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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

HYPERFORM HPN-68

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Compco Pty Ltd
Factory 10
19-23 Japaddy Street
Mordialloc VIC 3195

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:
Identity of chemical
Composition
Import volume
Identity of sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA

2. IDENTITY OF CHEMICAL

MARKETING NAME
Hyperform –HPN 68
METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD UV-Vis, IR and NMR Spectrum

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported as a powder at approximately 100%.

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

The notified polymer will be imported at up to 1 tonne/year for each of the first 5 years.

USE
The notified chemical is used in polypropylene and/or polyethylene manufacture.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
The notified chemical will be imported by sea into both Melbourne and Sydney. Air transport may occur in rare circumstances

IDENTITY OF RECIPIENTS
Notifier's site

TRANSPORTATION AND PACKAGING
It is expected that the notified chemical will be imported in either 200 kg steel drums or 25 kg plastic plastic pails.

5.2. Operation Description

The notified chemical is used as a polymer additive in polypropylene and/or polyethylene manufacture. The polymer manufacture is comprised of a primary and secondary stage. The notified chemical is normally added during secondary manufacture, where additives are mixed with polymer prior to article manufacture.

The notified chemical is weighed and then blended with modifier additives followed by extrusion, moulding and calendering to form the finished item. The process is expected to be enclosed and automated or in batches. Addition of the notified chemical to the secondary plastic manufacturing process will be achieved by contained automated dosing equipment.

Following extrusion/polymerisation processes, the notified chemical will be encapsulated by the polypropylene/polyethylene at high temperatures.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Importation workers	2	4 hrs/day	6 days/yr
Distribution	1	2 hrs/day	240 days/yr
Plastic manufacture	60	4 hrs/day	240 days/yr

Exposure Details
The main categories of workers likely to handle the notified chemical are those involved in transport and handling and those in polypropylene and/or polyethylene production manufacture (predominantly moulding of plastic articles). This operation is largely an enclosed automated process.

During secondary manufacture, workers may become exposed when weighing and adding the notified chemical from a container to a mixer. Addition of the notified chemical will be performed by contained automatic dosing equipment. Local exhaust ventilation will be used and workers will wear overalls, impervious gloves and eye protection.

Quality control testing of the final product will be performed in a fume cupboard. Once the notified chemical is consumed in the extrusion/polymerisation processes, it is encapsulated by the polypropylene/polyethylene at high temperatures, it is not expected to be available for exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Once imported, the notified chemical will be transported from the docks to warehouses and the container is destuffed and the chemical stored. No release of the notified chemical is anticipated during transport and storage, except in the event of an accidental spill.

The notified chemical will be transported to the customers site where it will be transferred into automated dosing equipment and added into polyethylene and polypropylene prior to article manufacture. The quantity of waste chemical annually is expected to be less than 5 kg in transfer between drum and manufacture process, below 10 kg incorporated in plastic waste and a maximum of

24 kg as drum residues.

RELEASE OF CHEMICAL FROM USE
The majority of the notified chemical will be encapsulated into plastic products from which release is not expected. A small amount will be disposed of to approved landfill as residues in empty containers

5.5. Disposal

Spills and drum residues will be disposed of to approved landfill.

It is likely that the plastic products containing the notified chemical will be disposed of in landfill at the end of their useful life.

5.6. Public exposure

The public may only be exposed to the notified chemical upon contact with a wide variety of plastic products such as automotive compounds and parts, pipes, bathroom fittings, furniture and stadium seating. At that stage, the polymer is encapsulated within the polymer matrix.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Solid odourless powder at 20ºC and 101.3 kPa

Melting Point Decomposes without melting
Decomposition temperature 352.85 ºC

METHOD ASTM E537-86 Method A1 and A2 of Commission Directive 92/69/EEC
Remarks Test material decomposed without melting from 503±0.5K at 101.15Kpa, by differential scanning calorimetry
TEST FACILITY SafePharm Laboratories (2002a)

Boiling Point >906.15ºC
METHOD Estimated using a modified method of Stein and Brown (Syracuse Research Corporation Inc., MPBP for Windows, version 1.40, William Meylan 1994-1999)
Remarks Test material decomposed without melting from 503±0.5K at 101.15Kpa, by differential scanning calorimetry
TEST FACILITY SafePharm Laboratories (2002a)

Density 1650 kg/m^3 at 21ºC

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Procedure used a gas comparison pycnometer
TEST FACILITY SafePharm Laboratories (2002a)

Vapour Pressure <5.6 x 10^{-5} Pa at 25ºC

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Method used a vapour pressure balance based on CI Electronics microbalance.
TEST FACILITY SafePharm Laboratories (2002b)

Water Solubility 37.5-40% w/w at 20ºC

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Analytical Method: observation of undissolved solid.
Shake flask method at a range of concentrations at 30 ºC for 72 h and to visual inspection. Solution pH (~9.7) recorded.
TEST FACILITY SafePharm Laboratories (2002a)

Hydrolysis as a Function of pH

METHOD EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ days*
4	25	>365
7	25	>365
9	25	>365

Remarks Less than 10% hydrolysis (HPLC) was observed at all pH values over the 5 days of the test at 50 ºC.
TEST FACILITY SafePharm Laboratories (2002a)

Partition Coefficient (n-octanol/water) log Pow at 22ºC = -2.08

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient (Shake-flask method).
Remarks Analytical Method: HPLC
TEST FACILITY SafePharm Laboratories (2002a)

Adsorption/Desorption log K_{oc} = <1.25 at pH 5.5.

METHOD EC Directive 2001/59/EEC C.19 HPLC Adsorption Coefficient.
Remarks The determination was carried out using an HPLC screening method. The retention time of a sample of the chemical was compared to a calibration graph of standard samples of known K_{oc}. As the sample eluted before any of the standards the value determined represents an upper limit.
TEST FACILITY SafePharm Laboratories (2002a)

Dissociation Constant PKa_1 ~ 4.1, PKa_1 ~ 6.5

Remarks During the determination of the adsorption coefficient the two dissociation constants were estimated. The results are quoted and no explanation of the method of determination is given.
TEST FACILITY SafePharm Laboratories (2002a)

Particle Size 18.0% particle size < 100 µm (Sieve method)
1.98% particle size <10 µm (Cascade impactor)

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.
Cascade impactor method:

Overall cumulative amounts of test chemical with a particle size less than 10 µm (%) from 4 determinations are:

Mean cumulative amount of test chemical less than 10 µm (%)	*Cumulative amount of test chemical (%)*
1.98	2.39
	1.80
	1.84
	1.91

Remarks Total amount of test chemical recovered from impactor cups, filter and artificial throat 2.9999 g
Few particles were of size less than 10µm
TEST FACILITY SafePharm Laboratories (2002a)

Flash Point Not determined

Flammability Limits Not classified as a flammable solid

METHOD Determination of flammability (solids).

EC Directive 92/69/EEC A.9 Flash Point.

Remarks The flammability (solids) was determined by measuring the burning rate of test material prepared as a pile of set dimensions.

The test material did not propagate combustion over the 200 nm of the preliminary screening test in under 4 minutes.

TEST FACILITY SafePharm Laboratories (2002c)

Autoignition Temperature 317ºC

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

Remarks The test chemical was heated in an oven and the relative self ignition temperature determined

TEST FACILITY SafePharm Laboratories (2002b)

Explosive Properties Predicted negative

Remarks No chemical groups present would infer explosive properties

TEST FACILITY SafePharm Laboratories (2002b)

Reactivity Predicted negative

ADDITIONAL TESTS

Oxidizing Properties Predicted negative

TEST FACILITY SafePharm Laboratories (2002b)

Dust Explosivity

METHOD Determination of Explosion Indices of Combustible Dusts in Air ISO 6184/1

Remarks Mean maximum values
Explosion pressure Pmax 7.2 bar
Rate of pressure rise (dP/dt)max 545 bars
Rate of pressure rise in a 1 m^3 vessel Kst value 148 bar.m/s

The values are measured using a 20 L spherical pressure test chamber. Pmax is recorded by piezo electric pressure transducers. The sample was tested as 100% <75 µm fine white powder.

TEST FACILITY Chilworth Technology (2002)

Thermal stability 1. Bulk Powder Test-Diffusion Cell Thermal Stability Screening Test
2. Powder Layer Test (Air over layer) Thermal Stability Screening Test.

METHOD 1. Bulk powder test is performed in a temperature programmed oven of 30 L which is fitted with explosion vents.
2. Powder layer test is performed in a temperature programmed horizontal furnace 70 mm diameter

Remarks When an exothermic reaction begins in the sample a temperature difference is seen:
1. Minimum onset temperature of exotherm 151 ºC
Sample peak temperature 557ºC

2. Minimum onset temperature of exotherm 274 ºC
Sample peak temperature 537ºC

TEST FACILITY Chilworth Technology (2002)

Minimum Ignition Energy 100-300 mJ

METHOD ASTM E-2019 Standard Test Method of a Dust Cloud in Air and BS 5958: Part 1: 1991 Control of Undesiredable Static Electricity

Remarks Minimum ignition energy is measured using the Vertical Tube Apparatus. A measured weight of dust is repeatedly measured through sparks of known energy. The minimym ignition energy is 100-300 mJ.
TEST FACILITY Chilworth Technology (2002)

Minimum Ignition Temperature 440-660°C

METHOD ASTM E-2019 Standard Test Method of a Dust Cloud in Air and BS 5958: Part 1: 1991 Control of Undesiredable Static Electricity
Remarks Minimum ignition energy is measured using the Golbert-Greenwald Furnace. The minimum ignition energy is 440-460°C
TEST FACILITY Chilworth Technology (2002)

Surface Tension 72.4 mN/m at 22°C (not considered to be a surface active material)

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Procedure used a ring method based on ISO304
Concentration at 1.00g/L solution
TEST FACILITY SafePharm Laboratories (2002a)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Assessment Conclusion*
Rat, acute oral	LD_{50} >2500 mg/kg bw low toxicity
Rat, acute dermal	LD_{50} >2000 mg/kg bw low toxicity
Rat, acute inhalation	Not submitted
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test.	Inadequate evidence of sensitisation.
Rat, repeat dose oral toxicity - 28 days	NOAEL 50 mg/kg/day
Mouse, repeat dose oral toxicity - 90days.	NOAEL 1419 mg/kg bw/day (10000 ppm)
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mouse lymphoma mutation assay	non mutagenic
Genotoxicity – in vitro chromosome aberration in human lymphocytes	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Sprague-Dawley
Vehicle Water
Remarks - Method

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
	3 females and 3 males	2000	No deaths

LD50 >2500 mg/kg bw
Signs of Toxicity No signs of systemic toxicity. No effect seen on body weight gains.
Effects in Organs No abnormalities at necropsy
Remarks - Results

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	SafePharm Laboratories (2001a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/Sprague Dawley
Vehicle	Water
Type of dressing	Semi-occlusive.
Remarks - Method	

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
	Five males and 5 females	2000	No deaths

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	No signs of dermal irritation No effects on body weight gains
Signs of Toxicity - Systemic	No signs of systemic toxicity
Effects in Organs	No abnormalities seen at necropsy
Remarks - Results	

CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	SafePharm Laboratories (2001b)

7.3. Acute toxicity – inhalation

Study not conducted. Inhalation toxicity is expected to be low as the notified chemical has low vapour pressure and is of low toxicity by the oral and dermal routes.

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 rabbits
Vehicle	None
Type of Dressing	Occlusive
Remarks - Method	

RESULTS

Remarks - Results	All individual scores were equal to zero. No evidence of skin irritation was noted during the study.
CONCLUSION	The notified chemical is non-irritating to skin.
TEST FACILITY	SafePharm Laboratories (2001c)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Remarks - Method Additional observation was made on Day 7.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.67	1	1.67	2	48 hrs	0
Conjunctiva: chemosis	1	0.33	1.33	2	24 hrs	0
Conjunctiva: discharge	1	0.33	0.33	2	24 hrs	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	1	1 hr	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results Moderate conjunctival irritation were noted in all treated eyes one and 24 hrs after treatment with minimal to moderate conjunctival irritation at the 48-hour observation. Minimal conjunctival irritation in 2 treated eyes at the 72 hr observation.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY SafePharm Laboratories (2001d)

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation – Maximisation method
Species/Strain Guinea pig/albino dunkin Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration: 50% and 35% topical
intradermal: 5 % and 1% w/w in distilled water
topical: 50%, 25%, 10% and 5% w/w in distilled water.
MAIN STUDY
Number of Animals Test Group: 10 Control Group: 5
INDUCTION PHASE Induction Concentration:
intradermal injection 5% in distilled water
topical application 50% in distilled water
Signs of Irritation
CHALLENGE PHASE
1st challenge topical application: 50% and 25% w/w in distilled water
Remarks - Method Ten test and five control animals

RESULTS The test chemical produced a 0% (0/10) sensitisation rate:

Remarks - Results *50% notified chemical in distilled water*: discrete or patchy to moderate and confluent erythema was noted at the challenge sites. The reactions did not persist at the 48-hr observation. Desquamation was noted at the challenge site of one animal at 48 hr observation.

25% notified chemical in distilled water: discrete or patchy to moderate and confluent erythema was noted at the challenge sites of 2 animals at 24 hrs. The reactions did not persist at the 48 hr observation period. Desquamation was noted at the challenge site of one animal at 48 hrs.

CONCLUSION	There was inadequate evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	SafePharm Laboratories (2001e).

7.7. 28-Day repeat dose oral toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rats/Sragues Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week;
Vehicle	Distilled water
Remarks – Method	Recovery group were maintained for 14 days after treatment for 28 days.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	Five males and five females	0	None
II (low dose)	Five males and five females	50	None
III (mid dose)	Five males and five females	250	None
IV (high dose)	Five males and five females	1000	None
V (control recovery)	Five males and five females	0	None
VI (high dose recovery)	Five males and five females	1000	None

Mortality and Time to Death

None

Clinical Observations and behavioural Assessments

Animals treated at the high dose displayed signs of ataxia. No effects were seen at 250 and 50 mg/kg bw/day. The recovery group did not show significant signs due to treatment. The clinical signs of ataxia in week 4 correlated with open field assessment.

No significant effects on bodyweight changes, food and water consumption.

Functional Observations; Behavioural and Sensory Reactivity Assessments and Functional performance Tests

No treatment related changes in the functional performance parameters, sensory reactivity and no significant changes in functional observations.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology: the only effects seen were a small but significant decrease in red blood cells and an increase in mean corpuscular haemoglobin in the recovery treated male groups. A reduction in total leucocyte count was observed in the corresponding female group.

Blood Chemistry: Only one change was seen at 1000 mg/kg bw, ie significant increase in sodium level in males. No effects were seen in the recovery group.

No significant effects seen urinalysis at any of the dose levels in any of the groups tested.

Organ weight

There was an increase in heart weight in the male recovery group and an increase in spleen weight in females at 250 mg/kg bw/day, but no dose-response relationship was established.

Pathology-macroscopic

At necropsy, no abnormalities were reported except for one female, treated at 250 mg/kg bw/day, showing

lungs with mottled appearance. The recovery group did not report any abnormalities.

Histopathological Findings
Microscopic examination of tissue sections revealed treatment-related stomach and caecum changes:

Stomach: mucosal changes characterised by agglomeration of secretion, superficial basophilia and increased mononuclear cell infiltrates in the lamina propria were seen in animals treated at 1000 mg/kg bw/day or 250 mg/kg bw/day. In the recovery group, partial regression of the stomach condition was observed.

Caecum: An increase in the severity of mononuclear cell infiltrates in the lamina propria was observed in relation to treatment of animals at 1000 mg/kg bw/day. The recovery group showed complete regression of the caecum condition.

Remarks – Results
The prepared formulations were within ±7% of the nominal concentration.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 50 mg/kg bw/day in this study, based on histopathological effects seen at 1000 and 250 mg/kg bw/day.

TEST FACILITY SafePharm Laboratories (2002d)

7.8. 90-Day repeat dose oral toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.
Species/Strain Mice/Crl:CD-1 (ICR)
Route of Administration Oral –diet
Exposure Information Total exposure days: 90 days;
Dose regimen: 7 days per week;
Remarks – Method

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	Ten males and ten females	0	None
II (low dose)	Ten males and ten females	78 (500 ppm)	None
III (mid dose)	Ten males and ten females	332 (2000 ppm)	None
IV (high dose)	Ten males and ten females	1419 (10000 ppm)	None

Mortality and Time to Death
No deaths occurred

Clinical Observations
Isolated incidents of hunched posture and/or tiptoe gait were recorded between days 69 and 73 of animals of either sex. Generalised fur loss was observed for several 2000 ppm males. Between Days 82 and 87, two control females and one 2000 ppm female showed persistent circling movement.
No significant changes on body weight gain and food consumption.

Functional Observations; Behavioural Assessments, Functional Performance Tests, Sensory Reactivity Assessments
No treatment related effects were detected. Detailed open field observations correlated with the clinical observations.

Laboratory Findings – Clinical Chemistry, Haematology
Statistical analysis of the data did not show any significant changes except for a slight but significant decrease on potassium level at all doses tested in females.
Opthalmology

One control female and 2 males and one female treated at 10000 ppm (1419 mg/kg bw/day) showed changes such as cataract and hyaloid remnant. These effects were regarded as incidental and not treatment related.

Organ weights

A statistically significant reduction in absolute kidney weight was detected for males treated with 10000 ppm (1419 mg/kg bw/day) compared with controls.

Pathology macroscopic

Necropsy studies reported incidental findings (small and/or malformed spleen) for males treated at 78 and 332 mg/kg bw/day and one male treated at 1419 mg/kg bw/day. A large and redenned ovary was reported for one control female. The changes seen were incidental and did not occur in a dose-related manner.

Histopathology

No significant changes were recorded.

Remarks – Results

CONCLUSION

The NOAEL was established as 10000 ppm (1419 mg/kg bw/day) in this study.

TEST FACILITY	Safepharm Laboratories (2002e).

7.9. Genotoxicity - bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Species/Strain	*S. typhimurium*: TA1538, TA1537, TA98, TA100. *E. coli*: WP2 uvrA.
Metabolic Activation System	Rat liver homogenate (S9)
Concentration Range in Main Test	a) With metabolic activation: 50, 150, 500, 1500 and 5000 µg/plate. b) Without metabolic activation: 50, 150, 500, 1500 and 5000 µg/plate.
Vehicle	
Remarks - Method	Experiment was repeated using the same dose range on a separate day. Preliminary toxicity study:0-5000 µg/plate.

RESULTS

Remarks - Results	The test chemical caused no reduction in the growth of the bacterial lawn at any dose level. No test material precipitate was observed on the plates at any of the doses tested in either the presence or absence of S9-mix. No significant increases in the frequency of revertant colonies with or without metabolic activation at any of the dose levels tested.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Safepharm Laboratories (2001f)

7.10. Genotoxicity – in vitro

TEST SUBSTANCE	Notified Chemical

METHOD	OECD TG 476 In vitro Mammalian Cell Gene Mutation Test. EC Directive 2000/32/EC B.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.
Cell Type/Cell Line	Mouse Lymphoma L5178Y cells
Metabolic Activation System	Aroclor activated S9 mix
Vehicle	Water
Remarks - Method	Preliminary experiment: 36, 78, 156, 313, 625, 1250, 2500 and 5000 µg/mL- 3 hr exposure with and without S9 mix and 24 hr exposure without S9 mix.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	39, 78, 156, 313, 625, 1250, 2500 and 5000	3 hr	48 hr	10-14 days
Test 2	39, 78, 156, 313, 625, 1250, 2500 and 5000	24 h	48 hr	10-14 days
Present				
Test 1	39, 78, 156, 313, 625, 1250, 2500 and 5000	3 hr	48 hr	10-14 days
Test 2	39, 78, 156, 313, 625, 1250, 2500 and 5000	3 hr	48 hr	10-14 days

*Cultures selected for metaphase analysis.

RESULTS

Remarks - Results	No significant increases in mutant frequency were observed in any of the tests either in the absence or the presence of S9 mix.
CONCLUSION	The notified chemical was not mutagenic to mouse lymphoma cells treated in vitro under the conditions of the test.
TEST FACILITY	Huntingdon Life Sciences (2001a)

7.11. Genotoxicity – in vitro

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration test
Cell Type/	Human lymphocytes
Metabolic Activation System	Aroclor activated S9 mix
Vehicle	Water
Remarks - Method	Preliminary experiment: 36, 78, 156, 313, 625, 1250, 2500 and 5000 µg/mL- 3 hr exposure with and without S9 mix and 24 hr exposure without S9 mix.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Treatment Period*	*Harvest time*	*Recovery period*
Absent				
Test 1	312.5, 625 and 1250	3 hr	2 hrs	17 hr
Test 2	1250, 2500 and 5000	20 hr continuous	20 hrs	-
Present				
Test 1	312.5, 625 and 1250	3 hr	2 hrs	17 hr
Test 2	1250, 2500 and 5000	3 hr	20 hrs	17 hr

Doses shown in the table above represent cultures selected for metaphase analysis.

RESULTS

Remarks – Results	Test 1: without S9- No reduction in mitotic index

With S9 mix- a reduction in the mitotic index to 76% at 312.5 µg/mL.

Test 2: without S9 mix-a reduction in the mitotic index to 54% at 5000 µg/mL.
With S9 mix-no reduction in mitotic index.

No significant increases in the proportion of metaphase figures containing chromosomal aberrations at any dose level

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

TEST FACILITY Huntingdon Life Sciences (2001b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE Notified chemical

METHOD OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum Activated sewage sludge micro-organisms from municipal sewage
Exposure Period 28 days
Auxiliary Solvent No
Analytical Monitoring Inorganic Carbon and TOC using TOC analyser
Remarks - Method Inoculum was aerated overnight in culture medium prior to the addition of test materials. Samples were collected from the first CO_2 absorber vessel on Days 0, 1, 2, 3, 4, 6, 8, 10, 12, 14, 18, 18, 20, 22, 24, 27, 28 and 29. Samples taken on Days 12 and 18 were not analysed. On day 28 test vessels were treated with 1 mL of concentrated hydrochloric acid to drive of any inorganic carbonates formed. TOC analyses were performed on samples of the culture medium on Days 0 and 28.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% degradation*	*Day*	*% degradation*
1	0	1	27
6	12	6	48
14	14	14	65
28	33	28	87

Remarks - Results The extent of degradation of the reference material validates the test. A toxicity control containing test material and sodium benzoate reached 47% degradation on day 28 indicating that the notified chemical is not toxic to sewage treatment organisms.

CONCLUSION The test substance is not readily biodegradable according to the terms of OECD Guideline No. 301B.

TEST FACILITY SafePharm Laboratories (2001g)

8.1.2. Bioaccumulation

Data regarding the bioaccumulation potential of the notified chemical were not provided for this notification. The notified chemicals high water solubility and low partition coefficient suggest that it is unlikely to cross biological membranes and bioaccumulate (Connell 1990).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 203 Fish, Acute Toxicity Test – 96 h semi-static
- Species: Rainbow Trout (*Oncorhynchus mykiss*)
- Exposure Period: 96 h
- Water Hardness: 150 mg $CaCO_3$/L
- Auxiliary Solvent: None
- Analytical Monitoring: HPLC
- Remarks - Method: Limit of quantification (LOQ) 4.7 mg/L. Water quality parameters of pH, water temperature, O_2 content were within normal limits throughout study.

Concentration mg/L		*Number of Fish*	*Mortality*					
Nominal	*Actual*		*1h*	*1h*	*24h*	*48h*	*72h*	*96h*
0	<LOQ	10	0	0	0	0	0	0
100	105	20	0	0	0	0	0	0

- LC50: > 100 mg/L at 96 hours.
- NOEC: 100 mg/L at 96 hours.
- Remarks – Results: The results of the limit study showed that no mortalities or sub-lethal effects were observed in any of the test vessels. The 96-hour EC_{50} for the notified chemical to *Oncorhynchus mykiss* is greater than 100 mg/L.

CONCLUSION: The ecotoxicity data indicates the notified chemical is practically non-toxic to fish.

TEST FACILITY: SafePharm Laboratories (2001h)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 202 Daphnia sp. Acute Immobilisation Test – 48 h static
- Species: *Daphnia magna*
- Exposure Period: 48 h
- Auxiliary Solvent: None
- Water Hardness: ~250 mg $CaCO_3$/L
- Analytical Monitoring: HPLC
- Remarks - Method: Limit of quantification (LOQ) 4.7 mg/L. Water quality parameters of pH, water temperature, O_2 content were within normal limits throughout study.

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	<LOQ	20	0	0
100	107	40	0	0

- LC50: >100 mg/L at 48 hours
- NOEC: 100 mg/L at 48 hours
- Remarks - Results: The results of the limit study showed that no immobilities or sub-lethal

	effects were observed in any of the test vessels. The 48-hour EC50 for the notified chemical to *Daphnia magna* is greater than 100 mg/L.
CONCLUSION	The ecotoxicity data indicates the notified chemical is practically non-toxic to daphnia.
TEST FACILITY	SafePharm Laboratories (2001i)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range Nominal	100 mg/L
Concentration Range Actual	97% of nominal
Auxiliary Solvent	None
Analytical Monitoring	HPLC
Remarks - Method	Limit of quantification (LOQ) 4.7 mg/L. Water quality parameters of pH, water temperature, O_2 content were within normal limits throughout study.
RESULTS	Algae were exposed the notified chemical at a nominal concentration of 100 mg/L under constant illumination and aeration. After 72 h, there was no significant inhibition of algal growth or biomass at the nominal concentration of 100 mg/L. Therefore, EC50 > 100 mg/L and NOEC is 100 mg/L.
CONCLUSION	The ecotoxicity data indicates the notified chemical is practically non-toxic to algae.
TEST FACILITY	SafePharm Laboratories (2001j)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range Nominal	1000 mg/L
Remarks – Method	Limit test conducted based on results of range-finding study.
RESULTS	The activated sludge study was conducted using sludge obtained from sewage treatment plant in Leicestershire, UK. The definitive study was conducted as a limit test with a concentration of 1000 mg/L. The reference material used in the study was 3,5-dichlorophenol. The 3-hour EC50 for the notified substance to activated sludge could not be quantified. However, the 3-hour EC50 for the notified substance to activated sludge is expected to be greater than 1000 mg/L. The EC50 of the reference substance was 11 mg/L, therefore confirming the suitability of the activated sludge.
IC50	>1000 mg/L
NOEC	1000 mg/L

CONCLUSION	The ecotoxicity data indicates the notified chemical is not toxic to activated sludge up to 1000 mg/L suspension.
TEST FACILITY	SafePharm Laboratories (2001k)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The majority of the notified chemical will be incorporated, at a low level, into a matrix of polypropylene or polyethylene plastics. Once this has solidified into plastic articles, the notified chemical is expected to pose minimum risk to the environment.

The main environmental hazard would arise from release of the notified chemical during storage or transport. The use of bunded containment minimises the risk of release at storage sites. Less than 40 kg of notified chemical may be released in landfill annually via spills, container residues and production waste. This release is expected to be distributed across several sites and will not be restricted to a single site, thus minimising the degree of risk to the environment at any given time.

The notified chemical will ultimately suffer the same fate as the finished article at the end of its useful life, ie be disposed of to landfill. Since it will be incorporated into the inert matrix of the polyurethane, it will pose minimum risk to the environment.

The compound is not readily biodegradable, has a low partition coefficient and a high water solubility, all indicating that any material released would eventually partition to water. However, given the notified chemical's cationic nature, it is expected to rapidly associate with soil and sediments.

Bioaccumulation is not expected due to the notified chemicals high water solubility suggests that it is unlikely to cross biological membranes (Connell 1990) and its low exposure to the aquatic environment.

9.1.2. Environment – effects assessment

The notified chemical is practically non-toxic to fish, daphnia, algae and sewage micoorganisms.

Acute results are available for three trophic levels. Applying an assessment factor of 100 to the ecotoxicity data, the predicted no effects concentration (PNEC) is > 1 mg/L.

9.1.3. Environment – risk characterisation

The notified chemical will be used as a nucleating agent in primary or secondary polypropylene and/or polyethylene manufacture. Once incorporated into these products the notified chemical is expected to remain within the product matrices. Hence, the majority of the notified chemical will share the fate of the articles into which it is incorporated. It is anticipated that these will be disposed of to landfill or incinerated at the end of their useful lifetime. In landfill it is expected that the notified chemical will remain immobile within the matrices. Incineration of the notified chemical will result in the formation of water vapour and oxides of carbon.

Very little will be released to water and it is not possible to calculate a reasonable predicted environmental concentration (PEC). However, with a PNEC of >1 mg/L, the risk quotient (PEC/PNEC) should be very small.

The above considerations indicate minimal hazard to the environment when the notified chemical is used in the manner and levels indicated by the notifier.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Potential exposure to the imported notified chemical (100%) is expected to occur mainly during polymer manufacture, in particular the secondary stage, where the notified chemical is added to polymer prior to article manufacture. Dermal and inhalation exposure may occur when opening the container containing the notified chemical in powder form, weighing and transferring into a reactor. Workers will operate under local exhaust ventilation.

Once the notified chemical is added to the mixer, the processes of blending with additives, extrusion, mouldering and calendering is largely enclosed and automated. Hence, the risk of exposure will be low. The notified chemical will be irreversibly cured in the polymer matrix and further exposure is not expected. The concentration of the notified polymer in the final product is typically less than 2000 ppm, but can be added to 5000 ppm.

Dermal exposure to the notified chemical was assessed using EASE model during manufacturing as being very low. The assumptions were:
Closed System
Non dispersive use
Sampling may occur
Not direct handling

During transport and delivery, exposure to the notified polymer (100% as solid) is not likely. It will be packed in 200 or 25 kg in plastic pails or steel drums and transported directly to the manufacturing site.

9.2.2. Public health – exposure assessment

Public exposure to the notified chemical may only occur from contact with plastic articles. The concentration of the notified chemical in the final product is very low (max 2000 ppm), and the chemical will be irreversibly bound in the polymer matrix. Public exposure from using the articles is not expected.

9.2.3. Human health - effects assessment

Extensive toxicology data were submitted on the notified chemical. It is of low acute oral and dermal toxicity in rats. Inhalation toxicity was not submitted; but the notified chemical is a solid with very low vapour pressure. It is expected that inhalation toxicity will be low.

The notified chemical was not irritating to rabbit skin and not a skin sensitiser in guinea pigs. But it was slightly irritating to eyes in rabbits. Repeat dose oral toxicity studies conducted in rats for 28 days (gavage) and in mice for 90 days (dietary) showed that the NOAEL was 50 mg/kg bw/day in rats based on histopathological effects on the stomach (mucosal changes characterised by agglomeration of secretion, superficial basophilia and increased mononuclear cell infiltrates in the lamina propria) and caecum (increase in the severity of mononuclear cell infiltrates in the lamina propria) at higher doses and 1149 mg/kg bw/day in mice (highest dose tested). The effects seen in the repeat dose studies did not warrant classifying the notified chemical as a hazardous chemical based on repeat dose effects.

The notified chemical was not genotoxic when tested in the bacterial reverse mutation assay and in *in vitro* assays using mouse lymphoma cells and human lymphocytes.

The notified chemical is imported as a solid with 18% less than 100 μm and 2% <10 μm. The Label for the notified chemical indicates that dust may irritate the eyes and respiratory tract.

9.2.4. Occupational health and safety – risk characterisation

The main hazards to the notified chemical are slight eye irritation and irritation from ocular and inhalation exposure to dust. Predicted worker exposure during blending and manufacturing of the polymer articles is estimated to be low as the process is largely enclosed and automated.

Contact with the notified chemical (100%) may occur when opening the container and transferring the notified chemical into the mixer. The risk of dermal, ocular and inhalation

adverse effects will be minimised by the use of gloves, goggles and dust mask. Local exhaust ventilation is provided.

Once the notified chemical is mixed with additives and cured into the polymer matrix, the health risk from exposure to the notified chemical is minimal, as the chemical will be irreversibly bound and is present at very low concentrations (typically less than 2000 ppm). Extrusion, mouldering and calendering will be fully automated and enclosed. Handling the finished item is not expected to pose a significant risk to workers.

9.2.5. Public health – risk characterisation

Public risk is considered low, since exposure may only occur to the finished item which contains very low concentrations of the notified chemical and is irreversibly bound into the polymer matrix.

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

Ecotoxicity data for the notified chemical for all trophic levels indicate that it is practically non-toxic (EC50/LC50 > 100 mg/L). Hence, the notified chemical cannot be classified under the OECD (2002) Globally Harmonised System for the Classification and Labelling of Chemicals.

10.2. Environmental risk assessment

On the basis of the available information, the overall environmental hazard of the notified chemical is expected to be low.

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 according to instructions.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of 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, 1994a). 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 the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). 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 engineering controls to minimise occupational exposure to the notified chemical:
  - *Automated and enclosed manufacturing process*
  - *Local exhaust ventilation*

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - *Avoid contact with eyes*
  - *Do not breath dust*

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - *Gloves, goggles and dust mask*

  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 into landfill.

Emergency procedures

- Spills/release of the notified chemical should be contained as described in the MSDS (ie. Contain with absorbent material and transfer to a sealable waste container) and the resulting waste disposed of in landfill.

Secondary notification

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

Under Subsection 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.

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