File No: NA/601

May 1998

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

# FULL PUBLIC REPORT

## Disodium Wheatgermamphodiacetate

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act), and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment 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, National Occupational Health and Safety Commission, 92-94 Parramatta Road, Camperdown NSW 2050, between the following hours:

| | |
|---|---|
| Monday - Wednesday | 8.30 am - 5.00 pm |
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For enquiries please contact the Administration Coordinator at:

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Director
Chemicals Notification and Assessment

# Disodium Wheatgermamphodiacetate

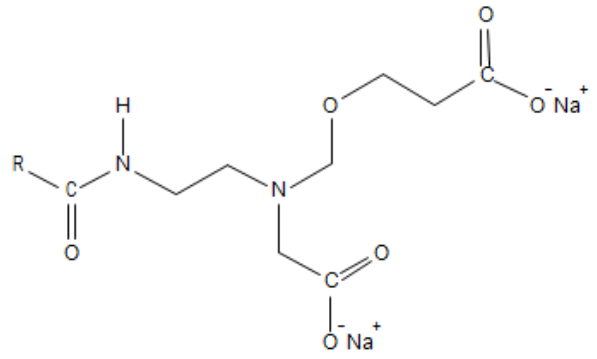
## 1. APPLICANT

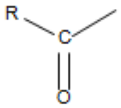
Bristol-Myers Squibb Australia Pty Ltd of 320 Victoria Road RYDALMERE NSW 2116 has applied for the following information relating to 'disodium wheatgermamphodiacetate'. No application for exempt information was submitted by the notifier and the report is published here in its entirety.

## 2. IDENTITY OF THE CHEMICAL

| | |
|---|---|
| **Chemical Name:** | imidazolium compounds, 1-(2-(carboxymethoxy)ethyl)-1-(carboxymethyl)-4,5-dihydro-2-norwheatgerm oil alkyl, hydroxides, inner salts, disodium salts |
| **Chemical Abstracts Service (CAS) Registry No.:** | not assigned |
| **Other Names:** | disodium wheatgermamphodiacetate |
| **Trade Name:** | MACKAM 2W |
| **Molecular Formula:** | A representative molecular formula based on the predominant fatty acid (linoleic acid) would be: $C_{26}H_{44}N_2O_6.2Na$ |

**Structural Formula:**



Where  represents the fatty acids derived from wheatgerm oil

**Molecular Weight:** the molecular weight corresponding to the representative molecular formula is 527 $g.mol^{-1}$; the molecular weight range for the constituents is 525-531 $g.mol^{-1}$.

**Weight Percentage of Ingredients:** 100%

| *Chemical Name* | *CAS No.* | *Weight %* |
|---|---|---|
| saturated fatty acids (eg stearic acid) | - | 15 |
| oleic acid | 112-80-1 | 30 |
| linoleic acid | 60-33-3 | 44 |
| linolenic acid | 463-40-1 | 11 |

**Method of Detection and Determination:** infra-red spectral data has been provided for the chemical

**Spectral Data:**
1 600 and 1 650 cm-1 (secondary amide)
700 and 3 020 cm-1 (cis C-C bonds)
1 450 and 1 600 cm-1 (carboxylic acid)
1 200 cm-1(tertiary amine)
1 150 cm-1 (ether)
2 900 cm-1 (carbon-hydrogen bonds)

## 3. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance at 20°C and 101.3 kPa:** clear amber viscous liquid with a mild organic odour

**Boiling Point:** ~105°C

**Specific Gravity:** 1.02

**Vapour Pressure:** not determined (see comments below)

**Water Solubility:** ~ 40% (see comments below)

**Partition Co-efficient (n-octanol/water):** log $P_{ow}$ ~ 0.5

**Hydrolysis as a Function of pH:** stated to be stable over a pH range of 3-11; outside this range it hydrolyses to the fatty acids of wheat germ oil and a chelating agent

**Adsorption/Desorption:** not determined (see comments below)

| | |
|---|---|
| **Dissociation Constant:** | not determined (see comments below) |
| **Flash Point:** | not determined - notified chemical is an aqueous solution |
| **Flammability Limits:** | not determined - notified chemical is an aqueous solution |
| **Autoignition Temperature:** | > 350°C |
| **Explosive Properties:** | not explosive |
| **Reactivity/Stability:** | non-reactive |

**Comments on Physico-Chemical Properties**

As the notified chemical is a disodium salt of a high molecular compound its vapour pressure is expected to be low.

No reports to support the water solubility and partition co-efficient were provided. Hence, the method by which these values were derived is unknown. As the chemical contains both polar and non polar moieties, it is likely that the chemical will display some surface activity. It is noted that any surface activity would affect the measurement of the partition co-efficient.

No data were provided for the adsorption/desorption behaviour of the notified chemical. Based on the high water solubility and low partition coefficient the chemical should not bind strongly to organic matter in the soil and may potentially be mobile. However, any surface activity would increase the binding of the chemical to soils and sediments.

The notified chemical contains a tertiary amine functionality and carboxylate funtionalities that are expected to have typical basicity. The conjugate carboxylic acid form of the notified chemical would be expected to display typical acidity.

## 4. PURITY OF THE CHEMICAL

| | |
|---|---|
| **Degree of Purity:** | > 99.9% |

**Toxic or Hazardous Impurities:**

| | |
|---|---|
| *Chemical name:* | chloroacetic acid |
| *CAS No.:* | 79-11-8 |
| *Weight percentage:* | < 100 ppm |

| | |
|---|---|
| *Toxic properties:* | toxic by inhalation; toxic in contact with the skin; toxic if swallowed;causes severe burns [1] |

**Non-hazardous Impurities (> 1% by weight):** none

**Additives/Adjuvants:** 3.04%

| | |
|---|---|
| *Chemical name:* | hexylene glycol |
| *CAS No.:* | 107-41-5 |
| *Weight percentage:* | 3% |
| *Toxic Properties:* | irritating to eyes and skin [1] |
| *Exposure Standard:* | 25 ppm (TWA); peak limitation 121 $mg.m^{-3}$ (STEL) [2] |

| | |
|---|---|
| *Chemical name:* | glycolic acid (formed by the breakdown of hexylene glycol) |
| *Weight percentage:* | < 4 % |
| *CAS No.:* | 79-14-1 |

| | |
|---|---|
| *Chemical name:* | butylated hydroxytoluene |
| *Synonyms* | 2,6-di-tert-butyl-*p*-cresol |
| *CAS No.:* | 128-37-0 |
| *Weight percentage:* | 0.02% |
| *Exposure Standard* | 10 $mg.m^{-3}$ (TWA) [2] |

| | |
|---|---|
| *Chemical name:* | hypophosphorous acid |
| *CAS No.:* | 14332-09-3 |
| *Weight percentage:* | 0.02% |

## 5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported as a 25% component of the product, Mackam 2W, in 200 L closed head plastic High Density Polyethylene drums. Import volumes for the notified chemical are expected to be around 200 kg per annum over the first five years.

The product, Mackam 2W, containing the notified chemical will be reformulated into a hair care product at a concentration below 1%. The hair care product will be

packaged in 14 mL sachets and will form part of a hair colourant kit. It is likely that the kits will be used at 4 to 6 weekly intervals by an individual.

## 6. OCCUPATIONAL EXPOSURE

The notified chemical will be stored in sealed unbreakable containers. Worker exposure should not occur during transportation and storage unless packaging is breached. This phase of operation occurs 25 days per year for approximately 2 hours per day.

Workers involved in quality assurance will manually remove appropriate quantities of the notified chemical for analysis. There is potential for exposure of these workers primarily via dermal contact.

Dispensing of the notified chemical involves insertion of a tap into elevated 200 L containers, and manual decanting of required amounts of the notified chemical into 50 L containers. The dispensing area is subject to cross flow ventilation. The closed 50 L containers are taken by trolley to the formulation area where the notified chemical is transferred to the blending vessels under local exhaust ventilation. Operators engaged in dispensing of the 25% aqueous solution of notified chemical for formulation are at most risk of exposure, primarily via dermal contact. All workers may be subjected to ocular exposure, however given the viscous properties of the notifed chemical, it is not so likely that splashes would reach the eye. Exposure by inhalation should be negligible on account of the predicted low vapour pressure of the notified chemical.

## 7. PUBLIC EXPOSURE

The notified chemical is reformulated into hair care preparations at a level of less than 1%. One application would contain less than 0.14 g of the notified chemical, and would be used once every 4 to 6 weeks. In addition, products containing the notified chemical would only be used by a proportion of members of the public who use hair colourant kits and the associated rinse-off hair conditioning products. Although there will be public exposure to the notified chemical, this will be low and restricted given that the concentration of the notified chemical in the products is low, the amount of product used is small and the use is relatively infrequent.

## 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 indicated that these washings will be disposed of through the plant's liquid waste treatment facility and will subsequently be discharged to the sewer. The notifier estimates that such waste would account for less than 1 kg of the notified chemical per annum.

The notifier has estimated that a maximum of 500 g of the product, Mackam 2W, will remain in the import drums after use. At the proposed maximum import of the product this would correspond to a maximum of 1.5 kg of the product (375 g of the notified chemical) per annum. The drums will either be recycled in-house or sold to a drum recycling company.

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

Mackam 2W is intended for use in hair care products and is expected to be released to the environment via consumer use through rinsing the chemical from the hair and into the sewerage system. In the sewer, it is anticipated that some would adsorb to sewage sludge due to the expected surface active nature of the chemical. The sludge will either be sent to landfill or be incinerated. Incineration products will include water and oxides of carbon and nitrogen.

The biodegradability of the notified polymer was not determined. This is acceptable for polymers with import volumes less than 1 tonne per year according to the Act.

No bioaccumulation of the chemical is expected because its very high water solubility and low octanol/water partition co-efficient.

## 9. ASSESSMENT OF TOXICOLOGICAL EFFECTS

No toxicological information was submitted with the notification statement as this is not a requirement for chemicals imported at less than one tonne per annum according to the Act.

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological information was submitted with the notification statement as this is not a requirement for chemicals imported at less than one tonne per annum according to the Act. Calculation of acute toxicity data for the linoleic acid component in acid form yielded $LC_{50}$ values for fish and daphnia between 1 and 5 $mg.L^{-1}$.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The vast majority of notified polymer will be discharged to sewer through product use. As the product will be available nationwide, and sent to sewage treatment plants in both city and country locations, a predicted environmental concentration (PEC) based on continental use has been calculated:

| | |
|---|---|
| Import Volume per annum | 200 kg |
| Amount discharged to sewer | 100% |
| Volume discharged per day | 0.55 kg |
| Sewer output per day* | 2 700 ML |
| Concentration in Sewage Treatment Plant | 0.20 $\mu g.L^{-1}$ (ppb) |

*Sewer output based on an Australian population of 18 million, each using 150 L water per day.

The notifier has estimated that 40% of the product containing the notified chemical will be sold in Sydney. A predicted environmental concentration (PEC) based on Sydney's water use for the year ending 1996 has been calculated:

| | |
|---|---|
| Volume Sold in Sydney per annum | 80 kg |
| Amount discharged to sewer | 100% |
| Volume discharged per day | 0.22 kg |
| Sewer output per day | 1 050 ML |
| Concentration in Sewage Treatment Plant | 0.21 $\mu g.L^{-1}$ (ppb) |

The widespread use, and the resultant low concentration of the chemical in surface waters (well below the estimated toxicities for fish and daphnia) indicates that the overall environmental hazard of the notified chemical can be rated as low.

## 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

No toxicological information was submitted for the notified chemical. However, as it is a typical surface active material with a pH ranging from 8 to 10 it has the potential to cause eye and skin irritation. Airborne mist or spray has the potential to irritate the respiratory tract. On this basis the notified chemical would be classified as hazardous according to the criteria of the National Occupational Health and Safety Commission.

Workers handling the pre-formulated notified chemical (as a viscous 25% liquid) are at most risk of exposure and any consequent adverse health effects. Workers may become contaminated by spills or drips. Given the viscous nature of the chemical, splashing resulting in either skin or eye contact is unlikely to be a major means of exposure. Chances of exposure should also be reduced if workers are equipped with suitable industrial clothing, gloves and goggles. Formulation will be carried out in a closed system and will be carried out under conditions designed not to create aerosols (sampling,dispensing and transfer). Accordingly, the risk of adverse effects on the respiratory system of workers conducting these tasks is likely to be negligible. Both hexylene glycol and butylated hydroxytoluene (ingredients in the mixture containing the notified chemical) have a National Occupational Health and Safety Commission exposure standard [2]. Employers are responsible for ensuring that these exposure standards are not exceeded.

Public contact with the notified chemical will occur, albeit it at relatively low concentrations (less than 1%), of short duration and of intermittent frequency. Provided that the products containing the notified chemical are rinsed-off, the risk of adverse health effects in users appears to be negligible

## 13. RECOMMENDATIONS

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

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 [3] to comply with Australian/New Zealand Standard (AS/NZS) 1337 [4];
- Industrial clothing should conform to the specifications detailed in AS 2919 [5];
- Impermeable gloves or mittens should conform to AS 2161 [6];
- All occupational footwear should conform to AS/NZS 2210 [7];
- Workers handling the formulation should also be informed that it contains hexylene glycol and hydroxybutylated toluene, both of which have exposure standards set by the National Occupational Health and Safety Commission [2];
- 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.

## 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* [8].

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. In particular, Environment Australia would require the notifier to supply test reports for physico-chemical results, full aquatic toxicity data and biodegradation studies if annual import quantities exceed 1 tonne. No other specific conditions are prescribed.

## 16. REFERENCES


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

2. National Occupational Health and Safety Commission, *Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment, [NOHSC:1003(1995)]*, in *Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards*. 1995, Australian Government Publishing Service: Canberra.

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

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

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

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

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

8. National Occupational Health and Safety Commission, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*. 1994, Canberra: Australian Government Publishing Service.