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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Dimethyl 2,6-naphthalene dicarboxylate

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Director
Chemicals Notification and Assessment

Dimethyl 2,6-naphthalene dicarboxylate

1. APPLICANT

Amoco Chemicals Pty Ltd of 28-34 Orange Grove Road LIVERPOOL NSW 2170 has submitted a standard notification statement for dimethyl 2,6-naphthalene dicarboxylate. No application for exempt information was made, hence the Full Public Report is published here in its entirety.

EXEMPT INFORMATION

2. IDENTITY OF THE CHEMICAL

Chemical Name: 2,6-naphthalenedicarboxylic acid, dimethyl ether

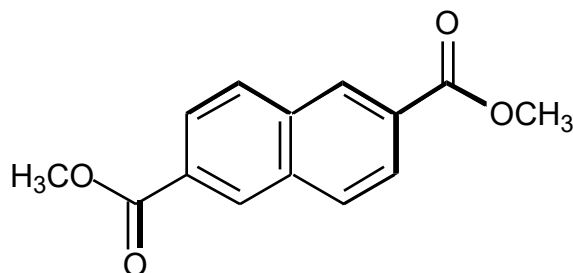
Chemical Abstracts Service (CAS) Registry No.: 840-65-3

Other Names: dimethyl 2,6-naphthalene dicarboxylate
2,6-dicarbomethoxynaphthalene
2,6-naphthalic acid dimethyl ester
dimethyl 2,6-naphthalene

Trade Name: Amoco DM 2,6-NDC

Molecular Formula: C₁₄H₁₂O₄

Structural Formula:



Molecular Weight: 244.15

Method of Detection and Determination: high performance liquid chromatography (HPLC) with ultra-violet detection for organic component, volatility test for remaining solvent, ash test for metals; Nuclear Magnetic Resonance (NMR) spectra for verification of proton shifts; infrared spectroscopy (IR) for identification of functional groups

Spectral Data: IR spectrum, major characteristic peaks at 778, 845, 915, 931, 958, 1 034, 1 132, 1 182, 1 232, 1 340, 1 978, 1 438, 1 678, 1 719, 2 972 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: white crystals

Melting Point 190°C

Boiling Point: 378°C

Specific Gravity/Density: 0.92 g.mL^{-1}

Vapour Pressure: 2.4×10^{-5} kPa at 25°C

Water Solubility: less than 1 mg.L^{-1} at 23°C (see comments below)

Partition Co-efficient (n-octanol/water): not determined (see comments below)

Hydrolysis as a Function of pH: not determined (see comments below)

Adsorption/Desorption: not determined (see comments below)

Dissociation Constant: not determined (see comments below)

Flash Point: not determined

Flammability Limits: not flammable

Autoignition Temperature: not determined

Explosive Properties: stable, normal dangers of organic dust with static charges

Reactivity/Stability: not an oxidising substance, no incompatibilities determined, not prone to spontaneous decomposition, stable

Comments on Physico-Chemical Properties

The data provided for the water solubility is an upper limit. The notifier anticipates that the notified chemical will have a water solubility limit below that of the free carboxylic acid form (see NA/503). Thus, the notified chemical is expected to have a water solubility of less than 1 mg.L⁻¹.

Dimethyl 2,6-naphthalene dicarboxylate is a white crystalline solid with low vapour pressure and high melting point. It is essentially insoluble in water and stable to decomposition at environmental pH and temperature. No non-aqueous solubility data is provided.

The chemical contains ester groups which are potentially able to undergo hydrolysis within the environmental pH range. However, this is not anticipated due to the low water solubility of the chemical.

No data on the partition coefficient of the notified chemical has been provided. A calculated partition coefficient (log P) of 2.84 estimated using the atom/fragment contribution method developed by Syracuse Research Corporation {Syracuse Research Corporation, 1997 #39}.

Absorptivity also has a strong negative correlation with solubility and the low solubility of the chemical suggests that it will have high absorptivity coefficients. The notifier has provided an estimate of log K_{OC} = 2.70 based on the method of Lyman *et al.* {Lyman, 1982 #40}. This value is essentially the same as that estimated for the acid (NA/503).

The notified chemical contains no dissociable hydrogens or basic functionalities.

4. PURITY OF THE CHEMICAL

Degree of Purity: 99.96%

Toxic or Hazardous Impurities: nil

Non-hazardous Impurities:

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight %</i>
2,6 naphthalene dicarboxylic acid	1141-38-4	< 0.001%
methyl formyl naphthoic ester	not available	< 0.004%
monomethyl-2,6,naphthalene dicarboxylate	not available	< 0.01%

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia, but will be imported as a white crystalline or flaky solid in 22.7 kg polyethylene lined fibre drums for distribution to customers. Dimethyl 2,6-naphthalenedicarboxylate may be used as a starting monomer in the manufacture of plastic polymers. The resulting plastic products may be processed into polyester films, containers and fibres used in a range of domestic products from food packages to automobile tyres.

The limited information available on the amount to be imported suggests sufficient for trial development studies only. Imports are expected by the notifier, to remain between 1 to 2 tonnes per annum until the year 2 000.

6. OCCUPATIONAL EXPOSURE

Dimethyl 2,6-naphthalenedicarboxylate will be imported in 22.7 kg polyethylene lined fibre drums, to be supplied to plastic manufacturers for trial product runs. Waterside, warehouse and transport workers will not come into contact with the notified monomer except in the event of accident or leaking packaging.

The potential for exposure is most likely during handling of the monomer during process trials and polymer production. Dermal exposure may occur when workers transfer the notified chemical to a process vessel. Accidental eye contact may also occur at this stage. The final concentration of the notified chemical in the polymer mix will vary but could be up to 100%.

The notifier states that inhalational, dermal and ocular exposure to the notified chemical will be minimised during polymer manufacture, as these processes essentially occur in continuous, enclosed automated plant, and will be carried out under local exhaust and general ventilation. If dimethyl 2,6-naphthalenedicarboxylate is used in full scale commercial manufacture of polymer, then it will be packaged in 1 000 kg bags. The system for transferring to processing from these bags is automated and enclosed. Due to these controls, the risk to workers is likely to be low.

Workers may also come into contact with plastic products containing the notified chemical after manufacture. Dermal contact would be expected to be the main route of exposure, for example when transferring raw polymer for further processing or loading polymer products into packages for delivery. Since the monomer will almost entirely be incorporated into the polymer, exposure to the notified chemical at this time would be negligible and limited to any remaining residual monomer.

7. PUBLIC EXPOSURE

No public exposure to the notified chemical is expected to occur during its distribution or storage at manufacturing sites.

The public is expected to have extensive contact with some polymer products containing the notified chemical such as food and beverage containers, and the packing material used for pharmaceuticals and cosmetics. However the public is unlikely to have significant contact with other products (used in the electronic and automotive industry) containing the notified chemical.

Migration of the notified chemical from PEN plastic to four food simulating solvents has been shown to occur (**notifier to provide full reference**). Water, olive oil and 15% and 3% w/v aqueous solutions of ethanol and acetic acid, respectively were used as solvents under test conditions of ten days at 40°C (all simulants) and two hours at 70°C (aqueous simulants only). Only low levels of the notified chemical were detected in each of the food simulants tested (< 0.024 mg.kg⁻¹ of each food simulant). The mean level of notified chemical in the PEN plastic was determined to be less than 0.001 mg.kg⁻¹. If public exposure were to occur, levels would be extremely low since migration of the notified chemical is not significant. No information was provided on the residual level of the notified chemical in PEN/PET polymers or its potential to migrate from such polymers. However, the notified chemical will be used at a lower concentration and therefore, the level of residual notified chemical and its potential to migrate from such plastics will most likely be lower.

8. ENVIRONMENTAL EXPOSURE

Release

No manufacturing of the polymer from the notified chemical is envisaged in the foreseeable future. Hence, it is anticipated that release of the notified chemical will be minimal. To provide a worst case estimate, the following releases of the notified chemical were generated assuming all the notified chemical was polymerised and used in the production of articles from the polymer.

Residues remaining in the drums will be disposed of with drums to landfill. The notifier has estimated that the residue remaining in each drum will be less than 227 g (< 1%). At the maximum rate of import, this corresponds to a maximum of 13 kg per annum of chemical, which will be disposed of to landfill with packaging.

Release to the environment of the polymer containing the notified chemical as a result of manufacturing into articles is expected to be minimal. Manufacturing takes place in a closed system. The polymer will be fed automatically into extrusion and moulding machinery from a hopper. Scrap will be reground and reused. Contaminated polymer scraps will be deposited into municipal landfills or incinerated. Overall, such waste streams would account for at most 0.5% of the annual import of the chemical (i.e. a maximum of 6.5 kg of polymerised waste chemical may be deposited in landfill at the maximum rate of import).

Used articles containing the polymer will also eventually be deposited in landfills or recycled. These aspects have been addressed in other separate notifications (PLC/52 and PLC/54).

Fate

No data from standard ready biodegradation tests have been provided by the notifier. The notifier has provided studies which indicate that the chemical undergoes biodegradation in waste water treatment. Measurement of the total organic carbon (TOC) of the effluent from a reactor system which was dosed at rates up to 500 ppm per day, indicated that virtually all the notified chemical was removed from the effluent when the trial was conducted over at least a 3 month period.

The notifier has presented results of a "Neely 100-Day Partition Pattern" which predicts that 93% would partition to water, with small fractions to ground and hydrosol (~3% each), and virtually none present in air. This was calculated from chemical properties which were estimated using quantitative structure activity relationship (QSAR) calculations {Montana State University Institute for Program Analysis, #41} including a water solubility of 56 mg.L^{-1} which is approximately greater than 10-fold greater than the water solubility estimated from measurement (4.8 mg.L^{-1}), and therefore should be treated with caution as partitioning to water is similar to the more soluble acid (NA/503).

Should the polymerisation of the notified chemical occur, the majority of the chemical would not be expected to be released to the environment until it has been polymerised and moulded into films, sheeting or containers. The end use products will either be deposited in landfill or recycled at the end of their useful life. Biodegradation of the polymers containing the notified chemical is unlikely.

Polymerisation of the notified chemical would produce polymers which are analogous to PET. Hence, would be expected to replace PET in some applications. As such, it is anticipated that it will become part of the PET waste stream which accounts for approximately 0.6% of the domestic waste stream {Planet Ark, 1997 #42}. The company has estimated that the current rate of recycling of PET is 30% Australia wide reaching 50% in capital cities. This is in accord with figures published by Planet Ark. In 1995 30% of the PET waste stream was recycled Australia wide (~15 000 tonnes of PET). The figure was higher in Sydney where it reached 53% {Planet Ark, 1997 #42}. It is anticipated that the recycling rates of the polymers containing the notified chemical will be similar to that of PET.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of dimethyl 2,6-naphthalenedicarboxylate

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD ₅₀ > 5 000 mg.kg ⁻¹	{Johnson, 1990 #58}
acute dermal toxicity	rat	LD ₅₀ > 2 000 mg.kg ⁻¹	{Johnson, 1990 #59}
acute inhalation	rat	LC ₅₀ > 2.15 mg.L ⁻¹	{Hartoum, 1987 #62}
skin irritation	rabbit	non-irritant	{Johnson, 1990 #60}
eye irritation	rabbit	non-irritant	{Johnson, 1990 #61}
skin sensitisation	guinea pig	not a sensitiser	{Donald, 1997 #45}

9.1.1 Oral Toxicity {Johnson, 1990 #58}

<i>Species/strain:</i>	rat/Sprague-Dawley (CrI:CD ¹ BR)
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	oral gavage in corn oil (1:1)
<i>Clinical observations:</i>	no treatment related clinical observations
<i>Mortality:</i>	none
<i>Morphological findings:</i>	none
<i>Test method:</i>	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
<i>LD₅₀:</i>	> 5 000 mg.kg ⁻¹
<i>Result:</i>	the notified chemical was of very low acute oral toxicity in a limit test in rats

9.1.2 Dermal Toxicity {Johnson, 1990 #59}

<i>Species/strain:</i>	New Zealand white rabbits
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	single dose (2 000 mg.kg ⁻¹) applied to a clipped area of skin; covered with gauze patch and secured with plastic sleeve; removed and wiped with 0.9% saline at 24 hours
<i>Clinical observations:</i>	slight signs of systemic toxicity
<i>Mortality:</i>	none
<i>Morphological findings:</i>	none
<i>Test method:</i>	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
<i>LD₅₀:</i>	> 2 000 mg.kg ⁻¹
<i>Result:</i>	the notified chemical was of low acute dermal toxicity in rabbits

9.1.3 Acute Inhalation Toxicity {Hartoum, 1987 #62}

<i>Species/strain:</i>	rat/Sprague-Dawley (CrI:CD ⁻ BR)
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	nose only exposure via aerosol at 2.15 mg.L ⁻¹ for 4 hours
<i>Clinical observations:</i>	salivation, redness around nose/eyes, discoloured facial fur; soiled, discoloured inguinal fur; 1 male with swollen face, 1 female with abdominal hair loss
<i>Mortality:</i>	nil
<i>Morphological findings:</i>	at autopsy, grey lungs in 9 out of 10 animals, 1 male with distended large intestine

<i>Test method:</i>	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
<i>LC₅₀:</i>	> 2.15 mg.L ⁻¹
<i>Result:</i>	the notified chemical was not acutely toxic by inhalation at the concentration tested; all rats survived, but evidence of potential long-term lung damage

9.1.4 Skin Irritation {Johnson, 1990 #60}

<i>Species/strain:</i>	rabbit - unspecified strain
<i>Number/sex of animals:</i>	3 (sex unspecified)
<i>Observation period:</i>	72 hours
<i>Method of administration:</i>	0.5 g of test substance to moistened shaved dorsal skin, wrapped for 4 hours, unwrapped, rinsed with 2 ml 0.9% saline, skin assessed at 30-60 minutes, 24, 48 and 72 hours after removal of dressing
<i>Draize scores {Draize, 1959 #4}:</i>	no Draize scores greater than zero
<i>Test method:</i>	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
<i>Result:</i>	the notified chemical was a not an irritant to rabbit skin

9.1.5 Eye Irritation {Johnson, 1990 #61}

<i>Species/strain:</i>	rabbit, unspecified strain
<i>Number/sex of animals:</i>	1 male; 2 females
<i>Observation period:</i>	72 hours
<i>Method of administration:</i>	0.1g in the right eye, untreated left eye served as control

Draize scores {Draize, 1959 #4}: of unirrigated eyes:

Animal	Time after instillation								
	1 day			2 days			3 days		
Conjunctiv a	r ^c	c ^d	d ^e	r ^c	c ^d	d ^e	r ^c	c ^d	d ^e
1	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0
3	2	1	0	1	0	0	0	0	0

^a see Attachment 1 for Draize scales

^c redness ^d chemosis ^e discharge

Test method: similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Result: the notified chemical is a slight irritant to the eyes of rabbits.

9.1.6 Skin Sensitisation {Donald, 1997 #45}

Species/strain: guinea pig/Dunkin-Hartley

Number of animals: 10 controls/20 test animals

Induction procedure: day 1 - each test animal was treated with 0.5 mL of 75% (topical application to the left flank) of the notified chemical in sterile distilled water; patches were occlusively wrapped for six hours, and then removed and cleaned with sterilised distilled water

the procedure was repeated once each week for three consecutive weeks

Challenge procedure: day 14 after the final induction application, 0.5 mL of a 75% solution of the notified chemical was applied to the right flank, and held with occlusive wrap. Patches were removed after six hours and cleaned with sterilised distilled water.

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	24 hours*	48 hours*	24 hours	48 hours
75%	0/20	0/20	0/10	0/10

* time after patch removal

** number of animals exhibiting positive response

Test method: similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Result: the notified chemical was not a skin sensitiser in guinea pigs

9.1.7 4 week Inhalation Toxicity {Hartoum, 1988 #63}

Species/strain:	rat/Sprague-Dawley (CrI:CD ⁻ BR)
Number/sex of animals:	4 groups of 10/sex; control, 0.99, 4.65 and 10.0 mg.m ⁻³
Observation period:	28 days
Method of administration:	exposure via aerosol for 6 hours/day, 5 days/week
Clinical observations :	salivation, redness around nose / eyes, slightly higher incidence treated over controls
Clinical measurements	no changes in biochemical or cytological pathology between treated and controls
Mortality:	nil
Morphological findings:	at autopsy lung foci present and lungs enlarged, similar incidence of focally reddened mandibular lymph nodes in both treated and control groups
Test method:	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
LC₅₀:	> 10.02 mg.m ⁻³ (> 0.01 mg.L ⁻¹)
Result:	possibility of the lung being the target organ, however results are not conclusive

9.2 90 Day Oral Repeated Dose Toxicity {Johnson, 1990 #73}

<i>Species/strain:</i>	rat/Sprague-Dawley
<i>Number/sex of animals:</i>	4 groups of 20 of each sex; control, 0.2 (2 000 ppm), 1.0 (10 000 ppm) and 5.0% (50 000 ppm)
<i>Method of administration:</i>	orally (administered in the diet)
<i>Dose/Study duration:</i>	10 rats from each group, sacrificed at 13 weeks; 10 rats kept on study for a 4 week recovery period
<i>Clinical observations:</i>	no treatment related effects
<i>Clinical chemistry/Haematology:</i>	no treatment related effects
<i>Histopathology:</i>	no treatment related effects
<i>Test method:</i>	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
<i>Result:</i>	no evidence of adverse effects, or target organ toxicity

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay {San, 1990 #52}

<i>Strains:</i>	TA 98, TA 100, TA 1535, TA 1537, TA 1538
<i>Concentration range:</i>	667, 1 000, 3 333, 6 667, 10 000 µg/plate
<i>Test method:</i>	according to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
<i>Note</i>	dose was delivered as a suspension in dimethylsulfoxide (DMSO), (see discussion)
<i>Result:</i>	the notified chemical was not mutagenic in the bacterial strains tested in the presence or absence of metabolic activation by rat liver S9 fraction

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse {Putman, 1990 #75}

<i>Species/strain:</i>	mouse/ICRI
<i>Number and sex of animals:</i>	5 male/sex
<i>Doses:</i>	1 250, 2 500 and 5 000 mg.kg ⁻¹
<i>Method of administration:</i>	single IP injection
<i>Test method:</i>	according to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
<i>Result:</i>	no increase in micronucleated polychromatic erythrocytes occurred and no cytotoxicity was observed

9.3.3 Chinese Hamster Ovary Cells (CHO)/ Hypoxanthine-Guanine Phosphoribosyl Transferase (HGPRT) Mutation Assay {Jacobson-Kram, 1990 #54}

<i>Strain:</i>	CHO-K1-BH ₄ cells
<i>Doses:</i>	62.5, 125, 250, 500 and 1 000 µg/ml with and without S9 mix
<i>Test method:</i>	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
<i>Note</i>	all doses insoluble in treatment medium (see discussion)
<i>Result:</i>	no dose related increase in thioguanine resistant mutants occurred in either the non-activated or S-9 activated test system

9.3.4 Chromosome Aberrations in Chinese Hamster Ovary Cells (CHO) {Putman, 1990 #74}

<i>Strain:</i>	CHO-K1 cells
<i>Doses:</i>	313, 625, 1250, and 2 500 µg.mL ⁻¹ with or without S9 mix.
<i>Test method:</i>	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Note the notified chemical was partially insoluble in solvent and treatment medium at all concentrations tested (see discussion)

Result: no increase in chromosomal aberrations was observed in either the non-activated or S9 fraction activated test system

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low acute oral and dermal toxicity in rats ($LD_{50} > 5\ 000\ \text{mg.kg}^{-1}$ and $2\ 000\ \text{mg.kg}^{-1}$, respectively). The notified chemical was not an eye irritant in rabbits, nor was it a skin sensitiser in a non-adjuvant type skin sensitisation study using guinea pigs. However, it was a slight irritant to the skin of rabbits.

Inhalation data shows lung pathology at very high doses (greater than $2150\ \text{mg.L}^{-1}$), however the repeat exposure inhalation study showed that an exposure of $10\ \text{mg.m}^{-3}$ caused no treatment related effects after 28 days in rats. The fact that 90% of the control male rats, and 30% of the female controls had lung foci, precludes the proper determination of lung effects caused by the notified chemical.

A repeat dose 28-day oral toxicity study in rats indicated no treatment related toxic effects.

The genotoxicity data show no significant increase in micronuclei, mutations or chromosomal alterations in a range of assays. However, all *in vitro* assays were complicated by the insolubility of the notified chemical in the media, casting doubt on the validity of these data. Although it is not possible to preclude the genotoxic potential of the notified chemical, it is likely to be low based on analogy to genotoxic studies on naphthalene {US Department of Health and Human Services, 1990 #92},

Based on the toxicological studies provided by the notifier, dimethyl 2,6-naphthalenedicarboxylate would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* {National Occupational Health and Safety Commission, 1994 #9}.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has provided estimates of the 96 h LC_{50} for aquatic species based on the primary mode of action (ester narcosis) and structure-toxicity relationships which are based on quantitative structure activity relationship (QSAR) calculations developed by Montana State University {Montana State University Institute for Program Analysis, #41}. These results are summarised below:

Species	LC ₅₀ (mg.L ⁻¹)
bluegill sunfish	21
fathead minnow	25
catfish	21
rainbow trout	21
mosquitofish	26
goldfish	29
<i>Daphnia magna</i>	22

These values are stated to have only a factor-of-two reliability and were calculated based on an estimated water solubility of 56 mg.L⁻¹ (approximately 50-fold of the estimate given in Section 3). Additionally, according to the supplied output from the QSAR System, the notified chemical does not contain structural features which are currently regarded as highly toxic to algae.

ECOSAR {USEPA ECOSAR, 1994 #43} estimates the fish acute 96 hour toxicity as 20 mg.L⁻¹ and daphnia 48 hour toxicity as 67 mg.L⁻¹ (again equal to the free acid form (NA/503). It also predicts a chronic value for algae of 1.6 mg.L⁻¹. Results were calculated on estimated water solubilities of 4.8 mg.L⁻¹ and using structure activity relationships developed for esters.

The above data suggests that the notified chemical has slight toxicity to fish and *Daphnia* and may have moderate toxicity to algae.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Disposal of the notified chemical to landfill is unlikely to present a hazard to the environment due to the limited release. The notifier has presented a worst case landfill leaching concentration of the chemical in the leachate of 0.5 mg.L⁻¹ (based on the dissolution of 13 kg waste chemical in a leachate volume of 2.529 x 10⁷ L in one year {Miller, 1980 #44}. The estimated concentration of the chemical in the leachate is below the estimated water solubility of the chemical. Incineration of the notified chemical will result in its destruction, producing oxides of carbon and water.

Should local polymerisation of the notified chemical occur, the chemical will be trapped in the polymer matrix of the end use articles and contaminated polymer scraps which will ultimately be disposed of to landfill. Biodegradation of the articles is also considered unlikely.

The low environmental exposure of the chemical as a result of the proposed use, together with its expected negligible environmental toxicity once polymerised, indicate that the overall environmental hazard should be negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Dimethyl 2,6-naphthalenedicarboxylate is a stable low molecular weight white crystalline solid with low vapour pressure. Despite its low aqueous solubility, if ingested, the notified chemical may be taken up and metabolised in a similar manner to naphthalene which is readily absorbed and localised in animal tissues {Services, 1992 #72}.

The notified chemical will not be manufactured in Australia but will be imported for plastic polymer formulation. Transport workers would only be exposed to the notified chemical in the unlikely event of an accident which could lead to acute dermal, eye and inhalation exposure. Worker exposure during plastic production is most likely to take place via inhalation. Based on the repeat-dose inhalation experiment, and a possibility of relationship to naphthalene (shown to have some long-term lung toxicity in animals), chronic inhalation of the notified chemical may have effects on the lungs of workers. The notifier expects plastic manufacture to involve an automated plant with little or no direct contact of workers with the notified chemical. Hence the risk to workers is low.

The notified chemical will be present at low levels in PEN and PEN/PET polymers and no significant migration of the notified chemical from such polymers is expected to occur. The use of PEN and PEN/PET plastics in products such as food and beverage containers and as packaging material for pharmaceuticals and cosmetics is therefore not expected to result in significant public exposure to the notified chemical. Therefore the proposed use of the notified chemical presents negligible risk to public safety.

Based on the described use pattern for dimethyl 2,6-naphthalenedicarboxylate, and the available toxicological and physico-chemical data, it is not considered that the notified chemical will pose a significant risk to workers exposed to the chemical and is not classified as hazardous according to Worksafe Australia criteria {National Occupational Health and Safety Commission, 1994 #9}.

13. RECOMMENDATIONS

To minimise occupational exposure to dimethyl 2,6-naphthalenedicarboxylate the following guidelines and precautions should be observed:

- It is good practice to wear industrial clothing which conforms to the specifications detailed in AS 2919 {Standards Australia, 1987 #18} and occupational footwear which conforms to Australian and New Zealand Standard (AS/NZS) 2210 {Standards Australia/Standards New Zealand, 1994 #24};
- 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 occupational atmospheric level for dimethyl 2,6-naphthalenedicarboxylate would be advised to be maintained below the time weighted average (TWA) atmospheric exposure standard as set for naphthalene of 10 ppm {National Occupational Health and Safety Commission, 1995 #14}. This level is approximately equal to the nuisance dust exposure standard (10 mg /m³) which would prevail in any industrial site {National Occupational Health and Safety Commission, 1995 #14}.
- Although the chemical is not classified as flammable and is not normally dust-generating, care should also be taken to limit atmospheric levels and possible static electricity discharge sources in the work environment. All carbon based powdered substances have the potential for combustion and explosion and attention to this possibility is advisable in the work environment.

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* {National Occupational Health and Safety Commission, 1994 #13}.

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

Secondary notification under Section 64 of the Act will be required if the method of use changes in such a way as to greatly increase the environmental exposure of the notified chemical, or if additional information becomes available on adverse environmental effects of the chemical. Ecotoxicity results for fish, daphnia and algae would be required to confirm the QSAR estimates should more significant exposure of the aquatic compartment be expected. Alternatively, QSAR estimates using the correct water solubility for the notified chemical should be provided.

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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

<i>Erythema Formation</i>	<i>Rating</i>	<i>Oedema Formation</i>	<i>Rating</i>
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

<i>Opacity</i>	<i>Rating</i>	<i>Area of Cornea involved</i>	<i>Rating</i>
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

<i>Redness</i>	<i>Rating</i>	<i>Chemosis</i>	<i>Rating</i>	<i>Discharge</i>	<i>Rating</i>
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

<i>Values</i>	<i>Rating</i>
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