File No: NA/303

Date: 22 April 1996

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

OCTADECANAMIDE

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989,* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 565-9466 **FAX (61) (02) 565-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

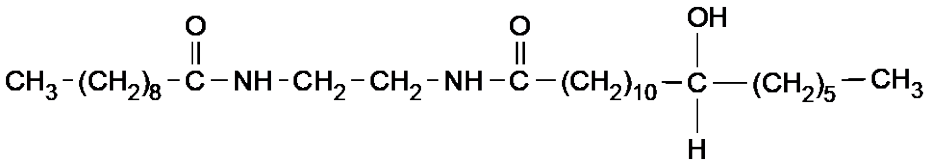
OCTADECANAMIDE

1. APPLICANT

TR Chemicals Pty Ltd of 195 Briens Road NORTHMEAD NSW 2152 has submitted a standard notification statement in support of their application for an assessment certificate for Octadecanamide.

2. IDENTITY OF THE CHEMICAL

Chemical name:	octadecanamide 12 hydroxy-n-(2-((1-oxo-decyl)amino)ethyl)
Chemical Abstracts Service (CAS) Registry No.:	146781-64-8
Other name:	EHR 100/3
Trade name:	not marketed as a pure substance but as a component of the flow control agent Crayvallac Super
Molecular formula:	$C_{30}H_{60}N_2O_3$
Structural formula:	



Number Average Molecular weight (NAMW):	496

Method of detection and determination: infrared spectrum analysis

Spectral data: infrared spectral data was provided for Crayvallac super which contains octadecanamide. The notified chemical does not exist outside this formulation

wave number (cm^{-1})	characteristic
3292	N-H amide stretch
3100	overtone of carbonyl group
2912	aliphatic C-H stretch
2852	aliphatic C-H stretch
1640	carbonyl C=0 of amide group (stretch)
1560	C-N of amide group, stretch, also N-H bend
1468	aliphatic CH_2 and CH_3 bend
1372	CH_3 bend
1200	CN stretch, NH bend
696	$(CH_2)_n$ rocking where n=4 or more

3. PHYSICAL AND CHEMICAL PROPERTIES

Physico-chemical properties are for the formulation, Crayvallac Super, containing the notified chemical and two other fatty acid amides produced by the reaction between ethylene diamine, decanoic acid and 12-hydroxystearic acid. Octadecanamide does not exist outside of this formulation.

Appearance at 20°C and 101.3 kPa: fine, off-white powder

Melting Point: 120-130°C

Specific Gravity: 0.99 at 25°C

Vapour Pressure: not determined

Water Solubility: < 670 mg/m^3

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

Hydrolysis as a function of pH: very slow hydrolysis could occur at high pH to release fatty acids and ethylene diamine

Adsorption/Desorption: not determined

Dissociation Constant

pK_a**:**	not determined
Flash Point:	>150°C
Flammability Limits:	not determined
Combustion Products:	carbon monoxide
Autoignition Temperature:	not determined
Explosive Properties:	is combustible and may pose a fire hazard when exposed to heat or flame
Reactivity/Stability:	not determined
Particle size distribution:	range 1.8-15 µm

Comments on physico-chemical properties

The notified chemical has not been isolated from the Crayvallac Super reaction mixture. Therefore, the physico-chemical properties given are for Crayvallac Super consisting of three amides.

The solubility of Crayvallac Super has been determined by refluxing a small amount of it in deionised water, cooling, filtering and then calculating the weight loss to the water medium. The figure obtained represents the combined solubilities of the three components and any hydrolysis products that may have formed.

The notifier suggests that the chemical may undergo slow hydrolysis at high pH to release ethylene diamine and the two fatty acids. An estimated half-life for hydrolysis of 190 days is reported in the US EPA's ASTER database for the similar fatty acid amide N,N-distearoylethylenediamine (CAS 110-30-5).

Partition coefficient has not been determined or estimated. For the related fatty acid amide ASTER predicted a very high unrealistic partition coefficient (Log P = 15.5). The partition coefficient of the notified substance would be expected to be high.

Due to the low solubility and expected high octanol-water partition coefficient the chemical may be expected to adsorb strongly to soil and sediment.

The chemical does not contain any readily dissociable groups.

4. PURITY OF THE CHEMICAL

Degree of purity: cannot be isolated as a pure product.

Toxic or hazardous impurities: none

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

impurity	CAS #	percentage
octanoic acid	124-07-2	0.28%
dodecanoic acid	143-07-7	0.28%
12 hydroxystearic acid	106-14-9	3.20%
decanoic acid	334-485-5	1.84%

5. INDUSTRIAL USE

The notified chemical will be imported as a component (33%) of Crayvallac Super, a powdered flow control agent for paint that has been used internationally for over 5 years. The import volume of the notified chemical will not exceed 10 tonnes per year.

6. OCCUPATIONAL EXPOSURE

Octadecanamide, as a component of Crayvallac Super (at approximately 33%), will be imported into the country in 25 kg multiwall paper bags within shipping containers. The containers will be shipped to a warehouse facility where the bags will be removed by up to eight warehouse workers, and shrink-wrapped on palettes to be stored under cover. Dispatch will be in 600 kg palette loads or bag quantities. Any torn bags will be sealed prior to dispatch. Ventilation/extraction systems will be utilised to minimise any possible dust explosion resulting from spillage.

At the customer site, up to twelve process workers will be involved in the manual discharge of the bags containing Crayvallac Super into the product mix or an intermediate container before adding to the mix. The quantity added to the paint mixture will be 0.5-2.0% of the paint formulation. The powder will be added into small scale industrial paint mixers containing solvents such as xylene and white spirits. The paint will then be tinned in volumes of 20 L or 200 L by automated processes to be distributed to sites of industrial application. Mechanical ventilation will also be utilised to reduce air borne dust and solvent vapour concentrations.

The paint formulations containing the notified chemical will be utilised in ventilated spray booths in vehicle finishing and industrial applications. As the extent of the future customer distribution is not known, the number of people potentially exposed to the notified chemical cannot be determined.

7. PUBLIC EXPOSURE

The paint, which is rapid curing, will be used in vehicle refinishing formulations and industrial applications, being applied in spray booths.

The potential for public exposure to octadecanamide is low. The chemical will not be sold to the public and is to be used only for industrial applications. The paint adheres to the surface of the painted article, and will not be released directly into the environment.

8. ENVIRONMENTAL EXPOSURE

Release

Formulation, handling and disposal

Crayvallac Super is transported by road in 600 kg loads, to four paint manufacturers, one in Queensland, two in Victoria and one in New South Wales. Occasional torn bags (estimated as 1 in 1000) are tape sealed. Environmental release during transport is expected to be negligible.

The company estimates that 0.5% of Crayvallac Super could be lost during paint formulation. These wastes are disposed of by landfill or incineration.

Use

The major source of release to the environment during use is the overspray that can vary from 5-20% depending on whether low or high pressure spray guns are used. Up to a maximum of 2 tonnes of the chemical can be released annually to the environment due to overspray. This held on protective medium such as paper, along with other minor wastes due to spills, are disposed of to either landfill or incineration.

Fate

The chemical will be released to the environment in two ways; (a) as the finished paint on vehicles and other industrial surfaces (b) in the form of waste from spillage during paint manufacture, overspray during application, unused paint, washing of spray equipment, etc.

Environmental exposure from finished paints will be low as the notified substance will be encapsulated in a durable matrix. Similarly, environmental exposure from wastes consigned to landfill will be low as the notified substance would be expected to have low mobility by virtue of its low water solubility. Incineration would destroy the notified substance.

The chemical may undergo slow hydrolysis releasing decanoic acid, 12 hydroxy-stearic acid and ethylene diamine. These breakdown products would not be expected to persist in the environment.

The low solubility and the expected high octanol-water partition coefficient indicate that the chemical has potential to bioaccumulate, but significant exposure of aquatic organisms is not expected.

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicity data is available for either octadecanamide or Crayvallac Super. A limited number of reports containing information on an analogue, ethylene bis stearamide, has been submitted. This information does not comply to an acceptable laboratory report standard, however, most of the reports appear to be written before the adoption of Good Laboratory Practice standards which may account for this. The analogue information has been accepted as indicative of the toxicology of octadecanamide on the basis of chemical similarity and a supporting independent toxicological review by Associate Professor G Crank of Unisearch Ltd (1). Professor Crank performed an independent literature search and assessment upon the notified chemical and it's proposed analogue .

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of ethylene bis stearamide (an analogue for octadecanamide)

Test	Species	Outcome	Reference
Acute oral toxicity	Rat Mouse	LD_{50} > 15.38 g/kg LD_{50} > 20.00 g/kg	(2)
Acute dermal toxicity	-	not determined	
Acute inhalational toxicity	Rat	not toxic by inhalation	(3)
Skin Irritation	Rabbit	non irritant	(2)
Eye irritation	Rabbit	slight irritant	(2)

9.1.1 Oral Toxicity (2)

Study 1

Species/strain: rat-strain not specified

Number of animals: 4 rats per treatment group

Observation period: not specified

Method of administration: ethylene bis stearamide was administered as a 50% suspension in corn oil between 1.35-15.38 g/kg

Clinical observations: not provided

Mortality: none

Morphological findings:	no abnormalities were observed
Test method:	not specified
LD_{50}:	> 15.38 g/kg
Result:	ethylene bis stearamide was not toxic by oral administration

Study 2

Species/strain:	mouse-strain not specified
Number of animals:	10
Observation period:	not specified
Method of administration:	ethylene bis stearamide was administered as a 50% suspension in corn oil at 20 g/kg
Clinical observations:	not provided
Mortality:	none
Morphological findings:	no abnormalities were observed
Test method:	not specified
LD_{50}:	> 20 g/kg
Result:	ethylene bis stearamide was not toxic by oral administration

9.1.2 Dermal Toxicity

not determined

9.1.3 Inhalation Toxicity (3)

Species/strain:	rats- strain not specified
Number/sex of animals:	not specified
Observation period:	172 hours/1 month
Method of administration:	rats were exposed to ethylene bis stearamide at 112 mg/m^3 for 6 hours. Fluids and cells were obtained with a bronchoalveolar lavage from control and treatment animals 0, 24, 48, 172 hours or 1 month post-exposure for cellular and biochemical assessment
Clinical observations:	ethylene bis stearamide produced a mild inflammatory response at 24 hours post-exposure but was comparable to control animals by 48 hours. This was probably due to the chemical acting as a nuisance dust; there were no significantly different biochemical parameters between treatment and control groups and there was no reported adverse effects on the morphological or phagocytic capacity of pulmonary macrophages
Mortality:	none
Morphological findings:	there were no pathologically significant findings
Test method:	none specified
Result:	ethylene bis stearamide was not toxic by inhalation

9.1.4 Skin Irritation (2)

Species/strain:	rabbit- strain not specified
Number of animals:	6
Observation period:	6 hours
Method of administration:	500 mg of ethylene bis stearamide in 1.2 ml of polyethylene glycol (a concentration of around 40%) was applied under dressing to the skin of the rabbit for 6 hours

Test method:	none specified
Result:	ethylene bis stearamide produced a slight irritation

9.1.5 Eye Irritation (2)

Species/strain:	rabbits- strain not specified
Number of animals:	6
Observation period:	24 hours
Method of administration:	100 mg of ethylene bis stearamide in 0.4 ml polyethylene glycol (concentration of about 25%) was instilled into the conjunctival sacs of the rabbits eyes and then rinsed 24 hours later with saline
Test method:	none specified
Result:	slight irritation (maximal after 1 hour); this may have been due to ethylene bis stearamide acting as a nuisance dust

9.2 Repeated Dose Toxicity (2)

Species/strain:	rats-strain not specified
Number/sex of animals:	study 1: 5/sex/treatment group study 2: 20/sex/treatment group
Method of administration:	oral administration of ethylene bis stearamide, vehicle not specified
Dose/Study duration::	rats were either controls or fed ethylene bis stearamide 0.5% (Low Dose), 2.0% (Medium Dose) or 5% (at 2.5 g/kg/day)(High Dose) for two studies-1) 15 weeks and culled after a week of normal feeding or 2) fed for 2 years before being culled
Clinical observations:	many rats died from intercurrent pneumonia infections, and survival after 2 years was only around 20% (Low Dose), 30% (Medium Dose) and 40% (High Dose) for the three test groups as compared with 40% of the controls of each

	sex
Clinical chemistry/Haematology	there were indications of an adverse effect on growth at all dose levels in the females, but there was no clear adverse effects on levels of haemoglobin and red or white blood cells or urine appearance
Histopathology:	there was no clear adverse effects the microscopic appearance of the heart, lung; observations after 2 years fails to show any treatment related effects, liver, kidney and spleen
Test method:	none specified
Result:	ethylene bis stearamide was not shown to be hazardous by repeat oral administration

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (2)

Strains:	*Salmonella typhimurium and Escherichia coli* - strains not specified
Concentration range:	not specified, was performed both with and without S9 rat liver metabolic activation
Test method:	ethylene bis stearamide was not found to be mutagenic
Result:	not specified

9.4 Overall Assessment of Toxicological Data

The assessment of octadecanamide is difficult given that the notified chemical does not exist outside the three component system of Crayvallac Super and therefore no toxicity data exists for the notified chemical, as well as there being no toxicity information on Crayvallac Super. The analogue data presented for ethylene bis stearamide, while inadequate, does appear to demonstrate the low toxicity of this class of compounds. It can be expected from extrapolating the analogue data that octadecanamide/Crayvallac Super would exhibit very low oral toxicity and inhalational toxicity, as well as having low skin and mild eye irritancy properties. There were no significant findings from repeat dose toxicity studies, also indicating that the notified chemical is unlikely to be a carcinogen. There were also no significant findings from bacterial mutagenicity studies. As the effective combined

molecular weight of Crayvallac Super due to crosslinking between components will be > 1000, it is not anticipated that it will cross any biological membranes.

These findings have been supported by an independent toxicological review of the submitted data by Unisearch Limited (1). The report confirms the similarity in nature of octadecanamide to ethylene bis stearamide and that the lack of toxicity in the analogue data does suggest that the notified chemical is unlikely to pose a toxicological hazard. It also adds that this class of fatty acid amides has not been identified in toxicological literature as being significantly toxic or a health hazard. It is suggested by the report that because of the low water solubility it is unlikely the notified chemical would be soluble in gastrointestinal fluids and thus it is unlikely that the compound would be significantly absorbed through the gastrointestinal tract and cause systemic toxic properties. This assumption is supported in published literature (4)

According to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (5), octadecanamide is not classed as hazardous on account of the expected low toxicity indicated by the analogue data.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

According to the Act, environmental effects testing is essential for chemicals with NAMW < 1000 and imported at rates greater than 1 tonne per year. The notifier has requested variation from this requirement on the basis that the notified substance is used as a surface coating, has low water solubility, and is expected to be of low toxicity as fatty acid amides of similar structure have low toxicity.

It is true that fatty acid amides of similar structure have low mammalian toxicity, but this does not allow the conclusion that toxicity to fish would also be low. No data are available on the toxicity of this class of chemical to fish.

The remaining arguments presented by the notifier, that the chemical is used in a surface coating and has low water solubility, allow the conclusion that exposure of aquatic organisms to the notified substance would be low. No adverse effects on aquatic organisms would be expected because of the low exposure.

Breakdown products may be toxic to aquatic organisms but would not be expected to reach toxic levels as environmental exposure to the notified substance will be low and the breakdown products will not persist in the environment.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Up to 6 tonnes of Crayvallac Super containing 2 tonnes of the notified chemical can be lost as waste generated mainly during spray painting operations.

Although the chemical has some potential to bioaccumulate its low solubility and expected high Log P_{ow} will ensure that the waste disposed to landfill will remain bound to soil with little chance of contaminating waterways.

Environmental hazard of the chemical can therefore be rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Because octadecanamide is not isolated, any exposure to the notified chemical will be as part of Crayvallac Super. Based on the analogue data provided for ethylene bis stearamide, octadecanamide is unlikely to cause any acute oral toxicity or repeat dose toxicity in humans. It is also unlikely that the notified chemical has any genotoxic potential in humans. As a part of Crayvallac Super, the notified chemical has the potential for mild respiratory, eye and skin irritation. These are not believed to be from any treatment related effect, rather the irritancy is more likely due to the powder's potential as a nuisance dust. This chemical was approved previously for a commercial evaluation, from which no adverse effects to workers were observed.

There is unlikely to be any significant exposure to the notified chemical during importation due to the containment of the bags containing Crayvallac Super. There is not expected to be any exposure during dispatch except in the event of a spill which would be easily contained as it is a powder. There may be a risk of dust explosion in the event of a spillage, however this should be minimised with the use of ventilation to reduce airborne particles.

At the customer sites during formulation of the notified chemical into paint products there may be the potential risk of a dust explosion and possibly breathing difficulties during direct discharge of the Crayvallac Super formulation into the mix or intermediate containers. Mechanical ventilation will be employed as a primary protective measure to reduce airborne particles and solvent. This will be complemented by the use of respiratory protection by the workers during formulation. It is also proposed to regularly check workers exposed to the solvents and Crayvallac Super powder for any skin or bronchial problems

There is potential of exposure to the notified chemical during paint application. Spray painting is expected to be used within ventilated booths by personnel with the appropriate protective clothing, protective eye wear and respiratory protection to reduce exposure to any possible hazardous constituents of the paint. It is expected that this should also reduce the potential for exposure to the notified chemical.

The potential for public exposure to octadecanamide is low. The chemical will not be sold to the public and is to be used only for industrial application. The chemical will not be released directly onto the environment. There is negligible risk of any direct exposure with the notified chemical as it is manufactured as part of a three component formulation and is never isolated from the Crayvallac Super.

In the case of accidental spillage during transport, the public may be exposed to Crayvallac Super containing octadecanamide. This would be minimised by the use of recommended practices for storage and transportation.

13. RECOMMENDATIONS

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

- local exhaust ventilation should be implemented where there is the likely hood of dust or aerosol generation. Levels of dust exposure should not exceed 10 mg/m^3

- if engineering controls and work practices are insufficient to reduce exposure to octadecanamide to a safe level, then:

  Spillage of Crayvallac Super.

  - all spillages should be swept up or vacuumed. If necessary water should be added to prevent dust generation. Disposal should be by incineration

  - the appropriate respiratory device should be selected and used in accordance with Australian Standard/ New Zealand Standard (AS/ NZS) 1715 (6) and should comply with AS/NZS 1716 (7)

  - eye protection should be selected and fitted in accordance with AS 1336 (8) and used in accordance with AS/NZS 1337 (9)

  - industrial clothing should conform to the specifications detailed in AS 2919 (10)

  - industrial gloves should conform to the standards detailed in AS 2161 (11)

  Formulation and Use

  - the appropriate respiratory device should be selected and used in accordance with Australian Standard/ New Zealand Standard (AS/ NZS) 1715 (6) and should comply with AS/NZS 1716 (7)

  - eye protection should be selected and fitted in accordance with AS 1336 (8) and used in accordance with AS/NZS 1337 (9)

  - industrial clothing should conform to the specifications detailed in AS 2919 (10)

  - industrial gloves should conform to the standards detailed in AS 2161 (11)

- keep containers securely sealed and store in a well ventilated area away from oxidisers and ignition sources

- a copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees

14. MATERIAL SAFETY DATA SHEET

The MSDS for octadecanamide was provided in an acceptable format according to Worksafe Australia's *National Code of Practice for the Preparation of Material Safety Data Sheets* (12).

This MSDS was provided by TR Chemicals Pty Ltd as part of their notification statement. The accuracy of this information remains the responsibility of TR Chemicals Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Octadecanamide 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. Crank, G, 1995, *Opinion on the Toxicology of EHR 100/3,* Unisearch Limited, Sydney, Australia.

2. Bibra Toxicology International, 1989, *Bibra Toxicity Profile - Ethylene Bis Stearamide,* Bibra Information and Advisory Service, Surrey, Great Britain.

3. Warheit, DB, Carakostas, MC and Hartsky, MA, 1977, "Assessments of lung toxicity to Acrawax C following acute inhalation exposure." *Drug Chem. Toxicol.,* 13(1), 1-18.

4. Klaassen, CD, 1980, 'Absorption, Distribution, and Excretion of Toxicants' in Doull, J, Klaassen, CD and Amdur, MO (eds) *Casarett and Doull's Toxicology*, MacMillan Publishing, New York.

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

6. Standards Australia, Standards New Zealand, 1994, *Australian/New Zealand Standard 1715-1994 Selection, Use and Maintenance of Respiratory Protective Devices.* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

7. Standards Australia, 1991, *Australian Standard 1716-1991 Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Australia.

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

9. 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.

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

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

12. National Occupational Health and Safety Commission, 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011 (1994),* AGPS, Canberra.