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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

2,6-Naphthalenedicarboxylic acid

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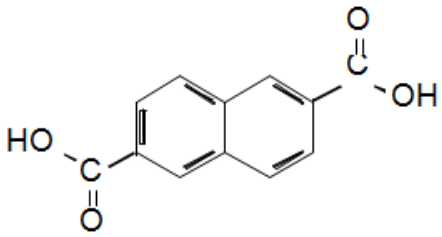
Director
Chemicals Notification and Assessment

2,6-Naphthalenedicarboxylic acid

1. APPLICANT

Amoco Chemicals Pty Ltd of 28-34 Orange Grove Road LIVERPOOL NSW 2170 has submitted a standard notification statement in support of their application for an assessment certificate for 2,6-naphthalenedicarboxylic acid. No application for exempt information was made, hence the Full Public Report is published in its entirety.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	2,6-naphthalenedicarboxylic acid
Chemical Abstracts Service (CAS) Registry No.:	1141-38-4
Other Names:	2,6-napthalic acid
Trade Name:	Amoco PNDA
Molecular Formula:	$C_{12}H_8O_4$
Structural Formula:	
Molecular Weight:	216.2
Method of Detection and Determination:	infrared (IR), nuclear magnetic resonance (NMR) spectroscopies
Spectral Data:	IR spectrum characteristic peaks 478, 585, 755, 778, 831, 915, 951, 1 104, 1 144, 1 180 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white crystalline or flake solid, no characteristic odour
Melting Point:	decomposes before melting point is reached; onset of decomposition at 300°C
Density:	1.5 $g.mL^{-1}$
Vapour Pressure:	not determined
Water Solubility:	1.03 $mg.L^{-1}$ @ 20°C (see comments below)
Partition Co-efficient (n-octanol/water):	log P_{ow} = -1.77 @ pH 7 (see comments below)
Hydrolysis as a Function of pH:	not determined
Adsorption/Desorption:	not determined
Dissociation Constant:	pK_{a1} = 3.8, pK_{a2} = 4.7 (estimated, see below)
Flash Point:	> 200°C
Particle size:	90% of flakes > 0.6 mm
Flammability Limits:	not flammable
Autoignition Temperature:	not available
Explosive Properties:	stable
Reactivity/Stability:	considered inert under atmospheric conditions; no incompatibilities determined; stable; not prone to spontaneous decomposition; if involved in fire, unpredictable decomposition products may be generated

Comments on Physico-Chemical Properties

The water solubility of the notified chemical was determined by extrapolating a linear regression of high temperature data (320-150°C). The regression line had an r^2 value of 0.999. The chemical contains carboxylic acid functionalities and the water solubility of the chemical is expected to depend on the pH of the medium. At low pH values, at which the chemical exists predominantly in the free carboxylic acid form, the solubility in water is expected to be very low. However, at higher pH the carboxylic acid groups will be deprotonated and the resulting water solubility of

the carboxylate form of the chemical will be higher.

No data on the hydrolytic behaviour of the chemical was provided by the notifier. The chemical contains no functional groups which would be expected to hydrolyse under environmental conditions.

The partition coefficient of the notified chemical was determined at pH 7. At this pH the chemical will be completely ionised, consequently the partition coefficient measured is that of the carboxylate form rather than the acid form. An estimated log K_{OW} = 2.93 was estimated for the acid form using the atom/fragment contribution method developed by Syracuse Research Corporation {Syracuse Research Corporation, 1997 #39}.

Based on the measured partition coefficient the chemical would not be expected to strongly adsorb to soil or sediment at pH 7 (i.e. in the carboxylate form). However, adsorptivity also has a strong negative correlation with solubility and the low solubility of the carboxylic acid form of the chemical suggests that it will adsorb more strongly. The notifier has provided an estimate of log K_{OC} = 2.67 based on the method of Lyman *et al.* {Lyman, 1982 #40}. It appears this estimate is based estimated on an estimated log K_{OW} for the acid form rather than the measured value of -1.77 for the carboxylate form.

The pK_a values for the chemical were estimated by reference to the literature and have an uncertainty of ± 0.2 pK_a units.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 99.5%

Impurities: < 0.5%

Chemical Name	*CAS No.*	*Weight%*
dicarboxy tetralin	-	< 0.08
formylnaphthoic acid	-	< 0.015
trimellitic acid	528-44-9	< 0.001
naphthoic acid + methyl (NA)	-	< 0.005
all others	-	< 0.02

none of the above are listed as having toxic or hazardous properties in Toxline {Toxline Silver Platter, 1996 #27}.

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will only be imported in limited quantities for trial development studies. The notified chemical is a monomer used to manufacture polyethylenenaphthalate (PEN) and polyethylenephthalate (PET) polymers and copolymers. PEN and PET polymers are used for packaging of pharmaceutical and cosmetic products, beverage and food containers, films for various purposes such as sailing, photographic and electrical applications. The maximum proportion of the notified monomer used in the polymers and copolymers will be less than 8%. The level of residual monomers including the notified chemical is low; the average is less than 210 ppm.

The estimated import volume will be nil for the first three years, followed by 0.4 tonne for the fourth year and 1.3 tonnes for the fifth year.

6. OCCUPATIONAL EXPOSURE

The notified chemical 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.

Dermal exposure may occur when workers transfer the notified chemical to a process vessel. Accidental eye contact may also occur at this stage.

The notifier states that inhalational, dermal and ocular exposure to the notified chemical will be minimised during polymer manufacture since these processes essentially occur in continuous, enclosed automated plants. In addition, these processes will be carried out under local exhaust and general ventilation.

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 in the polymer form, exposure to the notified chemical at this time would be negligible.

7. PUBLIC EXPOSURE

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

Disposal of any waste notified chemical by incineration or to landfill is not expected to result in significant public exposure. If spillage of the notified chemical were to occur it would be swept up and placed in sealed containers for re-use or disposal.

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 containing the notified chemical.

Migration of the notified chemical from PEN plastic to four food simulating solvents has been shown to occur (**complete reference to be provided by notifier**). 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^{o}C (all simulants) and two hours at 70^{o}C (aqueous simulants only). Only low levels of the notified chemical were detected in each of the food simulants tested (<0.05 mg of the notified chemical per litre of each food simulant[1]). The mean level of notified chemical in the PEN plastic was determined to be 0.21 mg.g^{-1}. Given that migration of the notified chemical is not significant, public exposure, if it were to occur, would be extremely low. Although no information was provided on the residual level of the notified chemical in PEN/PET polymers or its potential to migrate from such polymers, 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 is expected to 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. 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 94% would partition to water, with small fractions to ground and hydrosoil (~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 1.3 $g.L^{-1}$ which is greater than 1 000-fold the water solubility estimated from measurement (~1.03 $mg.L^{-1}$ at 20°C likely to be the fully ionised form).

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, and therefore, 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 2,6-naphthalenedicarboxylic acid

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 $mg.kg^{-1}$	{Johnson, 1991 #67}
acute dermal toxicity	rabbit	LD_{50} > 2 000 $mg.kg^{-1}$	{Johnson, 1991 #69}
inhalation toxicity	rat	4h LC_{50} > 1.23 $mg.L^{-1}$	{Ledbetter, 1988 #46}
skin irritation	rabbit	slight irritant	*{Johnson, 1991 #68}
eye irritation	rabbit	slight irritant	{Johnson, 1991 #70}
skin sensitisation	guinea pig	not a sensitiser	{Edgar, 1997 #78}

*summary only

9.1.1 Oral Toxicity {Johnson, 1991 #67}

Species/strain:	rat/ unknown
Number/sex of animals:	5 per sex
Observation period:	unknown
Method of administration:	gavage, dose of 5 $g.kg^{-1}$, prepared as a 33% (w/v) aqueous suspension
Clinical observations:	none
Mortality:	nil
Morphological findings:	none
Test method:	in accordance with US Food and Drug Administration (FDA) Good Laboratory Practice (GLP), protocol not identified
LD_{50}:	> 5 000 $mg.kg^{-1}$`
Result:	the notified chemical was of low acute oral toxicity to rats in a limit test

9.1.2 Dermal Toxicity {Johnson, 1991 #69}

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5 male/sex
Observation period:	14 days
Method of administration:	2 $g.kg^{-1}$ applied to moistened shaved backs for 24 hours (occluded) then removed and site washed with 0.9% saline solution
Clinical observations:	mild transient dermal irritation (erythema) in two rabbits following unwrapping
Mortality:	nil
Morphological findings:	one female rabbit had red areas on lungs at necropsy, all others normal
Test method:	in accordance with US Food and Drug Administration (FDA) Good Laboratory Practice (GLP), protocol not identified
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low acute dermal toxicity in rabbits

9.1.3 Inhalation Toxicity {Ledbetter, 1988 #46}

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5 males/sex
Observation period:	14 days
Method of administration:	rats exposed to a particulate aerosol for 4 hours with nose only exposure; time weighted average (TWA) was 2.25 $mg.L^{-1}$ with 54.6% of particles < 10μm, therefore actual respirable concentration was 1.23 $mg.L^{-1}$
Clinical observations:	inguinal area was soiled, animals were cold to the touch for approximately 2 hours after exposure, redness around nose; mean body weights increased during study

Mortality:	nil
Morphological findings:	at necropsy 2 males and one female rat had foci on lungs and one male had red foci on the thymus
Test method:	not stated
LC_{50}:	> 1.23 $mg.L^{-1}$
Result:	the notified chemical was of low acute inhalational toxicity in rats

9.1.4 Skin Irritation {Johnson, 1991 #68}

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/sex not specified
Observation period:	72 hours
Method of administration:	0.5 $g.kg^{-1}$ applied to moistened shaved backs for 24 hours (occluded) then removed and site washed with saline solution
Draize scores {Draize, 1959 #4}:	ranged from 0-8.0 at 48 hours, primary dermal irritation score was 0.2
Test method:	not specified
Result:	slight skin irritant in rabbits

9.1.5 Eye Irritation {Johnson, 1991 #70}

Species/strain:	rabbit strain not specified
Number/sex of animals:	3/sex not specified
Observation period:	72 hours
Method of administration:	0.1 g into the right conjunctival sac of one eye of each animal

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

	Time after instillation								
Animal	**1 day**			**2 days**			**3 days**		
Conjunctiva	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**	**r[c]**	**c[d]**	**d[e]**
1	1	1	0	0	0	0	0	0	0
2	2	3	1	1	1	0	0	0	0
3	1	1	0	1	0	0	1	0	0

[1] see Attachment 1 for Draize scales
[c] redness [d] chemosis [e] discharge

all iridal and corneal scores were zero

Test method: not specified

Result: slight eye irritant in rabbits

9.1.6 Skin Sensitisation {Edgar, 1997 #78}

Species/strain: guinea pig/Dunkin-Hartley

Number of animals: 10 controls/20 test animals

Induction procedure: day 1 - each 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 secured under an occlusive wrap 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: thirteen days 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

9.2 Repeated Dose Toxicity {Johnson, 1994 #51}

Species/strain: rat/Sprague-Dawley

Number/sex of animals: 20/sex/group

Method of administration: administered orally, admixed to the diet

Dose/Study duration:: 2 000, 10 000 and 50 000 ppm for 90 days

Clinical observations: transient diarrhoea in high dose animals; increased food consumption in middle and high dose males

Clinical chemistry/Haematology no toxicologically significant effects were observed on clinical chemistry or haematology parameters.

Histopathology: mean liver weights were decreased in high dose males however no microscopic changes were observed; dilation of caecum and/or colon in many high dose animals, insignificant dilation of the lumen of the colon in some of these animals

Test method: in accordance with US Food and Drug Administration (FDA), Good Laboratory Practice (GLP), protocol not identified

Result: no target organ identified; low toxicity following repeat doses

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay {San, 1991 #53}

Strains:	TA 98, TA 100, TA 1535, TA 1537, TA 1538
Concentration range:	667 - 10 000 μg/plate with or without rat liver S9 fraction, dose prepared in solution of dimethylsulphoxide (DMSO)
Test method:	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
Result:	the notified chemical was not mutagenic in this system with or without metabolic activation

9.3.2.1 Hypoxanthine-Guanine Phosphoribosyl Transferase (HGPRT) Mutation Assay with Chinese Hamster Ovary (CHO) Cells {Jacobson- Kram, 1991 #77}

Cell line:	CHO-K_1-BH_4
Doses:	685, 342.5, 171.3, 85.7, 42.9 μg/ml with or without rat liver S9 fraction; positive controls - ethyl methanesulphonate in non-activated tests and benzo(a)pyrene in activated tests
Test method:	in accordance with OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
Result:	the notified chemical was not mutagenic in this test system; untreated and positive controls gave appropriate responses

9.3.2.2 CHO Chromosomal Aberration Assay *in vitro* {Leddy, 1995 #55}

Cell line:	Chinese Hamster Ovary
Doses:	2 000, 1 000, 500, 250, 125 μg/ml with or without rat liver S9 fraction; vehicle controls, positive controls - cyclophosphamide and methyl methanesulphonate
Test method:	in accordance with OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}

Result:	slight precipitation was observed at 1 000 and 2 000 μg.mL^{-1}; some cytotoxicity at these doses; moderate increase in polyploidy at 2 000 μg.mL^{-1} with metabolic activation, some indication that this was dose related; the 1 000 μg/mL^{-1} sample indicated a level of clastogenesis that is higher than controls but not at the level of significance demonstrated in the 2 000 μg.mL^{-1} test; therefore the chemical is weakly clastogenic in this system; "weakly" indicating 5-10% aberrant cells excluding gaps; positive controls gave appropriate response; vehicle controls had levels of aberrations within the 95% confidence limits of the historical negative control data

9.3.2.3 CHO Chromosomal Aberration Assay *in vitro* {Putman, 1991 #57}

Cell line:	Chinese Hamster Ovary
Doses:	714, 357, 179, 89.5 μg.mL^{-1} with or without rat liver S9 fraction; dose selection dictated by solvent solubility; solvent DMSO; positive controls - cyclophosphamide and methyl methanesulphonate
Test method:	in accordance with OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
Result:	statistically significant increase ($p< 0.05$) in chromosomal structural aberrations at 714 and 89.5 μg.mL^{-1} in the non-activated test system; no apparent dose-response relationship (using Cochran-Armitage test); positive and negative control results acceptable; some evidence of clastogenesis, however results inconclusive

9.4 Overall Assessment of Toxicological Data

The notified chemical was of low acute oral toxicity in the rat with an LD_{50} in excess of 5 000 mg.kg^{-1}. A dermal toxicity study in rabbits also indicated low toxicity with an LD_{50} in excess of 2 000 mg.kg^{-1}. A rat inhalational toxicity study did not result in any mortality at doses of up to 1.23 mg.L^{-1}. On autopsy, 30% of animals showed lung foci. In a repeat dose study feeding of 90 days duration there was no

significant evidence of adverse effects at doses up to 50 000 ppm; the only effects were minor and included dilation of the caecum and colon, and a reduction in mean liver weight.

The notified chemical has some potential for both skin and eye irritation. Studies using rabbits gave slight erythema in a skin study and slight conjunctival redness in an eye irritation study. In both studies the level of irritation was below that requiring a hazardous classification according to the National Occupational Health and Safety Commission's *Criteria for Classifying Hazardous Substances* {National Occupational Health and Safety Commission, 1994 #9}. The notified chemical produced no response in a non-adjuvant skin sensitisation study in guinea pigs at challenge concentrations up to 75%..

A mutagenicity study using *Salmonella typhimurium* was negative both with or without metabolic activation using DMSO as a solvent. A Chinese Hamster ovary (CHO) assay (HGPRT locus) was negative, with or without metabolic activation. A CHO cell study to assess clastogenic potential indicated that clastogenesis was dose dependent; however, there were problems evident with precipitation of the test chemical. A second study gave significant levels of chromosomal aberrations without metabolic activation, however the level of aberrations were not clearly dose dependent. In summary, the notified chemical in two test systems *in vitro* was not mutagenic, however, it was weakly clastogenic in one *in vitro* study and possibly clastogenic in another.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has provided estimates of the 96 hour LC_{50} for aquatic species based on the primary mode of action (nonpolar 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:

Test	Species	$LC_{50}(mg.L^{-1})$
acute toxicity	bluegill sunfish	55
acute toxicity	fathead minnow	61
acute toxicity	catfish	52
acute toxicity	rainbow trout	53
acute toxicity	mosquitofish	64
acute toxicity	goldfish	73
acute toxicity	*Daphnia magna*	52

These values are stated to have only a factor-of-two reliability and were calculated based on an estimated water solubility of 1.3 $g.L^{-1}$. 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 19 $mg.L^{-1}$ and daphnia 48 hour toxicity as 67 $mg.L^{-1}$. It also predicts a chronic value for algae of 1.5 $mg.L^{-1}$. Results were calculated on estimated water solubilities of 2.9 $g.L^{-1}$ 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 2.529×10^7 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

The notified chemical is a stable, non-volatile, white crystalline solid which is of low solubility in water. It has a molecular weight of 216.2 which indicates that transmission across biological membranes is possible. The octanol-water partition coefficient does not preclude bioaccumulation.

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 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 is 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 the notified chemical, 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 2,6-naphthalenedicarboxylic acid the following guidelines and precautions should be observed:

- It is good practice to wear industrial clothing which conforms to the specifications detailed in Australian Standard (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-naphthalenedicarboxylic acid 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}

- 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.

Given that the products containing the notified polymer will be used as packing material for food and beverages, the notifier may need to contact the individual

Australian State jurisdictions, as State food laws require that manufacturers must ensure that materilas used in food packaging are fit for that purpose. In addition, given that the notified polymer will also be used to manufacture packaging material for pharmaceuticals, the notifier should submit an appropriate application to the Medical Devices Section of the Conformity Assessment Branch of the Therapeutic Goods Administration.

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 acid should be provided.

16. REFERENCES

1. Syracuse Research Corporation 1997, *LogKow Program*, Internet address; http://esc.syrres.com/~ESC/

2. Lyman, W., Potts, RG, Magil, GC 1982, User's Guide Chemest - A Program for Chemical Property Estimation, , Arthur D. Little Inc, Aciorn Park Cambridge MA.

3. Toxline Silver Platter 1996, *Toxline SilverPlatter CD-ROM database: January 1994-June 1996*, Silver Platter International, N.V.

4. Montana State University Institute for Program Analysis , *QSAR System; A Structure-Activity Based Chemical Modelling and Information System*, TDS Numerica™, Technical Database Services Incorporated, New York.

5. Planet Ark 1997, *The planet Ark Recycling Report*, http://www.planet.ark.com.au/recycle/index.htm

6. Johnson, W. 1991, *Acute oral toxicity study of 2,6-napthalene dicarboxylic acid (2,6-NDA) in rats*, Project no., 1659, Amoco Corporation, Chicago, Il, USA.

7. Johnson, W. 1991, *Acute dermal toxicity study of 2,6-napthalene dicarboxylic acid (2,6-NDA) in rabbits*, Project no., 1660, IIT Research Institute, Chicago, Il, USA.

8. Ledbetter, A. 1988, *Acute inhalation toxicity study of 2,6-naphthalene dicarboxylic acid in rats*, Project no., 1227, IIT Research Institute, Chicago, Il, USA.

9. Johnson, W. 1991, *Abbreviated acute dermal irritancy/corrosivitystudy of 2,6-naphthalene dicarboxylic acid (2,6-NDA) in rabbits*, Project no., 1658, IIT Research Institute, Chicago, Il, USA.

10. Johnson, W. 1991, *Abbreviated primary eye irritation study of 2,6-naphthalene dicarboxylic acid (2,6-NDA) in rabbits*, Project no., 1657, IIT Research Institute, Chicago, Il, USA.

11. Edgar, F. 1997, *2,6-Napthalene Dicarboxylic Acid Buehler Sensitisation Test in Guinea Pigs*, Project no., 15070, Inveresk Research, Tranet.

12. 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.

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

14. Johnson, W. 1994, *90-day oral (diet) toxicity study of 2,6-naphthalene dicarboxylic acid (2,6-NDA) in rats*, Project no., Project No. L08518, IIT Research Institute, Chicago, Il, USA.

15. San, R.H.C., Wagner, V. O. 1991, *Salmonella/mammalian microsome plate incorporation mutagenicity assay (Ames test) with a confirmatory assay*, Project no., T9571.501014, Microbiological Associates, Inc., Rockville, USA.

16. Jacobson- Kram, D. 1991, *CHO/HGPRT mutation assay with confirmation*, Project no., T9571.332001, Microbiological Associates Inc., Rockville, MD, USA.

17. Leddy, I.A., Innes, D. C. 1995, *2,6-napthalene dicarboxylic acid chromosommal aberration assay with Chinese hamster ovary cells in vitro.*, Project no., 10934, Inveresk Research International, Tranent, Scotland.

18. Putman, D.L., Morris, M. J. 1991, *Chromosome aberrations in Chinese Hamster Ovary (CHO) cells*, Project no., T9571.337, Microbiological Associates, Inc., Rockville, USA.

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

20. USEPA ECOSAR 1994, *A Computer Program fo Estimating the Ecotoxicity of Industrial Chemicals Based on Structure Activity Relationships*, United States Environment Protection Agency. EPA/748/R93/002, Washington DC.

21. Miller, D.W. 1980, *Waste Disposal Effects on Groundwater: A Comprehensive Survey of the Occurrence and Control of Groundwater Contamination Resulting from Waste Disposal Practices*, Premier Press Berkley California.

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

23. 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.

24. National Occupational Health and Safety Commission 1995, '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*, Australian Government Publishing Service, Canberra.

25. 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