: similar to OECD guidelines (1)

Result: the notified chemical was a strong irritant to the skin of rabbits in this test

9.1.5 Eye Irritation

Species/strain: rabbit/New Zealand White

Number of animals: 6

Method of Administration: a single intraocular application of 0.1 mL of notified chemical (2%) in one eye; the untreated eye served as a control

Test Method: according to US Codes of Federal Regulations 16

Observations: all Draize scores for the 7-day test period were zero

Result: the notified chemical was not an eye irritant in rabbits when tested at 2%

9.1.6 Skin Sensitisation (8)

Species/strain: guinea pig/Dunkin Hartley

Number of animals: 20 test; 10 control

Induction procedure: 0.5 mL of the notified chemical was applied

at a concentration of 20% w/w in safflower oil epicutaneously on a patch to the animal's right flank and occluded for six hours; the process was repeated each week for three consecutive weeks

Challenge procedure: 14 days after the last induction, the treated group were challenged with 0.5 mL of the notified chemical (10% w/w); this was applied using a occluded patch; exposure was for six hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
10%	17/20	14/20	0/10	2/10

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

Test method: similar to OECD guidelines (1)

Result: the notified chemical was a strong skin sensitiser when tested in guinea pigs

9.2 Repeated Dose Dermal Toxicity (10)

Species/strain: rat/Sprague-Dawley

Number/sex of animals: 30

Method of administration: semi occlusive application to the shaved dorsal area of each rat

Dose/Study duration: three groups of ten rats were treated with doses of 200, 400 and 600 $mg.kg^{-1}.day^{-1}$ The notified chemical was administered daily (except for day 7) for 14 days as 2%, 4% and 6% w/w homogenius solutions in safflower oil

Clinical observations: no signs of systemic toxicity; at high dose ranges erythema and eschar formation was observed at the test site; at the medium dose, animals exhibited peeling skin and erythema

Clinical chemistry/Haematology	no abnormalities
Histopathology:	no gross abnormalities in the major organs
Test method:	similar to OECD guidelines (1)
Result:	there were no signs of systemic toxicity in a 14-day repeat dose dermal toxicity test

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (11)

Strains:	TA100, TA98, TA1535, TA1537
Concentration range:	1, 10, 100, 1 000 and 5 000 µg per plate; vehicle was dimethylsulfoxide (DMSO)
Test method:	similar to OECD guidelines (1)
Result:	the notified chemical was not mutagenic under the conditions of the assay

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (12)

Species/strain:	mouse/B6C3F1
Number and sex of animals:	35/sex
Doses:	100 µL (1 $g.kg^{-1}$) of the notified chemical in safflower oil was administered to each mouse
Method of administration:	intraperitoneal injection
Test method:	similar to OECD guidelines (1)
Result:	the notified chemical was considered non-clastogenic in the mouse micronucleus test at the dose and time intervals evaluated

9.4 Overall Assessment of Toxicological Data

From the data provided the notified chemical was found to have low oral and dermal toxicity (LD_{50} greater tha 2 000 $mg.kg^{-1}$ for both studies), to be a slight eye irritant in rabbits when tested at a concentration of 2%. The notified chemical was also strongly irritating to the skin of rabbits, and to be a moderate to strong sensitiser to the skin of guinea pigs. In the presence or absence of metabolic

activation, the chemical was not mutagenic in bacteria and did not produce chromosome aberrations in a mouse micronucleus study. Repeat dose dermal toxicity studies did not cause any systemic toxicity nor target organ toxicity. According to the National Health and Occupational Safety Commission's *Approved Criteria For Classifying Hazardous Substances* (13), Necon LO-80 is classified as hazardous due to its skin irritancy and sensitisation potential.

The eye irritation studies only assess the eye irritancy potential of the notified chemical at a concentration of 2%. However, the notifier states (see Material Safety Data Sheet) that the notified chemical at 80% is a severe eye irritant and may cause eye damage.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier.

Eastern Rainbow fish

A sub-acute Fish Imbalance Toxicity (FIT) test has been carried out on the fry of the eastern rainbow fish *Melanotaenia duboulayi*, using NECON LO-80 (with 80% of the notified chemical), according to the OECD Guideline No 203. Acetone was used to solubilise the test substance. Four replicates in each of six test concentrations (0.05, 0.5, 1.2, 10, and 40 $mg.L^{-1}$) and water and solvent controls were used with 5 fish per replicate. The final concentration of acetone in the solutions was 0.015 $mg.L^{-1}$ or less. Test conditions were; temperature between 20.6 and 22.4°C, conductivity between 158-183 $\mu S.cm^{-1}$, pH 7.52-7.91 and dissolved oxygen concentration between 94-99 $mg.L^{-1}$. Whether the test solutions remained clear without precipitation throughout the test was not recorded. The 96 h EC_{50} value based on nominal concentrations was found to be 2.7 $mg.L^{-1}$ with a 95% confidence limit of 1.4-5.3 $mg.L^{-1}$. Up to 10% fish imbalance was observed in the diluent water control and the solvent control and this is within the limits allowed in the OECD protocol. The results indicate the test substance to be moderately toxic to fish.

Water flea

Static acute toxicity of NECON LO-80, on the common Australian water flea, *Daphnia carinata* was examined according to the OECD Guideline No 202. Dimethyl sulphoxide (DMSO) was used as the carrier. Synthetic pond water at a pH of 7.8 and $CaCO_3$ hardness of 67 $mg.L^{-1}$ and Mg hardness of 48 $mg.L^{-1}$ was used as the test medium. Six test concentrations (0.32, 0.5, 1.0, 3.2, 5.0, and 10.0 $mg.L^{-1}$) and water and carrier controls were used in replicates of four. DMSO concentration in the test solutions was 0.2 $ml.L^{-1}$ or less. The solutions of the highest two concentrations were slightly opaque indicating some precipitation of the chemical. Between nine and eleven neonate *D.carinata* (<24 h old) were placed in each solution (100 mL) taken in 250 mL beakers. Immobility and death were assessed after 24 h and 48 h with solutions being changed after the 24 h assessment. The immobility at the highest concentration used was only 44% at 24 h, with a NOEC of 1.79 $mg.L^{-1}$. At 48 h there was 100% mortality at the highest

two concentrations and the NOEC was 0.5 $mg.L^{-1}$. Using plots of adjusted probits and predicted regression lines, and nominal concentrations, 24 h EC_{50} of 11.0 $mg.L^{-1}$ (95% CI = 8.1-19.3) and a 48 h EC_{50} of 1.34 $mg.L^{-1}$ (95% CI = 1.1-1.6) were obtained. The test substance is moderately to highly toxic to *Daphnia*.

Algae

Algal growth inhibition test was carried out using NECON LO-80 and the fresh water green alga *Selenastrum capricornutum* according to the OECD Guideline No 210. Acetone was used as the carrier. Test solutions (50 mL) were made using algal culture medium containing EDTA. Testing was done at six concentrations (0.1, 0.5, 1.0, 2.5, 5.0, 10.0, and 20.0 $mg.L^{-1}$) plus water and carrier controls prepared in triplicate. The concentration of acetone in the test solutions was 0.1% or less. Algae were placed in the solutions at a concentration of 1.25 x 10^4 cells/mL and maintained at 24±2°C in continuous light of 4000±10% lux. The pH is said to have varied between 5 and 10 during the experiment but details have not been provided. The cell density was measured daily for 3 days and the growth rate determined as the slope of the regression line for log_{10} cell density versus time (h). Cell division rate per day (3.32 x growth rate x 24) was then calculated. The bioassay was considered valid if the controls had cell division rates greater than 1.5 doubling per day and values of ever 2.0 were observed. Results showed the 72 h LC_{50} to be 0.75 $mg.L^{-1}$ (95% CI 0.65-0.88) and the NOEC to be 0.1 $mg.L^{-1}$. The test substance is highly toxic to algae.

The results of environmental toxicity testing are summarised below:

Test	Species	Results (Nominal)
Sub-acute Fish Imbalance Toxicity	*Melanotaenia duboulayi*	96 h EC_{50} = 2.7 $mg.L^{-1}$
Acute Immobilisation	*Daphnia carinata*	24 h EC_{50} = 11.0 $mg.L^{-1}$ 24 h NOEC = 1.8 $mg.L^{-1}$ 48 h EC_{50} = 1.3 $mg.L^{-1}$ 48 h NOEC = 0.5 $mg.L^{-1}$
Algal Growth Inhibition	*Selenastrum capricornutum*	72 h EC_{50} = 0.75 $mg.L^{-1}$ 72 h NOEC = 0.1 $mg.L^{-1}$

Based on estimations using nominal concentrations of NECON LO-80 (containing 80% of the notified chemical) the ecotoxicity data indicate the notified chemical to be highly toxic to algae and moderately to highly toxic to aquatic invertebrates and fish.

Chemicals with aliphatic amine functionality are thought to exhibit acute toxicity even when they have high Log P_{ow} values because they self disperse forming micelles in water (3)

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The company has provided data on the expected national sales per annum for each of the four products containing the notified chemical. They also predict the sales in Sydney and Melbourne to be 20% and 15%, respectively, of the national sales. Using this information, the percentage of the chemical in the various products, and assuming that all of the chemical will enter the sewer, the average amount of chemical released to the sewer per day has been calculated as 1.5 kg for Sydney and 1.2 kg for Melbourne. The total daily effluent volumes discharged into the sewer systems in Sydney and Melbourne are about 910 ML and 890 ML respectively. With this large dilution the concentration of the chemical in the sewer would be 1.6 ppb in Sydney and 1.3 ppb in Melbourne. Given the low solubility and the expected high partition coefficient, most of the chemical entering the sewer would be adsorbed to the sludge. The concentration of the chemical in the water discharged from the sewer (ie the Expected Environmental Concentration, EEC) would therefore be several orders of magnitude below the toxicity limits of algae, the aquatic organisms most sensitive to the chemical. Hence significant aquatic hazard is unlikely.

Sludge containing the chemical after removal from the sewage treatment plants will be either landfilled or incinerated. In landfill the chemical will remain associated with the soil and undergo slow biodegradation. Incineration will destroy the chemical.

The environmental hazard from the notified chemical can therefore be rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Necon LO-80 was found to have low oral and dermal toxicity. It is a skin irritant, and has the potential to be a severe eye irritant. However, at the concentration tested (2%), the notified chemical was not an eye irritant. Due to its potential to induce skin sensitisation, skin irritation and eye irritation, the notified chemical is classified as hazardous according to Worksafe *Approved Criteria For Classifying Hazardous Substances* (13).

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.

Worker exposure (skin, eye and oral) to splashes of the notified chemical during the formulation of hair care products will pose the greatest hazard as the notified chemical is at a high concentration (approximately 80%).

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

The chemical will be incorporated at levels of 4% in a hair dye colourant and 2% in hair dye conditioners and therefore public exposure to the notified chemical will be significant. Animal toxicity studies suggest that the major public health concern is the potential for skin irritation and sensitisation. The colourant containing the notified chemical will be diluted 1:1 with a developer before being applied to the hair. Plastic disposable gloves will be provided with the hair dye kit for use when handling the colourant. The potential for minor public exposure to the undiluted chemical exists during reformulation, transport and disposal of the notified chemical if accidentally spilt.

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. Exposure may result in dermal irritancy and skin sensitisation in which case appropriate hand protection (plastic gloves) should be employed. The notifier states that less than 2% of the product would be used professionally as it is mainly for consumer use. It is predicted that repeat exposure in hair salons will be low.

The overall risk from Necon LO-80 is considered to be minor due to the reduced risk of any significant occupational exposure. There is a however, the potential for skin irritancy and sensitisation, and any dermal exposure to the notified chemical should be minimised.

13. RECOMMENDATIONS

To minimise occupational exposure to NECON LO-80, the following guidelines and precautions should be observed for workers:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (14) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (15);
- Industrial clothing should conform to the specifications detailed in AS 2919 (16);
- Impermeable gloves or mittens should conform to AS 2161 (17);
- All occupational footwear should conform to AS/NZS 2210 (18);
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

The Department of Health and Family Services recommend that the following warning statements be included on the labels of hair colourant containing the notified chemical for consumer protection:

May irritate the skin.
Repeated use may cause skin sensitisation.
Wear gloves when using this product.

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* (19).

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. Organisation for Economic Co-operation and Development 1995-1996, *OECD Guidelines for the Testing of Chemicals on CD-Rom*, OECD, Paris.

2. Connell, D.W. 1989, 'General characteristics of organic compounds which exhibit bioaccumulation', in *Bioaccumulation of Xenobiotic Compounds*, CRC Press, Boca Raton.

3. Nabholz, J.V., Miller, P. & Zeeman, M. 1993, 'Environmental Risk Assessment of New Substances under the Toxic Substances Control Act Section Five', in *Environmental Toxicology and Risk Assessment, American Society for Testing and Materials*, ASTM STP 1179, Philadelphia, pp. 40-55.

4. Brook, F. 1997, *Acute Oral Toxicity of NECON LO-80*, ICP Firefly Pty Ltd, Sydney, Australia.

5. Brook, F. 1997, *Acute Dermal Toxicity of NECON LO-80 in the Rat*, ICP Firefly Pty Ltd, Sydney, Australia.

6. Brook, F. 1997, *Acute Dermal Irritation/Corrosion of NECON LO-80 Batch 6RA5K3041 (MO306) in the Rabbit*, ICP Firefly Pty Ltd, Sydney, Australia.

7. Breach, J. 1996, *Full Public Report - NECON LO-80*, Worksafe Australia, Sydney, Australia.

8. Ho, E. 1997, *Skin Sensitisation Potential of NECON LO-80 in the Guinea Pig*, ICP Firefly Pty Ltd, Sydney, Australia.

9. Draize, J.H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, vol. 49, pp. 2-56.

10. Ho, E. 1997, *14-Day Repeated Dose Dermal Toxicity of NECON LO-80 in the Rat*, ICP Firefly Pty Ltd, Sydney, Australia.

11. Bonin, A.M. 1997, *Bacterial Mutagenicity Test of NECON LO-80*, ICP Firefly Pty Ltd, Sydney, Australia.

12. Bonin, A.M. 1997, *Genetic Toxicology Micronucleus Test of NECON LO-80 in the B6C3F1 Mouse*, ICP Firefly Pty Ltd, Sydney, Australia.

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

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

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

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

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

18. 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.

19. 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