File No: STD/1131

May 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Pamolyn 347

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

This Full Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

Chemical in Pamolyn 347

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Nuplex Industries (Aust) Pty Ltd (ABN 25 000 045 572) of 49-61 Stephen Rd, Botany, NSW, 2019.

and

Multichem Pty Ltd (ABN 47 006 115 886) of Suite 5, 400 High Street Kew VIC 3101.

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

Chemical Identity
Purity and Nature of Impurities

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

Toxicological data
Environmental fate data
Ecotoxicological data

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Pamolyn 347 contains approximately 40% notified chemical.

METHODS OF DETECTION AND DETERMINATION

METHOD	Infrared Spectroscopy
Remarks	Reference spectra provided for Pamolyn 347.

3. COMPOSITION

DEGREE OF PURITY
$\geq$ 90%.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia as a component of Pamolyn 347.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	5	5	5	5	5

USE
The notified chemical will be used in the manufacture of alkyd resins for industrial paint coatings.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Manufacture of the alkyd resin will take place at Nuplex Industries (Australia) Pty Ltd, Botany, NSW.

TRANSPORTATION AND PACKAGING
Pamolyn 347 containing the notified chemical is shipped to Australia in palletised 200 L drums.

5.2. Operation description

Pamolyn 347 (~ 40% notified chemical) will be pumped from 200 L drums into a closed reaction vessel via a drum spear where it will react with other ingredients to form the final alkyd resin. This resin will be filtered and packed through a sealed system into 200 L drums. The notified chemical is reported to be fully reacted during the manufacture of the alkyd resin, although trace level of residual notified chemical may remain and be incorporated into paints along with the resin.

Quality control technicians sample and test Pamolyn 347 to ensure it is within specifications.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/month)*
Alkyd resin manufacture	3*	20* hours	1
QC workers	1	1	1

* The manufacture process occurs 20 hours a day, at any one time one worker will be involved in the manufacture process.

Exposure Details

Dermal and possibly ocular exposure to the notified chemical (at a concentration of 40%) from drips spills and splashes and/or from contact with the spear could occur during the transfer to the reaction vessel. The notified chemical is consumed within the reaction vessel and hence exposure to the notified chemical following resin manufacture is not expected, however, exposure to trace amounts during QC analysis and end use is possible.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical is manufactured overseas as a constituent of a formulated product, Pamolyn 347. The notified chemical is never isolated from the product. The formulated product containing the notified chemical is imported into Australia. Hence there will be no releases of the notified chemical in Australia resulting from its manufacture. Releases of the notified chemical as a result of transport and storage of the product containing the notified chemical are not expected except in the case of accidental spills, which will be limited by size of the import containers.

The notifier estimates that less than 0.3% of the notified chemical will remain in the import containers

after emptying due to the low viscosity of Pamolyn 347. Hence less than 15 kg per annum of the notified chemical will remain in the import containers, which will be sent to drum reconditioners for reclamation.

Pamolyn 347 containing the notified chemical will be used in the manufacture of a resin used in industrial coatings. Manufacturing of the resin solution will take place in a closed reactor. Samples taken from the reactor are recycled back into the reactor. Residues collected in filter bags during the manufacturing process are sent to approved landfills. Spills occurring during drum filling will be contained by bunding on site. It is anticipated that all of the notified chemical will be consumed during resin manufacture.

The resin is to be transported to other company sites, or to the customers, in 200 L steel drums, by road transport. Details of environmental exposure during coatings manufacture are very brief, but are expected to be limited to during sampling and filling operations.

RELEASE OF CHEMICAL FROM USE

Once the chemical has been reacted into the resin it is not expected to be volatile, release to the environment during paint application processes would be of the solvents only. Such discharges would be contained within the paint application area, and would be expected to be collected in the atmosphere scrubber apparatus, or by filters within paint booths at painting plants. Any wastes generated during the painting process will be disposed of in landfill.

5.5. Disposal

The majority of the notified chemical, incorporated into the resin, will share the fate of the surfaces to which the coatings are applied and either be disposed of to landfill or destroyed during metal recycling.

Empty import containers will be sent to drum reconditioners who will process the drums and their residues (containing < 15 kg of the notified chemical) through the drum reconditioners trade waste treatment facility.

5.6. Public exposure

The notified chemical will not be supplied to the public. The notified chemical is consumed within the reaction vessel and hence exposure to the notified chemical following resin manufacture is not expected. Even in the case where trace levels of the notified chemical are present in the alkyd resin, this resin is supplied for industrial uses and hence public exposure would still not be expected.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical is never isolated from the product mixture, limited physicochemical data has been provided for Pamolyn 347 (containing 40% notified chemical)

Appearance at 20°C and 101.3 kPa Light amber slightly viscous liquid (Pamolyn 347)

Melting Point/Freezing Point 5°C (Pamolyn 347)

Remarks Data provided by notifier. Study Report not available.

Boiling Point > 350°C (Pamolyn 347)

Remarks Data provided by notifier. Study Report not available.

Density 900 kg/m^3 (Pamolyn 347)

Remarks Data provided by notifier. Study Report not available.

Vapour Pressure 0.133 kPa at 20°C (Pamolyn 347)

Remarks Data provided by notifier. Study Report not available.

Water Solubility Insoluble

METHOD In House
Remarks 50 mL of water was added to 50 mL of Pamolyn 347, vigorously shaken and allowed to stand. A sharp division between the water phase and Pamolyn 347 was observed at exactly 50 mL, indicating that the notified chemical is insoluble in water. The procedure was repeated by weighing 50.00 g of water and Pamolyn 347. Similar results were obtained to the volumetric approach with 50.00 g and 49.92 g of Pamolyn 347 and water were recovered, respectively. The slight decrease in the mass of water was attributed to transfer losses.

Hydrolysis as a Function of pH Not Determined

Remarks The notified chemical is never isolated and does not contain functional groups which would be expected to hydrolyse.

Partition Coefficient (n-octanol/water) Log Kow = 7.51 (Log Kow (version 1.67))

Remarks The partition coefficient of the notified chemical has been estimated using the Log Kow (version 1.67) software (US EPA) to be 7.51, indicating that the notified chemical will partition to the organic phase.

Adsorption/Desorption Log Koc = 4.1 (PCKOWIN v1.66)
Remarks The adsorption desorption behaviour of the notified chemical has been estimated using the PCKOWIN v1.66 software (US EPA). Based on the estimated log Koc the notified chemical will adsorb strongly to soils and sediments.

Dissociation Constant Not applicable

Remarks Although the notified chemical contains acidic functional groups, the notified chemical is not soluble in water.

Particle Size Not applicable

Remarks Notified chemical is a liquid under conditions of use.

Flash Point > 149 ºC

METHOD In House – Tag Closed Cup
Remarks Data provided by notifier. Study Report not available.

Flammability Limits Not determined

Remarks Based on the flash point, the Pamolyn 347 is not classified as a flammable liquid according to the Australian Dangerous Goods code (FORS, 1998).

Autoignition Temperature 315-371ºC (Pamolyn 347)

Remarks Data provided by notifier. Study Report not available.

Explosive Properties Not predicted to be explosive

Remarks There are no chemical groups that would imply explosive properties, therefore the result has been predicted negative.

Reactivity

Remarks Notified chemical is expected to be stable under normal conditions of handling.

Hazardous polymerisation will not occur.

The notified chemical contains a structural feature which may be susceptible to peroxide formation (Bretherick (1999)) and may form explosive peroxides when concentrated or distilled to dryness.

7. TOXICOLOGICAL INVESTIGATIONS

No toxicity study reports for the notified chemical were available. The notified chemical is marketed in numerous commercially available dietary supplements overseas and hence a number of references were provided for the systemic toxicological endpoints. Oral toxicity studies for a commercial product containing 75% notified chemical glycerol esters are considered to be indicative of the toxicity of the notified chemical as fatty acid esters of glycerol are expected to be completely hydrolysed in the gastrointestinal tract to the fatty acid. Toxicity data for related chemicals has been used to address some toxicity end points.

Endpoint	*Test Substance*	*Result and Assessment Conclusion*
Rat, acute oral	oleic acid, linoleic acid and tall oil fatty acids	low toxicity
Rat, acute dermal	oleic acid and linoleic acid	low toxicity
Rat, acute inhalation	-	not determined
Rabbit, skin irritation	oleic acid and linoleic acid	slightly irritating
Rabbit, eye irritation	oleic acid and linoleic acid	slightly irritating
Guinea pig, skin sensitisation – maximisation test	5% solution of oleic acid	no evidence of sensitisation
Rat, repeat dose oral toxicity – 90 days.	commercial product containing 75% notified chemical glycerol esters	NOAEL 2433-2728 mg/kg bw/day
Rat, repeat dose oral toxicity – 36 weeks.	notified chemical	NOAEL $\geq$ 467 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	commercial product containing 75% notified chemical glycerol esters	non mutagenic
Genotoxicity – in vitro chromosome aberration test	commercial product containing 75% notified chemical glycerol esters	non genotoxic
Genotoxicity – in vivo	-	not determined

7.1. Acute toxicity – oral

No toxicity data for the notified chemical was available. No mortality was observed in the repeat dose studies in animals treated with up to 1970 mg/kg bw of the notified chemical.

The following acute oral toxicity data is available for related chemicals to the notified chemical:

Test Substance	*Test Method*	*Species*	*Mortality*	*LD 50 (mg/kg bw)*	*Reference*
Linoleic acid	Not specified	Rat	Not specified	> 3200	(IPCS , 2006a)
Oleic acid	Not specified	Rat	Not specified	> 19200	(IPCS, 2006b/ Elder (1987)
Tall oil, fatty acids	OECD TG 401	Rat	0/10	> 10000	(US EPA, 2006)

Based on this and toxicity data for related chemicals the notified chemical is expected to be of low toxicity by the oral route.

7.2. Acute toxicity – dermal

No toxicity data for the notified chemical was available.

The following toxicity data is available for related chemicals to the notified chemical:

Test Substance	*Test Method*	*Route/Species*	*Mortality*	*LD 50 (mg/kg bw)*	*Reference*
Linoleic acid	Not specified	Guinea pig	Not specified	> 18000	(IPCS , 2006a)
Oleic acid	Not specified	Guinea pig	0/6	> 3000	Elder (1987)

Based on the toxicity data for related chemicals the notified chemical is expected to be of low toxicity by the dermal route.

7.3. Acute toxicity – inhalation

Not determined. The notified chemical is of low vapour pressure and aerosols are not expected to be generated during use, therefore inhalation exposure is not expected.

7.2. Irritation – skin

No toxicity data for the notified chemical was available. A single insult occlusive patch test on a related chemical oleic acid with six rabbits resulted in mild erythema 24 hours after treatment and a primary irritation index of 0.5 (Elder (1987)). A repeat open patch test with this same chemical in rabbits produced mild to moderate erythema after 24 hours, mild to marked after 48 hours and moderate to marked erythema and slight to moderate oedema after 72 hours (Elder (1987)).

Slight irritation was reported to be observed in guinea pigs in a 24-hour closed patch test with linoleic acid (IPCS (2006a)).

Based on the toxicity data for related chemicals the notified chemical is expected to be slightly irritating to the skin.

7.5. Irritation – eye

No toxicity data for the notified chemical was available. No or minimal conjunctival irritation was reported to be produced in eyes of six rabbits treated with 0.1 mL of oleic acid (Elder (1987)). Mild redness, completely subsiding in 72 hours, was reported to be observed in rabbits following application of linoleic acid (IPCS (2006a)). Based on the toxicity data for related chemicals the notified chemical is expected to be slightly irritating to the skin.

7.6. Skin sensitisation

No toxicity data for the notified chemical was available and limited information could be found for related chemicals. A formulation containing 5% of oleic acid was negative in the guinea pig maximization test, using Freund's complete adjuvant (Elder (1987)). Sufficient toxicological data is not available to predict the sensitisation potential of the notified chemical.

7.7.1. Repeat dose toxicity

TEST SUBSTANCE	Commercial product containing 75% glycerol esters of the notified chemical
METHOD	OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Wistar
Route of Administration	Oral –diet
Exposure Information	Total exposure days: 90 days Dose regimen: ad libitum Post-exposure observation period: 4 weeks
Vehicle	Diet
Remarks - Method	Study conducted in accordance with OECD principles of Good

Laboratory Practice (GLP).

From the information provided there were no significant protocol deviations, however, the range of haematological and clinical chemistry parameters measured were not reported, therefore any deviations from the protocol testing requirements for these endpoints cannot be verified.

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration*		*Mortality*
		Nominal <% w/w>	*Actual <mg/kg bw>*	
I (low fat control)	20 per sex	0	0	0/20
II (high fat control)	20 per sex	0	0	0/20
III (low dose)	20 per sex	1%	Not reported (~ 516 based on 5% data)	0/20
IV (mid dose)	20 per sex	5%	2433 (m), 2728 (f)	0/20
V (high dose)	20 per sex	15%	Not reported (~ 7740 based on 5% data)	0/20
VI (low fat control recovery)	10 per sex	0	0	1/10*
VII (high fat control recovery)	10 per sex	0	0	1/10*
VIII (high dose recovery)	10 per sex	0	0	0/10

* one control recovery was sacrificed. The paper did not report whether it was a high fat or low fat recovery animal.

Mortality and Time to Death

One control recovery animal was sacrificed on day 107. No other mortalities occurred during the treatment and recovery period.

Clinical Observations

There were reported to be no treatment related clinical signs. Opthalmoscopic examination did not reveal any treatment related ocular changes. There were no significant findings in the detailed clinical observations or neurobehavioural tests performed.

Food consumption was significantly lower in group V males and females compared to controls during the first 7-14 days. The reduced food intake resulted in a statistically significant reduction in bodyweight gain in group V males and females at day 7 and in high dose females at day 14 compared to both control groups. This delay in growth during the first weeks of the study resulted in consistently lower bodyweights in the high-dose animals throughout the study. Water consumption was similar in test and control groups during week 1 and week 6 of the study, however, in week 12 water consumption was significantly lower in group V males (20%) and females (24%) in comparison to both controls.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry

Enzymatic markers of liver cell damage were assessed at week 4, 8 and 13 and at the end of the recovery period. Alkaline phosphatase (AlkP) and alanine aminotransferase (ALT) were statistically significantly increased in group V males (30-45%, $p < 0.01$ (AlkP), 25-40%, $p<0.01$ (ALT)) and group V females (25-68%, $p < 0.05$ (AlkP), 7-40%, $p<0.05$ (ALT)) when compared to controls throughout the treatment period. Aspartate aminotransferase (AST) were also increased in these groups at week 13 (16%, $p<0.01$ (male), 7%, $p<0.05$ (female)). Sorbitol dehydrogenase levels were also increased in group V females at week 13 (53%, $p<0.05$).

ALT and AST levels remained significantly increased (20% ($p<0.05$) and 14% ($p<0.01$) respectively) when compared to the low fat controls in females at the end of the recovery period but all other effects were within the comparative controls at the end. All other significant differences in the enzyme markers during the treatment and recovery phases either showed no dose relationship or were only observed in week 4 and therefore were considered fortuitous.

Other effects observed in the group V males were significantly decreased cholesterol levels throughout the study (40-65%, $p<0.01$), significantly decreased glucose levels at week 13 (20%, $p<0.01$) and increased insulin levels throughout the treatment period (40-130%) but this was only significant at weeks 4 and 8. At the end of the recovery period insulin levels were within historical controls but decreased cholesterol (50%, $p<0.01$) and glucose (20%, $p<0.01$) levels were still observed.

Other effects observed in group V females were significantly increased triglyceride levels (50%-150%, $p<0.01$) throughout the treatment period and increased insulin levels throughout the treatment period (30-180%) but this was only significant at weeks 8 and 13. These effects were not observed at the end of the recovery period.

Haematology
Mean cell volume was lower (unspecified) in group V females compared to both controls but this was not accompanied by changes to red blood cell and packed cell volume. Absolute and relative numbers of white blood cells in group V males were lower (unspecified) compared with both control groups. No comment was provided regarding the observation of these effects at the end of the recovery period.

Urinalysis
Urinalysis measurements revealed an increase in urinary crystals in group V males, although this was only observed in 2/20 animals compared with 1 control animal and is therefore not considered adverse. No treatment related changes in urinary volume or density were noted.

Effects in Organs
Organ weight
Significantly increased relative kidney weights were noted in group V males (12%, $p<0.01$) and females (13%, $p<0.01$). These effects did not reverse during the recovery period. Increased absolute and relative spleen weights were also noted in group V males (10%, $p < 0.01$ (abs), 20%, $p<0.01$(rel)) and females (6%, not significant (rel), 12%, $p<0.01$). At the end of the recovery period this effect had fully reversed in the females but an increase (10%, not significant (rel), 12%, $p <0.05$ (abs)) was noted in the males.

Absolute and/or relative liver weights were significantly increased in group IV males (8%, $p< 0.05$ (abs), 5%, $p < 0.01$) and females (8%, $p < 0.05$) and group V males (12%, $p< 0.01$ (abs), 19%, $p <0.01$ (rel)) and females (52%, not significant (abs), 52%, $p <0.01$ (rel)). At the end of the recovery period the effects had reversed with the exception of the female relative liver weight (10% increase ($p < 0.01$).

Macroscopic Findings
The amount of brown adipose tissue was statistically significantly less (not specified) in group IV and group V males and in females of all treatment groups when compared to controls. This was still evident in high dose males at the end of the recovery period .

Histopathology
Slight multifocal hepatocellular hypertrophy was seen in the group V females (12/20). This had reversed in all but two animals at the end of the recovery period.

Remarks – Results
Only a summary of the study has been reviewed. Test data has not been cited, although results for some clinical chemistry, organ weights and histopathological parameters were provided in tabular form.

The reduced food consumption and associated reduced bodyweight was considered to be due to reduced palatability of the high dose feed. Female rats became accustomed to the diet more slowly than males.

The reduction in brown adipose tissue is not considered an adverse effect. The increase in liver weight in the high dose animals, correlated with the changes in clinical chemistry parameters possibly indicative of hepatotoxicity and minimal hepatocellular hypertrophy observed microscopically is considered to be

potentially adverse, although as effects appeared to reverse during the recovery period these changes may represent a metabolic adaptation. The liver weight effects in the mid-dose animals were slight (<10%) and not accompanied by other changes and were not considered adverse. The significant changes observed in the other organs were not accompanied by any test-substance related histopathological change and therefore not considered to be of toxicological relevance.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 2433-2728 mg/kg bw/day in this study, based on the effects observed in the liver and the serum triglyceride and insulin levels at the high dose of 7740 mg/kg bw/day.

TEST FACILITY O'Hagan (2003)

7.7.2. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	Repeated Dose 36 week Oral Toxicity Study in Rats.
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral –diet
Exposure Information	Total exposure weeks: 36 weeks
Vehicle	Basal diet
Remarks - Method	Twenty male rats received diet containing 1.5% notified chemical for a period of 36 weeks. Twenty control animals received undosed diet over the same period. The average daily dose of the notified chemical ranged from 467 – 1970 mg/kg bw/day during the study.

RESULTS

Mortality and Time to Death

There were no mortalities during the study period. One control animal was killed due to signs of distress.

Clinical Observations

Clinical signs were stated not to be apparent in the treated animals. Feed consumption and bodyweight gain were stated to be comparable to controls.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

There were stated to be no significant differences in any of the haematological parameters tested when compared to controls. Minor differences noted were stated to be elevated platelet and granulocyte count as well as depressed values for red blood cells, haemocrit and haemoglobin in a single control rat. There was no evidence that clinical chemistry or urinalysis parameters had been tested.

Effects in Organs

Organ weights

There was a significant ($p < 0.05$) decrease in thymus weight and a significant ($p < 0.05$) increase in adrenal weight when compared with control. The percentage change could not be determined from the information provided.

Histopathology

There were stated to be no histopathological changes related to the test material.

Remarks – Results

Only a summary of the study has been reviewed. Test data has not been cited.

The significant differences observed in the thymus and adrenals were not accompanied by any test-substance related histopathological change and therefore not considered to be of toxicological relevance.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as ≥ 467 mg/kg bw/day in this study, based on the absence of treatment related effects reported in this study.

TEST FACILITY Scimeca (1997)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Commercial product containing 75% glycerol esters of the notified chemical.

METHOD Plate incorporation (test 1) and Pre incubation procedure (test 2)(guideline not specified)

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	S9 fraction (source not specified)
Concentration Range in Main Test	Test 1 With and without metabolic activation: 1.6-3930 µg/plate (TA100) 1.6 - 5000 µg/plate (other strains) Test 2 With and without metabolic activation: 1.6-5000 µg/plate (all strains)
Vehicle	Not specified
Remarks - Method	The dose used for TA100 in test 1 was a result of a calculation error, however precipitation of the test article observed indicated that an acceptable dose limit had been achieved.

RESULTS A small (not specified) but statistically significant increase in revertant numbers was reported in some strains. However, these findings were stated not to be dose related as they occur solely at the lowest or intermediate dose level and were not reproducible.
Precipitation was observed at dose levels 786 µg/plate and 3930 µg/plate in test 1 and 2000 µg/plate and 5000 µg/plate in test 2.

Remarks - Results Only a summary of the study has been reviewed. Test data has not been cited.

CONCLUSION The test substance was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY O'Hagan (2003)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Commercial product containing 75% glycerol esters of the notified chemical.

METHOD In vitro Mammalian Chromosome Aberration Test (guideline not specified)

Species/Cell Type	Human Lymphocyte
Metabolic Activation System	S9 fraction (source not specified)
Vehicle	Not specified

Metabolic Activation	*Test Substance Concentration (µg/mL)selected for metaphase analysis*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	128, 160, 200	3	20
Test 2	192, 240, 300	20	20
Present			

Test 1	128, 160, 200	3	20
Test 2	153, 240, 300	3	20

RESULTS

The frequency of cells with chromosome aberrations, both structural and numerical, both in the presence and absence of activation were reported to be similar to those in the concurrent negative control.

A 3 and 4% reduction in the mitotic index was reported in the absence and presence of activation respectively in test 1 with a 0% and 4% in the absence and presence of activation respectively in test 2.

Remarks - Results: Only a summary of the study has been reviewed. Test data has not been cited.

CONCLUSION: The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY: O'Hagan (2003)

7.10. Genotoxicity – in vivo

Not determined.

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted. The notifier indicates that as the notified chemical is a fatty acid, it can be reasonably expected that it will be readily biodegradable in a similar manner to linoleic acid. No evidence was provided to support this assertion. Other similar fatty acids have been shown to be biodegradable without meeting the OCED criteria for ready biodegradability (US EPA (2006)).

The notified chemical is not expected to bioaccumulate due to its biodegradability and limited environmental exposure.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

No laboratory toxicity studies were provided for the notified chemical. ECOSAR modelling for the notified chemical determined a 14 day LC50 of 0.006 mg/L using the neutral organic structure activity relationship (SAR). The report noted that the chemical may not be soluble enough to measure the predicted effect, this is based on a calculated water solubility of 0.00299 mg/L.

The following toxicity data is available for related chemicals of the notified chemical as part of the US EPA High Production Volume (HPV) challenge program (US EPA (2006)).

Test Species	*Guideline*	*Conditions*	*Endpoint*	*Result**	*Year*
Golden orfe (*Leuciscus idus.)*	OECD Test Method 203	Static	LL50	> 1000	1994
Fathead minnows (*Pimephales promelas)*	OECD Test Method 203	Static	LL50	> 1000	2002
Rainbow trout (*Oncorhynchus mykiss.)*	OECD Test Method 203	Static	LL50	> 100	2002

*mg/L water accommodated fraction (WAF).

8.2.2. Acute/chronic toxicity to aquatic invertebrates

No laboratory toxicity studies were provided for the notified chemical.

The following toxicity data is available for an analogue of the notified chemical as part of the US EPA High Production Volume (HPV) challenge program (US EPA (2006)).

Test Species	*Guideline*	*Conditions*	*Endpoint*	*Result**	*Year*
Daphnia magna	OECD Test Method 202, Part 1	Static	EL50	>1000	1994
Daphnia magna	OECD Test Method 202, Part 1	Static	EL50	>1000	2002
Daphnia magna	OECD Test Method 202, Part 1	Static	EL50	>100	2002

*mg/L WAF

8.2.3. Algal growth inhibition test

No laboratory toxicity studies were provided for the notified chemical.

The following toxicity data is available for related chemicals of the notified chemical as part of the US EPA High Production Volume (HPV) challenge program (US EPA 2006).

Test Species	*Guideline*	*Results*	*Year*
Green alga (*Selenastrum capriconutum)*	OECD Test Method 201	The 72 hr EL50 for area under growth curve (AUC) was 854.90 mg/L WAF with a corresponding No Observed Effect Loading Rate ($NOEL_r$) of 500 mg/L WAF. The 72 hr. EL50 based on Average Specific Growth Rate was > 1000 mg/L WAF with a corresponding $NOEL_r$ of 500 mg/L WAF at 0-48 hr and 750 mg/L WAF at 0-72 hr. indicating some inhibition (<50%) compared to the control.	1994
Alga (*Scenedesmus subspicatus)*	OECD Test Method 201	The 72 hr Effective Loading Rate that reduced biomass by 50% (E_bLR50) was > 1000 mg/L WAF loading rate and the 24 hr Effective Loading Rate that reduced specific growth rate by 50% (E_rLR50) was > 1000 mg/L WAF loading rate.	2002

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

It is expected that very little exposure to the environment is likely to occur during the use of the imported notified chemical. The majority of wastes containing the notified chemical (<15 kg per annum) will be generated as residues in empty containers.

A small amount may be disposed of to sewers as a result of the reconditioning of drums. However, this likely to be very small and the calculation of the Predicted Environmental Concentration (PEC) cannot be done.

Most of the notified chemical will be incorporated into a resin which will be formulated into industrial coatings. In this case the chemical will be part of the inert matrix of the resin and be unavailable to the environment. At the end of their useful lives coated surfaces containing the notified chemical would be either disposed of to landfill or potentially recycled (if metal).

In soil environments, the notified chemical is not expected to be mobile or leach from the soil into ground or surface water, but rather is expected to bind to the organic phases in soils. Under these conditions it would be slowly degraded to gases such as carbon dioxide through the agency of abiotic and biotic processes.

Recycling of the metal surfaces would result in the incineration of the resin containing the notified chemical. Any incineration of the notified chemical or resin containing it will result in the destruction of the chemical and the formation of water and oxides of carbon.

9.1.2. Environment – effects assessment

Ecotoxicity data for analogues of the notified chemical indicate that it is not toxic to aquatic organisms up to the limit of its solubility. The lowest observed toxicity value was observed for green alga with a 72 h EL50 for area under growth curve (AUC) was 854.90 mg/L.

9.1.3. Environment – risk characterisation

A risk quotient cannot be calculated as an accurate PEC or PNEC cannot be estimated. The notified chemical does not pose a significant risk to the environment based on its reported use pattern because there will be very low environmental exposure. The majority of the chemical will form a cured polymeric matrix. The majority of the notified chemical will share the fate of the coated products at the end of their useful lives and eventually be disposed of to landfill or incinerated during metal recycling.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and warehouse worker exposure to the notified chemical is expected to be negligible except in the event of a spill or if packaging is accidentally breached.

The greatest potential for exposure is expected during the transfer of the notified chemical to the reaction vessel. The estimated dermal exposure is 168 mg based on EASE model (EASE) using reasonable worst-case defaults for the manual addition of liquids (European Commission, 2003) and assuming intermittent exposure and assuming the notified chemical is present at concentration of 40%. Therefore, for a 70 kg worker and a worstcase 100% dermal absorption factor, systemic exposure is estimated to be 2.4 mg/kg bw/day. Exposure would be further limited by the use of PPE.

The notified chemical is consumed within the reaction vessel and hence exposure to the notified chemical following resin manufacture is not expected, however, exposure to trace amounts during QC analysis and end use is possible.

9.2.2. Public health – exposure assessment

The notified chemical and the alkyd resin manufactured from the notified chemical are not supplied to the public and as such negligible public exposure is expected.

9.2.3. Human health – effects assessment

Acute toxicity.
No acute toxicity data was available for the notified chemical, however, based on the toxicity profiles of related chemicals, the notified chemical is expected to be of low toxicity by oral and dermal routes.

Irritation and Sensitisation.
No local toxicity data was available for the notified chemical. Based on the toxicity profiles of related chemicals the notified chemical is expected to be slightly irritating to skin and eyes. Sufficient read across data was not available to predict the sensitisation potential of the notified chemical, however, the notified chemical does not contain a structural alert for sensitisation (Barratt, 1994).

Repeated Dose Toxicity
In a 36 week oral study in rats using the notified chemical, no treatment related adverse effects were reported and a NOAEL of $\geq$ 467 mg/kg bw/day was established. In a 90 day oral study in rats with a commercial product containing 75% glycerol esters of the notified chemical, the NOAEL was established as 2433-2728 mg/kg bw/day, based on the effects observed in the liver and the serum triglyceride and insulin levels.

Mutagenicity
A commercial product containing 75% glycerol esters of the notified chemical was reported to be negative in an Ames test and an *in vitro* chromosome aberration test. The notified chemical is not expected to be mutagenic.

Observations on Human Exposure.
The notified chemical is found naturally in a number of foods. Typical intake of the notified chemical from a dietary survey was estimated to be 193 mg/day and 140 mg/day for men and women respectively (Ritzenthaler (2001).

Hazard classification for health effects.
Based on the available data for the notified chemical and related chemicals, the notified chemical is unlikely to be classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Worst-case exposure (dermal and inhalation) for workers involved in alkyd resin manufacture is estimated to be 2.4mg/kg bw/day. Based on a NOAEL of > 467 mg/kg bw/day, derived from a 28-day rat oral study the margin of exposure (MOE) is calculated as > 190. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences and therefore the risk of systemic effects using modelled worker data is acceptable for formulation workers. In addition, exposure is expected to be no more than that expected naturally through the diet.

The notified chemical is expected to be a slight skin and eye irritant and as such workers involved in the transfer of the notified chemical should wear appropriate PPE (coveralls, impervious gloves and eye protection).

Following alkyd resin manufacture only exposure to trace levels of the notified chemical is possible and as such the risk to QC workers and end users is expected to be low.

9.2.5. Public health – risk characterisation

Negligible exposure to the notified chemical is expected and as such the risk to public health is expected to be negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data for the notified chemical and related chemicals, the notified chemical is unlikely to be classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of Pamolyn 347 containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for Pamolyn 347 containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Coveralls,
  - Impervious gloves
  - Eye protection

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to

health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
  - Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

- The notified chemical should be disposed of by incineration or to landfill in accordance with State/Territory waste disposal regulations.

Storage

- The following precautions should be taken regarding storage of the notified chemical:
  - The notified chemical as introduced should not be stored for prolonged periods after opening.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by absorbing onto an inert material, scooping up and placing in marked containers for disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Bretherick (1999) Handbook of Reactive Chemical Hazards 6th edition, London, Butterworths, Volume 2, p 308 – 312.

Elder RL (1987). Final report on the safety assessment of oleic acid, lauric acid, palmitic acid, myristic acid, and stearic acid. J. Amer. Coll. Toxicol. 6: 321-401.

Estimation and Assessment of Substance Exposure (EASE). The EASE system was developed by the UK Health and Safety Executive in conjunction with the Artificial Intelligence Applications Institute. For a further description see: Marquart et al., Evaluation of Methods of Exposure Assessment for Premarket Notifications, TNO Report V 94.229 TNO Nutrition and Food Research (Zeist), 1994.

European Commission (2003) Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council Concerning the Placing of Biocidal Products on the Market – Part I. Institute for Health and Consumer protection, European Chemicals Bureau, European Communities.

FORS (Federal Office of Road Safety) (1998) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 6th Edition, Canberra, Australian Government Publishing Service.

HSIS (2005), National Occupational Health and Safety Commission, Hazardous Substances Information System. <http://www.nohsc.gov.au/applications/hsis/>. Accessed 2005 29 November 2005.

IPCS (2006a) Linoleic acid. International Programme on Chemical Safety (IPCS) databank. Accessed 13/2/06 at http://www.intox.org/databank/documents/chemical/linolac/cie558.htm

IPCS (2006b) Oleic acid. International Programme on Chemical Safety (IPCS) databank. Accessed 13/2/06 at http://www.intox.org/databank/documents/chemical/oleicac/cie385.htm

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

O'Hagan (2003) Published literature

Ritzenhaler (2001) Published literature

Scimeca (1998) Published literature

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.

US EPA (2006) High Production Volume (HPV) Challenge Program - Robust Summaries & Test Plans: Tall Oil Fatty Acids and Related Substances. Accessed 10 March 2006 at http://www.epa.gov/chemrtk/tofars/c13055tc.htm.