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May 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

NJ STAR NU-100

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Director
Chemicals Notification and Assessment

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NJ STAR NU-100

1. APPLICANT

Furnbird Pty Ltd of 80-84 Fairbank Road CLAYTON VIC 3169 (ACN No. 006 962 474) has submitted a standard notification statement in support of their application for an assessment certificate for NJ Star NU-100.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of exact use and import volume have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name:	NJ Star NU-100
Method of Detection and Determination:	UV/Visual (UV/Vis), Infrared (IR) and nuclear magnetic resonance (NMR) spectroscopy.
Spectral Data:	UV/Vis, IR and NMR spectra were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	White powder
Boiling Point:	Melts with decomposition at 379°C.
Boiling Point:	Boiling point is greater than 400°C.
Specific Gravity:	1.29 at 20.5°C
Vapour Pressure:	Negligible at 25°C.
Water Solubility:	Less than 1.4 mg/L at 20°C.
Partition Co-efficient (n-octanol/water):	log P_{ow} = 3.63 at 40°C.
Hydrolysis as a Function of pH:	Estimated half-life at 25°C: pH 4: 24.8 days. pH 7: > 1 year.

	pH 9: 112 days.
Adsorption/Desorption:	log K_{oc} = 3.37.
Dissociation Constant:	Not possible to measure a dissociation constant for the chemical as it is practically insoluble in water.
Flash Point:	Not applicable to a high-melting point solid.
Flammability Limits:	Not applicable.
Autoignition Temperature:	No self-ignition below 400°C.
Explosive Properties:	Predicted not to be explosive.
Particle Size:	14.9% of the particles have a mean diameter less than 100 micron and 13.5% of the particles have a mean diameter less than 10 micron.
Reactivity/Stability:	The chemical is predicted not to have oxidising properties based on chemical structure and experience in use. No specific information available regarding incompatibility with other substances and conditions contributing to instability. The chemical is considered to be stable. No hazardous decomposition products.

3.1 Comments on Physico-Chemical Properties

The vapour pressure (VP) of the notified chemical was determined by the vapour pressure balance method (OECD TG 104) using a sensitive electronic vapour pressure balance system. Determinations involved subjecting the notified chemical to temperatures varying between 207ºC and 225ºC, and measuring the change in mass. A VP curve was constructed using the log of the resulting mass readings against the reciprocal of temperature. The VP at 25ºC was extrapolated from these curves. Owing to the steep slopes of these curves, when extrapolated the results yielded very low and variable VP values and hence the mean was not determined, but rather the VP was said to be negligible at 25ºC (SafePharm Laboratories, 2000a).

The water solubility of the notified chemical was determined using the Flask Method. A preliminary test was conducted using 1.1 mg of the test material diluted in 1 L distilled water, and the extent of dissolution was assessed visually to be <1.1 mg/L. A definitive test was conducted using 3 test masses (1.1, 1.2, and 1.4 mg) diluted in 3 test flasks containing 1 L double-distilled water each. The test flasks were shaken for 24, 48, and 72 hours respectively, and allowed to stand for 24 h. The extent of dissolution was assessed visually and determined to be <1.4 mg/L (SafePharm Laboratories, 1997). Hence, the chemical is poorly soluble in water.

The partition coefficient was determined using the HPLC Method. A preliminary visual assessment was made based on the solubilities of the test substance in n-octanol and distilled water. A definitive test was conducted by comparing the retention time of the notified chemical in methanol against a series of reference standards. The calibration curve was constructed from the retention time of thiourea and reference standard solutions (SafePharm Laboratories, 1997). The partition coefficient indicates the chemical has a relatively high affinity to fat, and hence a potential to bioaccumulate in the environment (OECD, 1981).

A preliminary test for the Hydrolysis as a Function of pH was carried out at pH value of 4, 7 and 9, and at 50ºC for 7 days. Further tests were required to estimate the rate constant and were carried out at pH values 4 and 9 and at temperatures of 40, 50, 60 and 70ºC for periods of up to 7 days. The rate constant and half-life were calculated from the common logarithmic graph of concentrations versus time. The 25ºC rate constant and half life were extrapolated from the natural logarithm of the rate constants and reciprocal of temperature (SafePharm Laboratories, 2001a). The results of the hydrolysis test indicate that breakdown of the notified chemical by hydrolysis varies with pH, with it being most rapid (t½ several weeks) under acidic conditions and slowest (t½ >1 year) under neutral pH conditions, with t½ increasing to several months under alkaline conditions.

The Adsorption Coefficient (Koc) of the notified chemical was determined for adsorption on soils and sewage sludge using the HPLC screening method. In order to prepare a solution at a detectable level, it was first necessary to prepare a saturated solution of the notified chemical in methanol. The test substance was then ultrasonified and filtered to remove undissolved material, and further diluted in methanol. The capacity factor and logKoc value were determined with reference to a calibration curve constructed using formamide to establish dead time, and a suite of 11 reference standards to determine retention times (SafePharm Laboratories, 2001a). The results indicate that the notified chemical will strongly adsorb to organic matter and will be immobile in soils.

The dissociation constant was not determined because the chemical is not soluble in water. There are no groups likely to dissociate.

4. PURITY OF THE CHEMICAL

Degree of Purity: High.

Hazardous Impurities: None

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

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The substance is to be imported neat into Australia for use in polymer manufacture at less than 20 tonnes per year for the first five years. The notified chemical will be packaged in

10 kg poly lined paper sacks which will be packed into boxes using heavy duty corrugated cardboard. The net weight of each container will be 200 kg. The modified polypropylene resin can be used in a variety of applications such as garden furniture, containers and film.

6. OCCUPATIONAL EXPOSURE

Transport and Storage
The notified chemical will be imported in sealed bags contained in PAL boxes made from heavy duty corrugated cardboard. The net weight of each PAL box will be 200 kg. At the dockside the boxes will be off loaded from the container by forklift (driver 1) and transferred onto a wagon for transportation (driver 2) to warehouse. Maximum potential exposure duration for transport workers is 4 hours/day, 4 days/year. Occupational exposure is not expected except in the event of an accident.

Formulation of Polypropylene resin
Manufacture of the polypropylene resin containing 0.15-0.20% notified chemical is primarily in a closed system. The compounding process involves manually weighing individual bags containing the notified chemical in an environment fitted with dust extractors overhead and at the weigh scale to minimise inhalation exposure. An operative slits the bags in the blending area and the chemical is discharged into a sealed high-speed mixer under extraction. After blending, the powders are automatically charged into the extruder where they are heat compounded with polypropylene and no dust is generated. Normal batch size of the compounder is 100 kg. The resulting polypropylene compound is pelletised and bagged automatically.

Two workers are involved in the reformulation process. Maximum potential exposure duration for the warehouse worker, whose activity consists of removing the sealed bags from the PAL boxes as needed, is 2 hours/day, 20 days/year. The worker will only be handling sealed packages and therefore would not be exposed to the notified chemical under normal circumstances. The blending operator has potential exposure duration of 6 hours/day, 20 days/year. During manual handling at the mixing stage there is potential dermal and inhalation exposure to the notified chemical. The MSDS provided by the notifier indicates that workers involved should wear breathing apparatus with dust filter, impermeable gloves, safety glasses and industrial clothing.

End use
Workers handling final plastic products will not be exposed to the notified chemical as it should not be bioavailable.

7. PUBLIC EXPOSURE

Since final film polymers will be used in energy and industrial applications, the only likely exposure to the public will occur in the event of an accidental spill during transportation. According to the MSDS provided, spills should be collected and disposed of in accordance with local or national legislation. The notified chemical should be prevented from contaminating ground water and entering drains. Therefore, the risk of exposure of the general public to the notified polymer is considered low.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Release of the notified chemical into the environment is expected to be minimal as it is not manufactured in Australia. No release is expected during transport or storage unless an accidental spill occurs.

It is anticipated that some release of the chemical will occur during the mixing of the chemical with polypropylene to form the modified resin. Release may also occur through residues left in containers.

The notifier estimated about 0.3% of the imported volume will be released as dust, 0.1% may be released from incidental spills, and about 0.1% will remain in used containers. It is expected that residues, spills and filtered dust, amounting to about 100 kg per year, will be disposed of by incineration.

8.2 Fate

Usage patterns indicate that over 99.5% of the notified chemical will be fixed in polypropylene resin products such as garden furniture and resin containers. According to the notifier's estimates, the remaining 0.5% or approximately 100 kg of chemical will be disposed of by incineration.

The fate of the majority of the notified chemical will follow that of the products into which it is incorporated. At the end of their useful life, it is expected that resin furniture and other products containing the notified chemical will be disposed of in landfill. At landfill sites, it is most likely that these products will be either incinerated or buried. Incineration of the chemical will result in its destruction and the release of combustion products including oxides of carbon and nitrogen.

Burial in landfill of the polypropylene products containing the notified chemical would likely result in their eventual degradation by biotic and abiotic processes. However, the results of a ready biodegradation test, OECD TG 301C Modified MITI Test (I), indicate the notified chemical is not readily degraded by microorganisms under aerobic conditions. During the test, performed using microorganisms in activated sewage sludge, only 7% of the notified chemical was degraded at the end of the 28-day test period. This compared to 55% of the reference substance, aniline, degraded after 7 days and 68% degraded after 14 days, indicating the test was viable (KRL, 1996). The results of the hydrolysis test indicate that abiotic breakdown of the notified chemical is possible, particularly under acidic conditions. Many fungi have the ability to oxidise aromatic hydrocarbons such as naphthalene (Gibson DT, 1980), which could also contribute to its eventual breakdown if buried in landfill. Degradation of the resin products containing the chemical would be expected to occur much more slowly than the raw chemical because access to the chemical substrates would be restricted.

The log Koc value indicates the notified chemical will strongly adsorb to organic matter and will be immobile in soils. Hence, the notified chemical is not expected to leach from the soil

and to enter waterways. In the event of accidental release of the chemical into waterways it is expected that most of the chemical would either float on the surface, or sink to the bottom, and would not become associated with the water compartment as it is water insoluble.

A Bioaccumulation in Carp Test was carried out to determine the degree of bioconcentration of the notified chemical in the bodies of fish. The test was conducted in continuously flowing water against 11 Carp (*cyprimus carpio)* per concentration over a period of 8 weeks (KRL, 1995). No depuration test was conducted. The principal method of uptake of a chemical in the running water test is assumed to be through the gills (OECD, 1981).

The test solutions were prepared by dissolving the test substance, crystal sugar (at 10 times the amount of initial test substance) and HC0-20 (at 20 times the amount of initial test substance) in ion-exchange water to produce a crude solution containing concentrations of 0 (control), 0.5 and 0.05 mg/L of test material. Measurements of the concentration of the test substance accumulated within the test fish (C_f) were carried out during week 2, 4, 6, and 8 using HPLC. Measurements of the concentrations of the notified chemical in test water (Cw) were performed twice weekly during the exposure period. The measured concentrations of test substance in water always exceeded 79% of the set concentration, and hence verify the exposure levels.

The bioconcentration factor (BCF) (Cf/Cw) was determined to be $\leq$ 1.9 in fish exposed to the first test concentration (0.5 mg/L) and $\leq$ 20 in fish exposed to the second test concentration (0.05 mg/L) at each analytical period. Hence the BCF was highest for the lowest test concentration. The concentration in tissue reached a plateau (steady state) after the second week at both the high and low exposure concentrations, and remained constant from week 2 through to week 8.

The BCF values, determined from the bioaccumulation test against carp, indicate only a slight ability of the notified chemical to bioconcentrate in fish (Mensink B J W G et al, 1995). In aquatic environments, the dominant mechanism for accumulation is by direct diffusion from the ambient medium, with indirect accumulation via the food chain less important (OECD, 1981). Hence, the low bioaccumlation factor measured in carp may reflect the low concentrations available for diffusion across membranes in the test medium owing to the low water solubility of the chemical. The bioconcentration factor was highest from the test medium containing the lowest test concentration suggesting that at the higher concentration levels the chemical did not reside in the water soluble fraction.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of NJ Star NU-100

Test	***Species***	***Outcome***	Reference

acute oral toxicity	rat	LD_{50} > 2000 mg/kg	(Medical Safety Research Centre, 1992)
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	(SafePharm Laboratories, 2000b)
skin irritation	rabbit	Non-irritating	(SafePharm Laboratories, 2000c)
eye irritation	rabbit	Slight irritant	(SafePharm Laboratories, 2000d)
skin sensitisation	guinea pig	Non-sensitiser	(SafePharm Laboratories, 2000e)

9.1.1 Oral Toxicity (Medical Safety Research Centre, 1992)

Species/strain: rat/Wistar

Number/sex of animals: 5/sex.

Observation period: 14 days.

Method of administration: Oral (gavage); vehicle: corn oil; dosage: 2000 mg/kg.

Test method: OECD TG 401

Mortality: None.

Clinical observations: None reported.

Morphological findings: None.

LD_{50}: > 2000 mg/kg

Result: The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (SafePharm Laboratories, 2000b)

Species/strain: rat/Sprague-Dawley.

Number/sex of animals: 5/sex.

Observation period: 14 days.

Method of administration: Semi-occluded dermal application of undiluted test material for 24 hours; dose, 2000 mg/kg.

Test method: OECD TG 402

Mortality: None.

Clinical observations:	None.
Morphological findings:	None.
Comment:	No signs of skin irritation at the treatment sites.
LD_{50}:	> 2000 mg/kg.
Result:	The notified chemical was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity

No data provided.

9.1.4 Skin Irritation (SafePharm Laboratories, 2000c)

Species/strain:	rabbit/New Zealand White (NZW).
Number/sex of animals:	3 males.
Observation period:	72 hours.
Method of administration:	0.5 g of the test substance moistened with 0.5 mL of distilled water under semi-occluded dressing for 4 hours.
Test method:	OECD TG 404
Comment:	Neither erythema nor oedema was observed in any animal at the treatment site at 1, 24, 48 or 72 hours after patch removal.
Result:	The notified chemical was not irritating to the skin of rabbits.

9.1.5 Eye Irritation (SafePharm Laboratories, 2000d)

Species/strain:	rabbit/NZW.
Number/sex of animals:	3 males.
Observation period:	72 hours.
Method of administration:	59 mg (0.1 mL) of the test substance was placed in the conjunctival sac of the right eye of each animal, the left eye being the untreated control.
Test method:	OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation											
Animal	***1 hour***			***1 day***			***2 days***			***3 days***		
Cornea	No scores above zero.											
Iris	No scores above zero.											
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	1	2	1	0	0	0	0	0	0	0	0
2	2	1	1	1	0	0	0	0	0	0	0	0
3	2	1	2	1	1	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

Result: The notified chemical was slightly irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation (SafePharm Laboratories, 2000e)

Species/strain: guinea pig/Dunkin-Hartley.

Number of animals: 5 control, 10 test.

Induction procedure:

test group:

day 1 Pairs of intradermal injections (0.1 mL) to the scapular region as follows:

- Freund's Complete Adjuvant (FCA), 1:1 in distilled water;
- test substance,10% w/v in arachis oil;
- test substance,10% w/v in FCA, 1:1 in distilled water.

day 7 50% w/v test substance in arachis oil under occlusive patch for 48 hours.

control group: Test substance omitted and the 3 pairs of injections were with FCA 1:1 in distilled water, arachis oil and 50% w/v arachis oil in FCA/distilled water (1:1). Topical induction was the same as for the test group except with the absence of the test substance.

Challenge procedure:

day 21 25% and 50% w/v test substance in arachis oil under occlusive patch for 24 hours.

Test method: OECD TG 406

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
25%	0/10**	0/10	0/5	0/5
50%	0/10	0/10	0/5	0/5

* time after patch removal
** number of animals exhibiting positive response

Result: The notified chemical was not sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity (Chemicals Safety Centre, 1995a)

Species/strain: rat/Sprague-Dawley.

Number/sex of animals: 6/sex/dose group.

Method of administration: Oral (gavage); vehicle: gum arabic.

Dose/Study duration: 0, 40, 200 and 1000 mg/kg/day for 28 consecutive days. The dose groups were control, low, medium and high dose, respectively. Additional control and high dose groups were allowed a 2-week recovery period prior to sacrifice.

Test method: OECD TG 407

Clinical observations

Loss of hair was observed in two males at the high dose (one in the recovery group at 28 days) and one male in the recovery group after the recovery period. One female in the control and high dose (non-recovery) groups also exhibited hair loss. One male in the high dose recovery group exhibited scab formation at 28 days and the end of the recovery period. One female in the control group exhibited scab formation and one high dose female exhibited exudate.

No effects were observed on body weight or food consumption.

Clinical chemistry/Haematology/ Urinalysis

Clinical chemistry

Reduced potassium levels were observed in both sexes of the low dose group. Elevated cholinesterase levels were observed in the male mid-dose group. Females of the high dose

recovery group exhibited reduced inorganic phosphorus levels.

Haematology

Reduced monocyte ratio in the female high dose group. Reduced white blood cell count and monocyte ratio in the male high dose recovery group.

Urinalysis

No observations.

Macrosopic effects/ Organ weights

White spots on the kidneys were observed in one male of the mid dose group and black spots on the mucosa of the glandular stomach in one female of the high dose recovery group.

Relative to body weight, liver weight was reduced and brain weight elevated in low dose females. Reduced spleen weight relative to body weight and elevated absolute brain weight were observed in high dose recovery females.

Histopathology

Granulomas and flecks of fat peripheral to the liver lobules were observed in the male and female high dose groups but also in the control groups. Basophilia of the uriniferous tubules, cell infiltration, cortical calcification and cyst formation with or without focal fibrosis were observed in kidneys of mid dose males. Cyst formation with or without focal fibrosis was observed was observed in one female of the high dose group. One female in the control group had corticle fibrosis of the kidneys. In the female recovery group one animal exhibited ulceration of the mucosa of the glandular stomach.

Comment

No consistent organ toxicity could be ascribed to treatment with the test substance.

Result

The NOAEL (No Observed Adverse Effect Level) for the notified chemical was 1000 mg/kg/day for 28 days when administered orally.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Huntingdon Research Centre, 1993)

Strains:	*S. typhimurium* strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100 and *E. coli* strain WP2 *uvr*A.
Metabolic activation:	S9 fraction from the livers of Sprague-Dawley rats induced

with Aroclor 1254.

Concentration range: 0, 312.5, 625, 1250, 2500 and 5000 microgram/plate.

Test method: OECD TG 471

Comment: The test substance was diluted in 1% methyl cellulose which also served as the negative control and gave the expected background levels for the tester strains. Positive controls demonstrated the sensitivity of the test, gave the expected responses and were: N-ethyl-N'-nitro-N-nitrosoguanidine (strains TA 100, TA 1535 and WP2 *uvr*A), 9-aminoacridine (TA 1537), 2-nitrofluorene (TA 98 and TA 1538) all – S9; 2-aminoanthracene (all strains + S9).

Result: The notified chemical was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay in Chinese Hamster Lung (CHL) Fibroblasts (Chemicals Safety Centre, 1995b)

Cells: CHL cells.

Metabolic activation system: S9 fraction from the livers of Phenobarbital-induced rats.

Dosing schedule:

Metabolic Activation	*Experiment Number*	***Test concentration (μg/mL)***	***Controls***
-S9	1	treatment time = 24 hours dosage = 0*, 1250*, 2500* and 5000* microgram/mL	Positive: mitomycin C (0.05 microgram/mL) Negative: 0.5% methylcellulose
	2	treatment time = 48 hours dosage = 0*, 1250*, 2500* and 5000* microgram/mL	
	3	treatment time = 6 hours; incubation time = 24 hours dosage = 0*, 1250*, 2500* and 5000* microgram/mL	
+S9	3	treatment time = 6 hours; incubation time = 24 hours dosage = 0*, 1250*, 2500* and 5000* microgram/mL	Positive: cyclophosphamide (10 microgram/mL) Negative: 0.5% methylcellulose

* - cultures selected for metaphase analysis

Test method:	not specified in details but appears to be similar to OECD TG 473.
Result:	The notified chemical was non clastogenic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity in rats (LD50 > 2000 mg/kg) and low acute dermal toxicity in rats (LD50 > 2000 mg/kg). No organ toxicity was detected in a 28-day repeated dose oral study in rats and the NOAEL was equal to 1000 mg/kg/day. The notified chemical was not a skin irritant in rabbits, was a slight eye irritant in rabbits, was not a skin sensitiser guinea pigs and was neither mutagenic in bacteria nor clastogenic in Chinese Hamster Lung cells.

The notified chemical is not determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has provided toxicity tests for fish, daphnia, algae and microorganisms. Unless otherwise recorded, all test were carried out in accordance with the protocols and standards outlined in the OECD GLP Principles, and were conducted following the OECD Test Guidelines. The results of the tests are summarised in the table below.

Test	*Species*	*Results*
Acute Toxicity to Fish Test (OECD TG 203)	Rainbow Trout *Oncorhynchus mykiss*	96 h LC50 > 0.48 microgram/L NOEC = 0.48 microgram/L
Acute Toxicity Test in Fish (JIS K 0102-1993 §71)	Japanese Killifish *Oryzias latipes*	48 h LC50 > 200 mg/L
Acute Immobilisation Test (OECD TG 202)	Water Flea *Daphnia magna*	48 h EC50 > 12 microgram/L NOEC = 12 microgram/L
Algal Growth Inhibition Test (OECD TG 201)	Green Alga *Scenedesmus subspicatus*	72 h EC50 > 0.48 microgram/L NOEC = 0.48 microgram/L
Activated Sludge Respiration Inhibition Test (OECD TG 209)	Microorganisms	3 h EC50 > 1000 mg/L NOEC = 1000 mg/L

* NOEC - no observable effect concentration

Toxicity to Fish

Oryzias latipes

A preliminary Acute Toxicity Test to Fish was performed against Japanese Killifish, *Oryzias latipes,* following the procedures outlined in Methods of Testing Industrial Waste Water, in order to determine appropriate concentrations for the bioaccumulation test (see section 8.2). During the test, 10 fish per test vessel were exposed for up to 48 hours to a nominal concentration of 200 mg/L of the notified chemical. The test solutions were prepared by dissolving the test substance, crystal sugar (1000 mg) and HC0-20 (2000 mg) in ion-exchange water to produce a crude solution containing the required concentrations of test material. The water was changed every 8 to 16 hours. No fish mortalities were observed during the test (KRL, 1995).

Rainbow Trout

An Acute Toxicity to Fish Test was conducted against Rainbow Trout following the procedures outlined in the OECD TG 203. A preliminary range finding test was carried out under semi-static conditions over 96 hours against 2 groups of 10 Rainbow Trout per concentration, using nominal concentrations of 0 (control), and 27 microgram/L of test substance (SafePharm Laboratories, 2000f).

Following the range finding test, a limit test was carried out under semi-static conditions over 96 hours against 3 groups of 10 Rainbow Trout per concentration. A modification of the standard method of preparation of aqueous media was required because of the poor water solubility of the test substance. This involved preparing a saturated solution by adding excess test material to dechlorinated tap water (ie. 1000 mg/L) and then mixing the media using a magnetic stirrer until a maximum measured concentrations was reached (after 95 hours), followed by a 1 hour standing period. The aqueous phase was then separated by siphon and the test animals exposed to the saturated solution.

The preliminary analysis of the unfiltered test media at 0 hours showed concentrations ranging from 6.98 microgram/L to 8.92 microgram/L. Analysis of the expired test media after 24 and 92 hours showed concentrations ranging from 4.28 to 8.24 microgram/L in unfiltered samples, whereas in the filtered samples the concentrations were below the limit of quantification, determined to be 0.48 microgram/L. No fish mortalities were observed in the fish exposed to the test media having a mean measured concentration of 7.95 microgram/L (ie. as measured in the unfiltered freshly prepared test media at 0 hours).

On the basis of the limit of quantification of the dissolved concentration of test material in the test medium, the 96 h LC50 was determined to be > 0.48 microgram/L, and the NOEC was = 0.48 microgram/L.

Toxicity to Daphnia

An Acute Immobilisation Test was performed against *Daphnia magna*. Following a preliminary range finding test, a limit test was carried out under static conditions for 48 hours against 10 young daphnids per test vessel using nominal loading rates of 0 (control) and 100 mg/L of the notified chemical. The concentration of the test material in solution was verified by chemical analysis at 0 and 48 hours. Water samples taken from the 4 replicate vessels

containing the notified chemical were pooled prior to analysis for Total Organic Carbon. No daphnids exposed to the Water Soluble Fraction (WSF) of the test material were immobilised during the test (SafePharm Laboratories, 1999).

A modification of the standard method of preparation of aqueous media was required because of the poor water solubility of the test substance. This involved preparing a WSF by adding the nominal concentration of test material to water and then mixing the media using a magnetic stirrer until a maximum measured concentrations was reached (after 23 hours stirring). After a 1 hour standing period, the Water Soluble Fraction was removed by filtration through 0.2 micron membrane filters. The concentration of the test medium containing the 100 mg/L loading rate WSF was below the detection limit of the analytical method, assessed to be 0.012 mg/L. Therefore, the 24 and 48 hour EC_{50} values were determined to be greater than 0.012 mg/L, and the NOEC was determined to be equal to 0.012 mg/L, on the basis of the limit of quantification of dissolved concentrations of the notified chemical. The 48 hour ELR50 was > 100 mg/L loading rate WSF.

Toxicity to Algae

An Algal Growth Inhibition Test was performed against Green Freshwater Algae. Following a preliminary range finding test, a definitive test was carried out against *Scendesmus subspicatus* (10^4 cells/mL), exposed to test controls (3 replicates) containing no test material and to saturated solutions (6 replicates) of the test substance over 72 hours (SafePharm Laboratories, 2001b).

Saturated test solutions were prepared by adding excess (1000 mg/L) of the notified chemical and stirring for 95 hours until saturation. The aqueous phase of the test material was then removed from the mixing vessel by a siphon placed at mid depth in the vessel. Samples of filtered and unfiltered media were analysed at 0 and 72 hours. The filtered samples give a measure of the dissolved and hence bio-available test material present, while the unfiltered samples give a measure of the total amount of test material present in dissolved and dispersed forms. The concentration of the test substance in both the filtered and unfiltered test samples was found to be less than the limit of quantification (LOQ) of the analytical method, assessed to be 0.48 microgram/L

Algal cell densities were determined using a haemocytometer and light microscope at the start of the study and after 72 hours. Algal growth was monitored using a Coulter Multisizer Particle Counter at 0, 24, 48 and 72 hours. Neither the growth rate (r) nor the biomass (b) were affected by the presence of the notified chemical (SafePharm Laboratories, 2001a).

The EC50 results were based on the LOQ values of the filtered samples because the concentration of dissolved test material in the saturated solution was less than LOQ, and there was no observed toxicity at saturation.

Toxicity to Microorganisms

A study was performed to assess the effects of the notified chemical on the respiration of activated sewage sludge. Following a preliminary range finding test, activated sewage sludge from domestic sewage was incubated in an aqueous dispersion containing 0 (control) and 1000 mg/L (3 replicates) of test material and for 3 hours. The test medium was observed to form a light grey dispersion with test material visible throughout the test medium and floating

on the surface.

The rate of respiration was determined after 30 minutes and at 3 hours and the results were compared to the respiration rates of microorganisms in a reference material, 3,5-dichlorophenol. The respiration rates in the 2 controls were within 15% of each other, and the 3 h EC50 for the reference substance (17 mg/L) was within the accepted range, hence the test was deemed valid. The notified chemical had no measurable effects on the respiration rates of microorganisms in sewage sludge (SafePharm Laboratories, 2000g).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Up to 20 tonnes of the notified chemical, NJ Star NU-100, will be imported into Australia each year. Up to 99.5% of the imported chemical will become incorporated into polypropylene resin products, the remaining 0.5% may be released into the environment as a result of residues and spills.

Release of the chemical into the aquatic environment is unlikely to occur, either during mixing of the chemical, or at end use. In the end use products, the chemical will be bound up in tough polypropylene resin where it will remain until the products reach the end of their useful life. Ultimately, all of the imported chemical will be disposed of either in landfill or incinerated.

The toxicity tests indicate the notified chemical is not toxic to aquatic organisms at the levels likely to be encountered dissolved in the aquatic compartment. Many of the properties of the notified chemical, including the chemical structure (aromatics), high Pow and low molecular weight suggest a strong potential for the chemical to bioaccumulate (Connell, 1990). However, the bioaccumulation test against carp indicated only slight ability to bioconcentrate in these organisms.

Based on these results and the anticipated usage patterns, the notified chemical is not expected to enter the aquatic environment or pose any significant hazard to aquatic organisms.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

The notified chemical was of very low acute oral toxicity in rats (LD50 > 2000 mg/kg) and low acute dermal toxicity in rats (LD50 > 2000 mg/kg). No organ toxicity was detected in a 28-day repeated dose oral study in rats and the NOAEL was equal to 1000 mg/kg/day. The notified chemical was not a skin irritant in rabbits, was a slight eye irritant in rabbits, was not a skin sensitiser guinea pigs and was neither mutagenic in bacteria nor clastogenic in Chinese Hamster Lung cells.

The notified chemical is not determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

The only potential health effects from exposure to the notified chemical may be respiratory irritation from nuisance dust and slight eye irritation presumably from mechanical effects as 13.5% of the particles are within the respirable range and the rest are inspirable.

Occupational Health and Safety

The notified chemical will be imported in sealed bags contained in PAL boxes made from heavy duty corrugated cardboard. The net weight of each PAL box will be 200 kg. Occupational exposure is not expected during transport and storage except in the event of an accident.

Manufacture of the polypropylene resin containing 0.15 – 0.20% notified chemical is primarily in a closed system. The compounding process involves manually weighing individual bags containing the notified chemical in an environment fitted with dust extractors overhead and at the weigh scale to minimise inhalation exposure. An operative slits the bags in the blending area and the chemical is discharged into a sealed high-speed mixer under extraction. After blending, the powders are automatically charged into the extruder where they are heat compounded with polypropylene and no dust is generated. Normal batch size of the compounder is 100 kg. The resulting polypropylene compound is pelletised and bagged automatically.

During manual handling at the mixing stage there is potential dermal and inhalation exposure to the notified chemical although dust levels should be low through the use of local exhaust ventilation. The MSDS provided by the notifier indicates that workers involved should wear breathing apparatus with dust filter, impermeable gloves, safety glasses and industrial clothing. The risk of respiratory or eye irritation during polypropylene manufacture is low. However, employers are responsible for maintaining nuisance dust levels below the NOHSC exposure standard of 10 mg/m3 (NOHSC, 1995).

Workers handling final plastic products will not be exposed to the notified chemical as it should not be bioavailable and therefore there is no risk of adverse health effects.

Public Health

The notified polymer will not be available to the general public and will be used in industrial and energy applications. Therefore, the risk to public health from the notified chemical is expected to be low.

13. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - local exhaust ventilation should be employed over the polypropylene mixing vessel

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  – spillage of the notified chemical should be avoided and any spills should be cleaned up promptly and placed in containers for disposal

- Employers must ensure that the NOHSC exposure standard for nuisance dust is not exceeded in the workplace.

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

- The MSDS for the notified chemical should be amended to include:

  - the NOHSC exposure standard for nuisance dust (10mg/m^3) in section 8, Exposure Controls/Personal Protection, and
  - the fact that the chemical is a slight eye irritant in section 11, Toxicological Information, Local effects.

- 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.

13.1 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.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (1994).

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.

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Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize *et al*., 1944) 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

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