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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component of IRGATEC CR 76

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals (ABN 97 005 061 469)
235 Settlement Road
THOMASTOWN VIC 3074

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 Name
Other Names
CAS Number
Molecular Formula
Structural Formula
Molecular Weight
Spectral Data
Purity
Identity of Impurities (>1%)
Identity and % weight of additives/adjuvants.
Percentage of notified chemical in Master Batch Preparations and in end-use (Plastic articles)
Import Volumes
Sites of use

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
Italy (Notification Number: 03-05-0487-00).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
IRGATEC CR 76 (contains <5% notified chemical)

METHODS OF DETECTION AND DETERMINATION

METHODS ^{1}H Nuclear Magnetic Resonance
Electrospray Ionisation-Mass Spectrometry
Infrared Spectroscopy

3. COMPOSITION

DEGREE OF PURITY
>80%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. The notified chemical will be imported as a <5% component of IRGATEC CR 76 in 20 kg plastic bags in fibreboard boxes.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.9-1.0	0.9-1.0	0.9-1.0	0.9-1.0	0.9-1.0

USE
The notified chemical is used as a chemical additive (<1%) in non-woven fabrics.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
IRGATEC CR 76 will be stored and distributed from the notifier's warehouse. From this site, IRGATEC CR 76 is on-sold to a nonwoven manufacturing mill.

TRANSPORTATION AND PACKAGING
IRGATEC CR 76 containing the notified chemical will be imported in 20 kg plastic bags in fibreboard boxes. The chemical will be transported by road from the port to the warehouse. No repackaging operations will be carried out at the notifier's site. IRGATEC CR 76 will then be transported by road unopened to the nonwoven manufacturing mill.

5.2. Operation description

Transport and storage
IRGATEC CR 76 will be stored in dry and well-ventilated area at the notifier's site and then on-sold and transported to a nonwoven manufacturing mill.

Manufacture of melt blown non-woven fabrics
At the manufacturing mill, IRGATEC CR 76 will be used as a chemical additive. Melt-blowing is a one-step extrusion process designed to produce non-woven webs directly from resin pellets.

A mixture of air and polymer is ejected from a spray nozzle onto a moving screen. High velocity hot air is used to attenuate molten polymer into very fine fibres. IRGATEC CR 76 is fed to the extruder where it is melted and heated to the appropriate temperature required for fibre formation. The extruder feeds a specially designed melt flowing die. As the molten resin emerges from the die orifices it is contacted by a jet of hot air, which attenuates the polymer into a blast of fine fibres. The fibres are quenched and solidified by cooling air, which is aspirated into the primary jet. The fibres are collected on an endless and moving screen placed in front of the blast. The fibres (fibre lengths in the order of a few cm) are entangled on the screen to form a cohesive web. The speed of the air flow (range 0.1 – 0.3 or more kg/min) determines the softness of the web. Refer to the figure below. The non-woven fibres will contain <1% of the notified chemical.

Cleaning and maintenance of machinery after manufacture of non-woven fabrics
Cleaning of machinery is not required. The machinery may be serviced twice a year depending on usage.

End use of non-woven fabrics
End use of non-woven fabric containing the notified chemical will be for products such as diapers, hygiene products, cleaning wipes and filtration products.

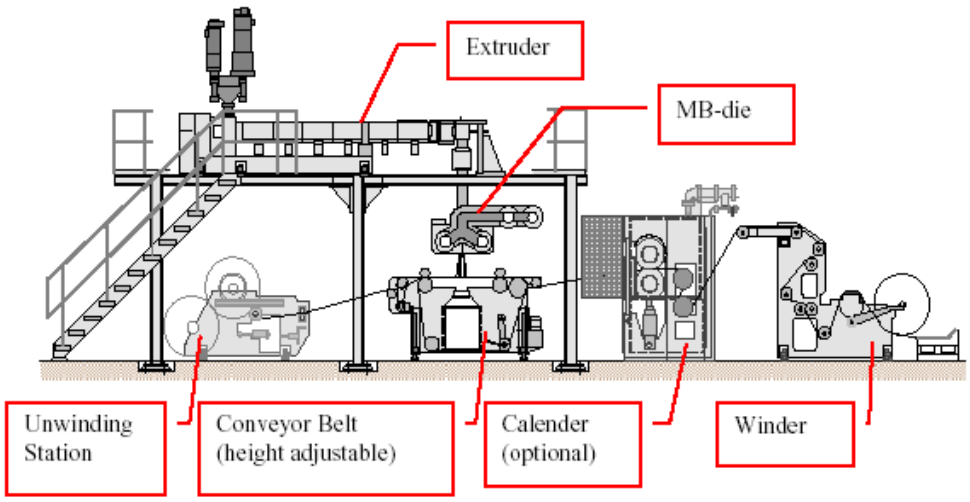

Figure 1: Essential features of a REICOFIL® meltblown system

5.3. Occupational Exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	10	4 hours/day	10 days/year
Warehouse	3	2 hours/day	24 days/year
Manufacturing Mill for non-woven fabric:			
• Weighing	3	6 hours/day	200 days/year
• Extrusion plant operators	3	6 hours/day	200 days/year
	1-2	2 hours/day	10 days/year
• Maintenance of equipment	4	6 hours/day	200 days/year
• Handling of end product	1	6 hours/day	200 days/year

Exposure Details

Transport and storage

Waterside workers, transport drivers and warehouse workers would only be exposed to the notified chemical in the event of an accident. Accidental exposure would be minimized by the physical form of IRGATEC CR 76 – which is supplied as solid pellets and is packaged in 20 kg plastic bags in fibreboard boxes.

Manufacturing of non-woven fabric

At the manufacturing site, IRGATEC CR 76 is manually weighed and fed into the extruder under local exhaust ventilation, to capture any fugitive dust and thus minimise inhalation exposure to particles. The meltblown process is fully automated and no exposure will occur during this process. After the process is completed the non-woven fabric comes out on a conveyor machine and is cut into appropriate roll sizes. This process is fully automated and sealed under local exhaust ventilation. To minimise exposure, workers will wear PPE such as gloves, face shields or safety glasses, safety boots and overalls.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured or repackaged in Australia. Local operations will include transport and storage of plastic pellets containing the notified chemical, manufacture of non-woven fabric and end use of fabric in diapers, hygiene products, cleaning wipes and filtration products. IRGATEC CR 76 (master batch in solid plastic pellet form) containing the notified chemical will be transported to Australia by ship in 20 kg plastic bags in fibreboard boxes and will be transported directly to the notifier's warehouse for housing before being distributed to non-woven manufacturing mills. Release to the environment may occur at the notifier's site in the unlikely event of an accident during transport or if the packaging is damaged.

RELEASE OF CHEMICAL FROM USE

Non-woven Manufacturing Mill

Release to the environment may occur at nonwoven textile mills in the unlikely event of an accident during transport or if the packaging is damaged. No residues are expected to remain in bags containing the master batch pellets. Environmental impact from the melt blowing process will be minimised due to spill response procedures (described in the MSDS) and engineering controls (eg. bunding, container size and specification, automated and sealed meltblown process). There is limited potential for the notified chemical to be released to the aquatic environment during its use. The notifier estimates that release to the aquatic compartment through leaching of the encapsulated notified chemical from non-woven fabric is unlikely, particularly given the low concentration (<1%) present.

5.5. Disposal

Emptied imported bags and any residual dust from pallets will be disposed of to landfill. Waste from residues should be disposed of by incineration or to landfill. At the end of their useful life, treated non-woven products are likely to be sent to landfill for disposal.

5.6. Public exposure

IRGATEC CR 76 containing the notified chemical will not be sold directly to the public, but will be formulated and applied to nonwoven fabrics at manufacturing mills. Once applied to the fabric, the notified chemical is strongly fixed to the fibre. Given the low concentration in the nonwoven fabric (<1%), the potential for public exposure to the notified chemical during all phases of its life cycle (i.e. use in diapers, hygiene products, cleaning wipes and filtration products), is considered to be low.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Slightly yellow liquid.

Freezing Point -12.7ºC

METHOD	Commission Directive 92/69/EEC, A.1 Melting/Freezing Temperature. OECD TG 102 Melting Point/Melting Range.
Remarks	Thermal analysis was conducted using a cooling batch and thermocouples. No heat effect from which freezing can be deduced was observed. Therefore, the phase transformation was determined visually.
TEST FACILITY	(RCC Ltd, 2003a)

Boiling Point ~645°C at 101.3 kPa (estimated)

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	No boiling point could be determined, as the substance decomposes before boiling occurs. The decomposition temperature was found to be 245°C. The calculation of the boiling temperature via Meissner's Method yielded 645°C.
TEST FACILITY	(RCC Ltd, 2003a)

Density 984.3 kg/m^3 at 20ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined with an oscillating densitometer.
TEST FACILITY (RCC Ltd, 2003b)

Vapour Pressure 9.31 x 10^{-12} kPa at 25ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks The vapour pressure was calculated via the Modified Watson Correlation (Lyman *et al*., 1990) by extrapolation of the boiling point of the test item, calculated using Meissner's Method as645°C. The notified chemical is only very slightly volatile (Mensink *et al*., 1995).
TEST FACILITY (RCC Ltd, 2003c)

Water Solubility <5.2 mg/L at 25ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks The calculated water solubility is below the reproducible limit of detection for this assay. Calculations with the WS-KOW program yielded a water solubility of 4.35 x 10^{-9} mg/L.
TEST FACILITY (RCC Ltd, 2003d)

Hydrolysis as a Function of pH Not performed.

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.
Remarks Three solubility tests were carried out, using up to 20% acetonitrile as the cosolvent. The notified chemical did not dissolve in this solvent, and thus hydrolysis testing could not be performed. Other solvents were considered to be unsuitable because they could interfere with the hydrolytic process: Alcohols, could react with test item, especially during the hydrolysis test at elevated temperatures, and dimethylsulfoxide (DMSO) or dimethylformamide (DMF) could accelerate the kinetics of the hydrolysis. Based on the low water solubility, hydrolysis is not considered to be an environmental fate pathway for the test item even though it contains a hydrolysable group.

Ecotoxicity testing with analytical determination of test material and degradation products in test solutions reported that the portion of the notified chemical that dissolved (<2% after 96 h) in water was unstable and rapidly hydrolysed (RCC Inc, 2003r,s).
TEST FACILITY RCC (2003e)

Partition Coefficient (n-octanol/water) log P_{ow} = 12.1

METHOD log P_{ow} was estimated using KOWWIN v1.66 program calculation method (Meylan and Howard, 1995) based on theoretical fragmentation of the molecule into substructures for which reliable log P_{ow} increments are known and summing the fragmented values and the correction terms for intramolecular interactions.
Remarks The HPLC and flask-shaking methods (Commission Directive 92/69/EEC A.8) were not able to be used due to very low water solubility.
TEST FACILITY RCC (2003d)

Fat (or n-octanol) Solubility Miscible in standard fat at a ratio of 1:1 at 37°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
EC Directive 84/449 A.7 Fat Solubility.
Remarks A simplified flask method was used. Miscibility was tested at 3 different ratios (1:20, 1:1, 20:1). Samples were incubated at 37°C for 72 h and agitated. Solubility and miscibility was evaluated visually. At 1:20 and 1:1, one clear phase was observed and the test substance was miscible in fat; however, at 20:1, it was not miscible and thread-like material was observed.
TEST FACILITY RCC Ltd (2003f)

Adsorption/Desorption – screening test log K_{oc} > 5.63 at 25°C.

METHOD EC Directive 2001/59/EEC, C.19 Estimation of the adsorption coefficient (K_{OC}) on soil and sewage sludge using high performance liquid chromatography (HPLC)

OECD 121 (2001): Estimation of the Adsorption Coefficient (Koc) on Soil and Sewage Sludge using High Performance Liquid Chromatography (HPLC).
Remarks Standard compounds were analysed for comparative purposes with log K_{oc} in the range 1.25-5.63. The test substance was dissolved in 2-propanol (10 mL) to prepare a stock solution (3500 µg/mL) from which a dilution standard of 350 µg/mL of pH 6.3 was prepared for HPLC injection with methanol cosolvent. The test substance was only eluted when the volume fraction of acetonitrile was 100% during chromatography. The test material eluted after the standard with the highest log Koc tested. The test substance has a very high affinity to organic matter and is likely to partition in sediments/soils where it will be immobile (Mensink *et al*., 1995).
TEST FACILITY RCC (2003g)

Dissociation Constant The compound has one site that can be protonated. The pKa for the protonated form was estimated as 0.1 (± 0.7).

METHOD Calculation with the pKa prediction module of ACD, Inc. LogD Solubility Suite v.7.0 (ACD Labs, 2003).
Remarks The notified chemical is protonated at pH 0.1 and below. Thus it will be present in its neutral form over the environmentally relevant pH range (pH 4-9).
TEST FACILITY RCC Ltd (2003h)

Surface Tension 68.7 mN/m at 19.6 ± 0.3°C

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension
Remarks The concentration of the test substance was 90% of the saturation concentration. Surface tension was determined with a tensiometer, using the ring method. Based on the criteria in guideline A.5, the notified chemical is not a surface active substance.
TEST FACILITY RCC Ltd (2003i)

Particle Size Not applicable as the notified chemical is a liquid.

Flash Point 59°C Closed Cup

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks The Pensky-Martens flash point apparatus was used.
TEST FACILITY RCC Ltd (2003j)

Flammability Limits Not determined.

Remarks The notified chemical is not expected to be flammable.

Autoignition Temperature 373°C

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY ISS (2003)

Explosive Properties Not explosive under influence of a flame.

METHOD Expert Statement
Remarks The explosive properties were estimated based on the UN Recommendations on the Transport of Dangerous Goods (Manual of Tests and Criteria, Annex 6, Orange Book, 3rd Edition, 1999) where a set of criteria is compiled.

1. Reactive groups:
The molecule contains a bond which might be associated with explosive properties.

2.Oxygen Balance:
The oxygen balance was calculated to be -264.6 which is below the limit of -200 requiring experimental testing.

3. Calorimetric test:
The exothermic decomposition energy was determined using DSC in a closed, gold plated high pressure vessel and was found to be about 172.3 J/g thus being far below the UN limit of 500 J/g.

Conclusion:
Based on items 2 and 3, the test substance is not classified as explosive material and no experimental determination is required.
TEST FACILITY RCC Ltd (2003k)

Reactivity May be reactive in contact with strong acids, bases and oxidizing agents.

Oxidising Properties Non-oxidising

METHOD Expert Statement.
Remarks The oxidising properties were screened based on the UN Recommendations of the Transport of Dangerous Goods (Manual of Test and Criteria, Annex 6, Orange Book, 3rd Edition, 1999). The oxygen balance was calculated as –265, which indicates that the test substance is considered to be non-oxidising and therefore does not need to be tested experimentally.
TEST FACILITY RCC Ltd (2003l)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	Low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	Low toxicity
Rat, acute inhalation	No data available
Rabbit, skin irritation	Non-irritating
Rabbit, eye irritation	Non-irritating
Mice, Local Lymph Node Assay (notified chemical at 10%, 25%, 50%)	Evidence of sensitisation
Mice, Local Lymph Node Assay (product containing notified chemical at 5%)	No evidence of sensitisation
Mice, Local Lymph Node Assay (product containing notified chemical at 10%)	No evidence of sensitisation
Rat, Oral repeat dose toxicity - 28 days.	NOEL could not be established.
Genotoxicity - bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro Chinese Hamster V79 cells	Non clastogenic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical.

METHOD — OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain	Rat/Han BrI: Wist (SPF)
Vehicle	PEG 300
Remarks – Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	6 females	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	All animals survived until the end of the study period. No clinical signs were observed during the course of the study. One female showed a loss of body weight (0.5%) between test day 8 and the end of the observation period. The body weight of the other animals was within the range commonly recorded for this strain and age.
Effects in Organs	No macroscopic findings were recorded at necropsy.
Remarks – Results	None.

CONCLUSION — The notified chemical is of low toxicity via the oral route.

TEST FACILITY — (RCC Ltd, 2003m)

7.2. Acute toxicity – dermal

TEST SUBSTANCE — Notified chemical.

METHOD — 92/69/EEC, B3 Acute Dermal Toxicity
OECD TG 402 Acute Dermal Toxicity

Species/Strain	Rat/HanBrI: WIST (SPF)
Vehicle	None, test substance administered as supplied.
Type of dressing	Semi-occlusive.

Remarks – Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	No deaths occurred during the study. No clinical signs were observed during the observation period.
Signs of Toxicity - Systemic	One female animal showed a loss of body weight (0.9%) one week after treatment. It recovered between test day 8 and the end of the observation period. Another female animal lost body weight (1.5%) from day 8 to 15. The body weight of the remaining animals was within the range commonly recorded for animals of this strain and age.
Effects in Organs	No macroscopic findings were observed at necropsy.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	(RCC Ltd, 2003n)

7.3. Acute toxicity – inhalation

REMARKS Test was not conducted. Inhalation exposure would be unlikely due to the low vapour pressure of the notified chemical.

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation / Corrosion EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White, SPF
Number of Animals	3 (animals of both sexes were used)
Vehicle	None, test substance administered as supplied.
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks – Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0		
Oedema	0	0	0	0		

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

Remarks – Results	The test item caused no staining of the treated skin, and no other clinical signs of substance related effects were observed.
CONCLUSION	The notified chemical is non-irritating to skin.
TEST FACILITY	(RCC Ltd, 2003o)

7.5. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White, SPF
Number of Animals	3 (animals of both sexes were used).
Observation Period	7 days
Remarks – Method	No significant protocol deviations.

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	0.67	0.33	0.67	2	3 days	0
Conjunctiva: chemosis	0.00	0.00	0.00	1	1 hour	0
Conjunctiva: discharge						
Corneal opacity	0.00	0.00	0.00	0	0	0
Iridial inflammation	0.00	0.00	0.00	0	0	0

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

Remarks – Results	The instillation of the test item into the eye resulted in mild, early-onset and transient ocular changes, such as reddening of the conjunctivae and sclerae, discharge and chemosis. These effects were reversible and were no longer evident 7 days after treatment. No abnormal findings were observed in the cornea or iris of the animal at any of the examinations. No corrosion, no staining and no other clinical signs of the substance related effects were observed.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	(RCC Ltd, 2003p)

7.6.1 Skin sensitisation – mouse local lymph node assay (LLNA)
- notified chemical at 10%, 25%, 50%

TEST SUBSTANCE	Notified chemical
METHOD	OECD Guidelines for Testing of Chemicals, Updated Guideline 429: Skin Sensitisation: Local Lymph Node Assay (adopted 24 June 2002).
Species/Strain	Mouse/CBA/CaOlaHsd
Vehicle	Acetone : Olive oil, 4:1 (v/v)
Remarks – Method	No significant protocol deviations.

RESULTS

	Test Item Concentration % (w/v)	Stimulation Index (S.I.)
Group 2	10	2.5
Group 3	25*	2.9*
Group 4	50*	6.2*
	EC3 = 25.8% (w/w)	

* The value was used in calculation of EC3

Remarks – Results	On the second application day, a slight ear swelling was observed at both dosing sites in all mice of Group 4 (50%), persisting for the remainder of the in-life phase of the study. No test item-related clinical signs were observed in any animals of the other groups.

CONCLUSION There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY (RCC Ltd, 2003q)

7.6.2 Skin sensitisation – mouse local lymph node assay (LLNA)
- product containing notified chemical at 5%

TEST SUBSTANCE 5% notified chemical in polypropylene, incorporated by extrusion at 175°C, and then ground and used in the test.

METHOD OECD TG 429: Skin Sensitisation: Local Lymph Node Assay (adopted 24 April 2002).
Species/Strain Mouse/CBA/CaOlaHsd
Vehicle Acetone : Olive oil, 4:1 (v/v)
Remarks – Method No significant protocol deviations.

RESULTS

	Test Item Concentration % (w/v)	S.I.
Group 2	2.5	1.0
Group 3	5	1.0
Group 4	10	1.0

Remarks – Results None.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to polypropylene containing 5% notified chemical.

TEST FACILITY (RCC Ltd, 2003r)

7.6.3 Skin sensitisation – mouse local lymph node assay (LLNA)
- product containing notified chemical at 10%

TEST SUBSTANCE 10% notified chemical in polypropylene, incorporated by extrusion at 175°C, and then ground and used in the test.

METHOD OECD TG 429: Skin Sensitisation: Local Lymph Node Assay (adopted 24 April 2002).
Species/Strain Mouse/CBA/CaOlaHsd
Vehicle Acetone : Olive oil, 4:1 (v/v)
Remarks – Method No significant protocol deviations.

RESULTS

	Test Item Concentration % (w/v)	S.I.
Group 2	1	0.6
Group 3	2.5	0.9
Group 4	5	0.9

Remarks – Results When 10% product was applied to the dosing site, a moderate ear swelling was noted at the 24-hour observation. Thus, 5% product was chosen as the highest dose.

CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to polypropylene containing 10% notified chemical.
TEST FACILITY	(RCC Ltd, 2003s)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat, HanBrI:WIST (SPF)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days
Vehicle	Corn Oil
Remarks – Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	50	0
III (mid dose)	5/sex	200	0
IV (high dose)	5/sex	1000	0
V (control recovery)	5/sex	0	0
VI (high dose recovery)	5/sex	1000	0

Mortality and Time to Death

All animals survived until scheduled necropsy.

Clinical Observations

Slightly lower mean body weights and lower body weight gain was noted in males treated at 200 mg/kg bw/day and 1000 mg/kg bw/day compared with controls. These changes were considered to be test item relevant. The mean body weight gain during the recovery period was similar in all groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Increased gamma glutamyl transferase activity was noted after 4 weeks treatment in females at 200 mg/kg bw/day and in both sexes at 1000 mg/kg bw/day when compared with the controls. This finding was considered to be a test item-related adaptive change, and was reversible after two weeks recovery. Changes in electrolytes, mean protein levels and globulin levels were either within historical control limits, not dose-related, or occurred at the same levels in treated and control animals.

In animals receiving 1000 mg/kg bw/day, the platelet count was increased in males, and the hemoglobin distribution width was increased in females. Both of these values were within the range of historical controls and are not considered to be related to treatment with the notified chemical. The mean thromboplastin time of males treated with 200 and 1000 mg/kg bw/day was abbreviated, and the mean cell hemoglobin of males treated with 200 mg/kg bw/day was significantly decreased. Neither of these changes showed a clear dose-response relationship and are considered to be incidental. Changes to many haematological parameters were seen after the recovery period. However, as these changes were not noted at the end of treatment, they are considered to be unrelated to the notified chemical.

None of the minor differences in the urine parameters were considered to be of toxicological relevance.

Effects in Organs

There were a number of changes to organs, primarily in the rats treated with 200 mg/kg bw/day and 1000 mg/kg bw/day. All of these changes were reversible in the recovery period.

Elevated absolute liver weights were noted in females treated with 200 mg/kg bw/day, and in both sexes

treated with 1000 mg/kg bw/day. Liver-to-body weight ratios were increased in females treated with 50 mg/kg bw/day, 200 mg/kg bw/day and in both sexes treated with 1000 mg/kg bw/day, whereas elevated liver-to-brain weight ratios were noted in females treated with 200 mg/kg bw/day, and in both sexes treated with 1000 mg/kg bw/day.

Elevated absolute and relative spleen weights were noted in females treated with 200 mg/kg bw/day and 1000 mg/kg bw/day. There was no evidence of microscopic lesions associated with these findings.

Macroscopic/microscopic findings:
At the end of the treatment and following recovery period, no test item-related gross lesion were observed. Under the conditions of this study, the test item induced histopathological changes in liver, thyroid gland and stomach.

In the liver, an increased incidence of a minimal to slight hepatocellular hypertrophy was recorded in animals treated with 1000 mg/kg bw/day, which correlated to increased organ weight. After the recovery period, this change reverted to normal levels. It was regarded as an adaptive change most likely to be caused by the metabolic biotransformation of the test item.

In the thyroid gland, a minimal to slight hypertrophy of the follicular epithelium was recorded in males treated with 1000 mg/kg bw/day. It was regarded as an adaptive change most likely caused by compensation of an increased degradation of thyroid hormones. After the recovery period, the incidence of follicular hypertrophy was largely reduced.

In the stomach a minimal to slight glandular ectasia was recorded in some males treated with 1000 mg/kg bw/day. The slightly dilated crypts often were filled with mucus. After the recovery period, the glandular ectasia was not recorded; therefore this finding was regarded as an adaptive effect. None of these findings were considered to be of adverse character.

CONCLUSION
A no-observed-effect-level (NOEL) could not be established.

A no-observed-adverse-effect-level (NOAEL) of 50 mg/kg bw/day was established, based on low body weight and low body weight gain in animals receiving higher doses.

TEST FACILITY (RCC Ltd, 2003t)

7.8. 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, TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA. Plate incorporation and preincubation tests.
Metabolic Activation System	Phenobarbital/β-naphthoflavone induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 33-5000 µg/plate. b) Without metabolic activation: 33-5000 µg/plate.
Vehicle	Ethanol
Physical Form	Not applicable.
Remarks – Method	The following reference mutagens were used as positive controls and showed a distinct increase of induced revertant colonies: Sodium azide 4-Nitro-o-phenylene-diamine Methyl methane sulfonate 2-Aminoanthracene

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	> 5000	> 5000	-	Negative
Test 2				
Absent				
Test 1	> 5000	> 5000	-	Negative
Test 2				

Remarks – Results: No toxicity or precipitation was observed. The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of metabolic activation. Negative controls were within the historical limits. Positive controls confirmed the sensitivity of the test system.

CONCLUSION: The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: (RCC Ltd, 2003u)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line: Chinese Hamster V79 cells
Metabolic Activation System: Phenobarbital/β-naphthoflavone induced rat liver S9
Vehicle: Ethanol
Physical Form: Gas/vapour.
Remarks – Method: No significant protocol deviations

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	50, 100*, 200*, 400*, 800, 1000 µg/ml	4	18
Test 2	125*, 250*, 500*, 1000, 2000 and 3000 µg/ml	18	18
Test 3	125*, 250*, 500, 1000, 2000 and 3000 µg/ml	28	28
Present			
Test 1	50, 100*, 200*, 400*, 800 and 1000 µg/ml	4	18
Test 2	50*, 100*, 200*, 400, 800 and 1000 µg/ml	4	28

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	3000 µg/ml	None	400 µg/ml	None
Test 2	None	None	500 µg/ml	None
Test 3	None	None	250 µg/ml	None
Present				
Test 1	Not stated	None	400 µg/ml	None
Test 2	None	None	200 µg/ml	None

Remarks – Results	Cytotoxicity was not observed at any test concentration. No statistically or biologically significant increases in the percentage of aberrant cells above the vehicle control levels, were recorded for any cultures treated with the test substance in either the presence or absence of metabolic activation. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified chemical was not clastogenic to Chinese Hamster V79 cells treated in vitro under the conditions of the test.
TEST FACILITY	(RCC Ltd, 2003v)

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 and 92/69/EEC, C.4-C, 1992: Carbon dioxide evolution, Modified Sturm Test
Inoculum	Aerobic activated sludge from a wastewater treatment plant (ARA Ergolz II, Füllinsdorf, Switzerland)
Exposure Period	28 days
Auxiliary Solvent	Sodium Benzoate
Analytical Monitoring	TOC (Total Carbon Content)
Remarks – Method	Samples were collected for CO_2 analysis (via inorganic carbon) on days 2, 5, 7, 9, 12, 14, 19, 22, 27, 28, and 29. Test solution pH: 7.3-7.5.

RESULTS

Test substance (21 mg/L)		*Sodium Benzoate (25.7 mg/L)*	
Day	*% degradation*	*Day*	*% degradation*
2	0.2	2	39.2
7	8.8	7	61.3
14	17.8	14	71.7
19	22.2	19	77.4
28	30	28	85.5

Remarks – Results	The test substance was found to be moderately biodegradable (30%) under the test conditions within the 28 day exposure period. However, the pass level for ready biodegradability, i.e. a CO_2 production of at least 60% of the TOC in a 10 day window within the 28 day period of the test was not reached. No degradation of the test substance was noted in the abiotic control and the poisoned test medium control (using mercuric chloride 10 mg/L) at the end of the 28 d exposure period (acceptable). In the toxicity control containing both the test substance and reference item (sodium benzoate) had no inhibitory effect on activated sludge micro-organisms. The reference substance achieved 71% degradation by day 28, verifying the viability of the activated sludge. The toxicity control, containing both the test item and the reference item, showed a similar rate of biodegradation as the reference item only, indicating that the test substance was not inhibitory to the test micro-organisms. Within 14 days of exposure, biodegradation amounted to 36% (>25% is acceptable).
CONCLUSION	Under the conditions of the test, the notified chemical cannot be classed as readily biodegradable but was not inhibitory to sewage sludge micro-organisms.
TEST FACILITY	RCC Inc. (2003w)

8.1.2. Bioaccumulation

Not determined

The low water solubility and high fat solubility indicates that the notified chemical has a high affinity to lipids/fats. However, the very high estimated log Kow (12.1) indicates a low potential for bioaccumulation (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 – Acute Toxicity, 96-Hour Static Test and EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Acute Toxicity, 96-Hour Static Test.
Species	Zebra Fish (*Brachydanio rerio*)
Exposure Period	96 h
Auxiliary Solvent	No auxiliary solvent or emulsifier was used.
Water Hardness	250 mg/L as $CaCO_3$
Analytical Monitoring	Two degradation products of the test item were monitored by GC/FID.
Remarks – Method	Preliminary and definitive tests were performed. Due to the low water solubility of the test item (<5.2 mg/L), a supersaturated dispersion with a loading rate of 100 mg/L was continuously stirred at room temperature in the dark for 96 h, filtered (0.45 μm) just before the start of the test, and used as the test medium. Contrary to hydrolysis test report (RCC, 2003e), pre-test experiments indicated that the test substance had a short half-life in water. Thus, two undisclosed degradation products were analytically determined. The analytically measured concentration of one was below the LOQ of 0.002 mg/L. The other product was unstable (1.12 mg/L at day 0, 0.44 mg/L at 48 h and 0.38 mg/L at 96 h or 34% of initial value). However, in a pre-experiment without fish, the concentration of the degradation product was constant for 96 hours. The losses observed in the study were therefore considered to be due to adsorption or absorption in the fish. Test conditions: 16:8 photoperiod with 30 min transition period, temp. 22°C, pH 7.9, dissolved oxygen 8.3-8.6 mg/L (>60% saturation; acceptable).

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	Not determined	7	0	0	0	0	0
100 (loading rate)	Not determined	7	0	0	0	0	0

LC50	>100 mg/L (nominal loading rate) at 96 h
NOEC	100 mg/L (nominal loading rate) at 96 h
Remarks – Results	No mortality or other visible abnormalities were observed during 96 hours in undiluted filtrate, which remained clear and colourless during the test. Spike recoveries for products were within an acceptable range and the analytical blank showed no detectable products. No sublethal effects were observed during the test.
CONCLUSION	The test substance and its degradation products had no acute toxic effects on *Brachydanio rerio* up to their solubility limit in the test water.
TEST FACILITY	RCC (2003x)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test and Reproduction Test – Immobilisation Test, 48 hours. EC Directive 92/69/EEC C.2 Acute Toxicity for *Daphnia* – Immobilisation Test, 48 hours.
Species	*Daphnia magna* (<24 h old)

Exposure Period	48 h
Auxiliary Solvent	No auxiliary solvent or emulsifier was used.
Water Hardness	250 mg/L as $CaCO_3$
Analytical Monitoring	Two degradation products of the test item were monitored by GC/FID.
Remarks – Method	Preliminary and definitive tests were performed. Due to the low water solubility of the test item (<5.2 mg/L), a supersaturated dispersion with a loading rate of 100 mg/L was continuously stirred at room temperature in the dark for 96 h, filtered (0.45 µm) just before the start of the test, and used as the test medium. Contrary to hydrolysis test report (RCC, 2003e), pre-test experiments indicated that the test substance had a short half-life in water. Thus, two undisclosed degradation products were analytically determined. The analytically measured concentration of one was below the LOQ of 0.002 mg/L. The other product was detected and stable during the test (~0.45 mg/L). Therefore, no losses were attributed to adsorption or absorption in daphnids. Test conditions: 16:8 photoperiod with 30 min transition period, temp. 20-21°C, pH 8.0, dissolved oxygen 8.5-8.8 mg/L (acceptable).

RESULTS

Concentration mg/L *Dilution*	*Number of D. magna*	*Number Immobilised* *24 h*	*48 h*
Control	20	0	0
1:16	20	0	0
1:8	20	0	0
1:4	20	0	0
1:2	20	0	0
Undiluted filtrate (loading rate 100 mg/L)	20	0	0

EC50	>100 mg/L (nominal loading rate) at 48 h
NOEC	100 mg/L (nominal loading rate) at 48 h
Remarks – Results	The test material was clear and colourless during the test.

CONCLUSION The test substance and its degradation products had no acute toxic effects on *Daphnia magna* up to their solubility limit in the test water.

TEST FACILITY RCC Inc (2003y)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	Green algal species *(Scenedesmus subspicatus)*
Exposure Period	72 hours
Concentration Range	For a degradation product:
Nominal	undiluted filtrate (100 mg/L loading rate) and dilutions 1:2, 1:4, 1:8, 1:6
Actual	1.19, 0.45, 0.19, 0.07 and 0.03 mg/L.
Auxiliary Solvent	No auxiliary solvent or emulsifier was used.
Water Hardness	24 mg/L (as $CaCO_3$)
Analytical Monitoring	Two degradation products of the test item were monitored by GC/FID.
Remarks – Method	Preliminary and definitive tests were performed. Due to the low water solubility of the test item (<5.2 mg/L), a supersaturated dispersion with a loading rate of 100 mg/L was continuously stirred at room temperature in the dark for 96 h, filtered (0.45 µm) just before the start of the test, and used as the test medium. At the start, 10,000 algal cells/mL were incubated (acceptable). The undiluted filtrate of the stock dispersion with

the maximum concentration of dissolved degradation product (1) and dilutions of 1:2, 1:4, 1:8 and 1:16 were used as test media. Test conditions included 3 replicates per test concentration and 6 control replicates.

The test item has a short half-life in test water. The main degradation product in the undiluted filtrate was detected initially but the concentration declined to 0.37 mg/L (31% of the initially measured value) during the test period of 72 hours. However, in a pre-experiment (without algae), the concentration of this product was constant at a light intensity of 50-500 Lux during a period of 96 hours. Thus, the losses observed in the study were considered to be due to degradation resulting from the intense irradiation of the test flasks. The lower test concentrations (dilution 1:2, 1:4, 1:8 and 1:16) were not analysed at the end of the exposure period. Test temp: 22-23°C. The pH of the test solutions ranged from 7.0-9.0, increasing over time probably due to carbonate formation by the algae.

RESULTS

Dilution	*Density of algal cells (cell number X 10,000/mL)*		
	24 h	*48 h*	*72 h*
Control	4.07	11.66	64.45
Dilution 1:16	3.52	11.55	64.38
Dilution 1:8	4.35	11.83	65.15
Dilution 1:4	4.70	12.75	73.22
Dilution 1:2	5.42	12.98	71.92
Undiluted filtrate (loading rate 100 mg/L)	5.07	12.57	73.95

*Values in table are mean values.

Remarks – Results: Algal cell growth in the control increased by a factor of 16 of the test period (acceptable).

CONCLUSION: The test substance and its degradation products had no acute toxic effects on the growth of the green algae *S. subspicatus* up to their solubility limit in the test water.

TEST FACILITY: RCC Inc. (2003z)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.

Inoculum: Activated sludge from a wastewater treatment plant treating predominantly domestic wastewater.

Exposure Period: 3 h

Concentration Range

Nominal: 6.25, 12.5, 25, 50 and 100 mg/L

Remarks – Method: Respiration was monitored during the test using an oxygen electrode. Two controls and three concentrations of reference toxicant (3,5-dichlorophenol; 5, 16 and 50 mg/L) were tested.

RESULTS

IC50: >100 mg/L (at 3 hours)

NOEC: 100 mg/L after 3 hours

Remarks – Results: The reference toxicant produced an acceptable IC50 of 11.7 mg/L .

	Duplicated control oxygen consumption rates differed by 3% (acceptable).
CONCLUSION	The test substance (up to 100 mg/L) did not inhibit the growth of sewage sludge micro-organisms.
TEST FACILITY	RCC Inc. (2003za)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is only slightly soluble in water, is essentially non-volatile and will strongly bind to organic matter. Although it will associate with fat/lipids, the estimated very high log K_{ow} indicates bioaccumulation is unlikely. The proposed use and disposal pattern indicate a very low potential for release of the notified chemical to the aquatic environment, and no predicted environmental concentrations could be determined. The majority of the notified chemical will be sent to landfill, incorporated into plastic materials for disposal in a diffuse manner, where it is likely to degrade due to biotic and abiotic processes over time to form oxides of carbon, nitrogen and water.

9.1.2. Environment – effects assessment

Ecotoxicity data for the notified chemical are available for 4 trophic levels of freshwater organisms (fish, Daphnia, green algae and sewage sludge micro-organisms). The notified chemical was not toxic up to its limit of water solubility (loading rate 100 mg/L but actually <2 mg/L) to fish, Daphnia and green algae. Although not readily biodegradable, the notified chemical did not inhibit the growth of activated sewage sludge micro-organisms at the only concentration tested (ie. 100 mg/L nominal). A predicted no effect concentration (PNEC) for the notified chemical of >20 μg/L has been derived by dividing the lowest available L(E)C50 of >2 mg/L (assuming <2% of the 100 mg/L loading rate is dissolved) by an assessment (safety) factor of 100.

9.1.3. Environment – risk characterisation

Most of the notified chemical imported will eventually be disposed of to landfill. This includes wastes from spills, emptied imported containers and treated non-woven textiles at the end of their useful life. In landfill, the notified chemical is bound and is not expected to be mobile. It will eventually degrade due to biotic and abiotic processes to give water and oxides of carbon and nitrogen. The very low expected release, coupled with an inability to demonstrate aquatic toxicity at 4 trophic levels of freshwater organisms, suggests a low environmental impact.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Waterside workers, transport drivers and warehouse workers would only be exposed to the notified chemical in the event of an accident. Exposure should be minimized by the physical form of IRGATEC CR 76, which is supplied as solid pellets containing <5% of the notified chemical and packaged in fibreboard boxes.

At the manufacturing site, the required amount of the IRGATEC CR 76 is manually fed to the extruder where it is melted and heated to the appropriate temperature required for fibre formation. Again, the physical form of the product greatly reduces the exposure to the notified chemical. Weighing and introduction to the extruder is carried out under local exhaust ventilation, to capture any fugitive dust and thus inhalation exposure to particles is minimal. Workers will wear PPE such as gloves, face shields or safety glasses, safety boots and overalls.

Once added to the extruder, there is little chance of exposure to the notified chemical as the meltblown process is sealed and fully automated. After the meltblown process is completed the

non-woven fabric comes out on a conveyor machine and is cut into appropriate roll sizes. This process is fully automated and occurs under local ventilation. At this stage, the notified chemical is bound or immobilised within the polymer matrix and therefore there will be no exposure.

9.2.2. Public health – exposure assessment

The notified chemical is a component in a polymer additive that is used only by industrial users. Public exposure is therefore limited to dermal contact with final non-woven fabrics, which contain <1% notified chemical. In such material the notified chemical is bound or immobilised within the polymer matrix and is generally not biologically available.

9.2.3. Human health – effects assessment

The notified chemical is a slightly yellow liquid that is very hydrophobic. Substantial dermal absorption or bioaccumulation are unlikely to occur, due to the MW (>500) and the very high estimated log Kow (12.1). Furthermore, the notified chemical is bound within a polymer matrix while being handled and thus is unlikely to be bioavailable.

The notified chemical was of low acute oral toxicity (LD_{50} > 2000 mg/kg) and low acute dermal toxicity (LD_{50} > 2000 mg/kg) in rats. It was non-irritating to rabbit skin and non-irritating to the rabbit eye. Although no acute inhalation studies have been conducted, the notified chemical is not expected to be an inhalation hazard based upon its low vapour pressure. In bacterial mutagenicity and Chinese Hamster V79 cell chromosomal aberration tests, there was no indication of genotoxicity.

There was evidence of sensitisation in the mouse Local Lymph Node Assay using the notified chemical, and an EC3 of 25.8% (w/w) was determined. LLNA tests were also supplied for 5% and 10% notified chemical in polypropylene, and these products did not exhibit evidence of sensitisation.

Thus, the notified chemical is assigned the risk phrase R43 May cause sensitisation by skin contact. However, the use of this risk phrase is not necessary for up to 10% notified chemical in polypropylene.

In a 28-day repeat dose oral toxicity study, a large number of reversible adaptive changes were observed. Slightly lower mean body weights and lower body weight gain were noted in males treated at 200 mg/kg bw/day and 1000 mg/kg bw/day compared with controls. A NOAEL of 50 mg/kg bw/day was established, based on low body weight and low body weight gain in animals receiving higher doses.

Based on the above results, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002).

9.2.4. Occupational health and safety – risk characterisation

Exposure to the notified chemical will be low. In the imported product, it is immobilised in a polymer matrix at a concentration of <5%, and the meltblown process is completely enclosed and automated. Engineering controls and PPE further reduce the likelihood of exposure. Thus the risk of skin sensitisation is low.

9.2.5. Public health – risk characterisation

The risk of adverse health effects for the public is negligible, as the only exposure will be to non-woven fabrics in which the notified chemical is immobilised and thus not biologically available.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:
R43: May cause sensitisation by skin contact

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Skin sensitiser	1	May cause allergic skin reaction

10.2. Environmental risk assessment

The notified 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 as a chemical additive in non-woven fabrics

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product 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 the product 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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R43: May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - >1%: R43: May cause sensitisation by skin contact

  (This does not apply to products containing up to 10% notified chemical immobilised in a polymer matrix.)

Health Surveillance

- As the notified chemical is a skin sensitiser, employers should determine if health surveillance is necessary, according to the National Code of Practice for the Control of Workplace Hazardous Substances [NOHSC:2007(1994)] and Guidelines For Health Surveillance [NOHSC:7039(1995)].

- Sensitised workers should be advised not to further handle the notified chemical.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - local exhaust ventilation should be used during the meltblown process involving handling the pellets containing the notified chemical

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - face shield or safety goggles
  - protective gloves
  - industrial clothing

  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

Disposal

- The notified chemical should be disposed of to incinerator or landfill in accordance with local regulations.

Emergency procedures

- Spills/release of the notified chemical should be handled by sweeping up and shovelling spilled pellets into suitable labelled containers for collection by authorised waste disposal contractors.

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(1) of the Act; if
- the notified chemical is imported at greater than 10% concentration, bound in a polymer matrix
- the notified chemical is imported is a form such that it is not bound in a polymer matrix.

or

(2) 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.

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RCC Ltd (2003p) [notified chemical]: Primary eye irritation study in rabbits. RCC study number 848426. RCC Ltd, Itingen, Switzerland (unpublished report submitted by the notifier).

RCC Ltd (2003q) [notified chemical]: Local lymph node assay (LLNA) in mice (identification of contact allergens). RCC study number 848427. RCC Ltd, Itingen, Switzerland (unpublished report submitted by the notifier).

RCC Ltd (2003r) 5% [notified chemical] in PP / 175°C: Local lymph node assay (LLNA) in mice (identification of contact allergens). RCC study number 850010. RCC Ltd, Itingen, Switzerland (unpublished report submitted by the notifier).

RCC Ltd (2003s) 10% [notified chemical] in PP / 175°C: Local lymph node assay (LLNA) in mice (identification of contact allergens). RCC study number 850012. RCC Ltd, Itingen, Switzerland (unpublished report submitted by the notifier).

RCC Ltd (2003t) [notified chemical]: 28-day oral toxicity (Gavage) study in the Wistar rat. RCC study number 848428. RCC Ltd, Itingen, Switzerland (unpublished report submitted by the notifier).

RCC Ltd (2003u) *Salmonella typhimurium* and *Escherichia coli* reverse mutation assay with [notified chemical]. RCC study number 848430. RCC Ltd, Itingen, Switzerland (unpublished report submitted by the notifier).

RCC Ltd (2003v) In vitro chromosome aberration test in chinese hamster V79 cells with [notified chemical]. RCC study number 848431. RCC Ltd, Itingen, Switzerland (unpublished report submitted by the notifier).

RCC Ltd (2003w) Ready biodegradability of [notified chemical] in a CO2 evolution (modified Sturm) test. RCC Study Number 848440. RCC Ltd, Itingen, Switzerland (unpublished report submitted by the notifier).

RCC Ltd (2003x) Acute toxicity of [notified chemical] to Zebra fish (*Brachydanio rerio*) in a 96-hour static test. 37 pp. RCC Study Number 848432. RCC Ltd, Itingen, Switzerland (unpublished report submitted by the notifier).

RCC Ltd (2003y) Acute toxicity of [notified chemical] to *Daphnia magna* in a 48-hour immobilisation test. RCC Study Number 848434. RCC Ltd, Itingen, Switzerland (unpublished report submitted by the notifier).

RCC Ltd (2003z) Toxicity of [notified chemical] to *Scenedesmus subspicatus* in a 72-hour algal growth inhibition test. RCC Study Number 848436. RCC Ltd, Itingen, Switzerland (unpublished report submitted by the notifier).

RCC Ltd (2003za) Toxicity of [notified chemical] to activated sludge in a respiration inhibition test. RCC Study Number 848439. RCC Ltd, Itingen, Switzerland (unpublished report submitted by the notifier).

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.