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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

2-Propenoic acid, 2-cyano-3,3-diphenyl-, 2,2-bis[[(2-cyano-1-oxo-3,3-diphenyl-2-propenyl)oxy]methyl]-1,3-propanediyl ester

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN 62 008 437 867) of 500 Princes Highway Noble Park VIC 3174.

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

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
EU (1999), USA (1999), Japan (2001), Korea (2002), Canada (2002), and China (2003).

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
2-Propenoic acid, 2-cyano-3,3-diphenyl-, 2,2-bis[[(2-cyano-1-oxo-3,3-diphenyl-2-propenyl)oxy] methyl]-1,3-propanediyl ester

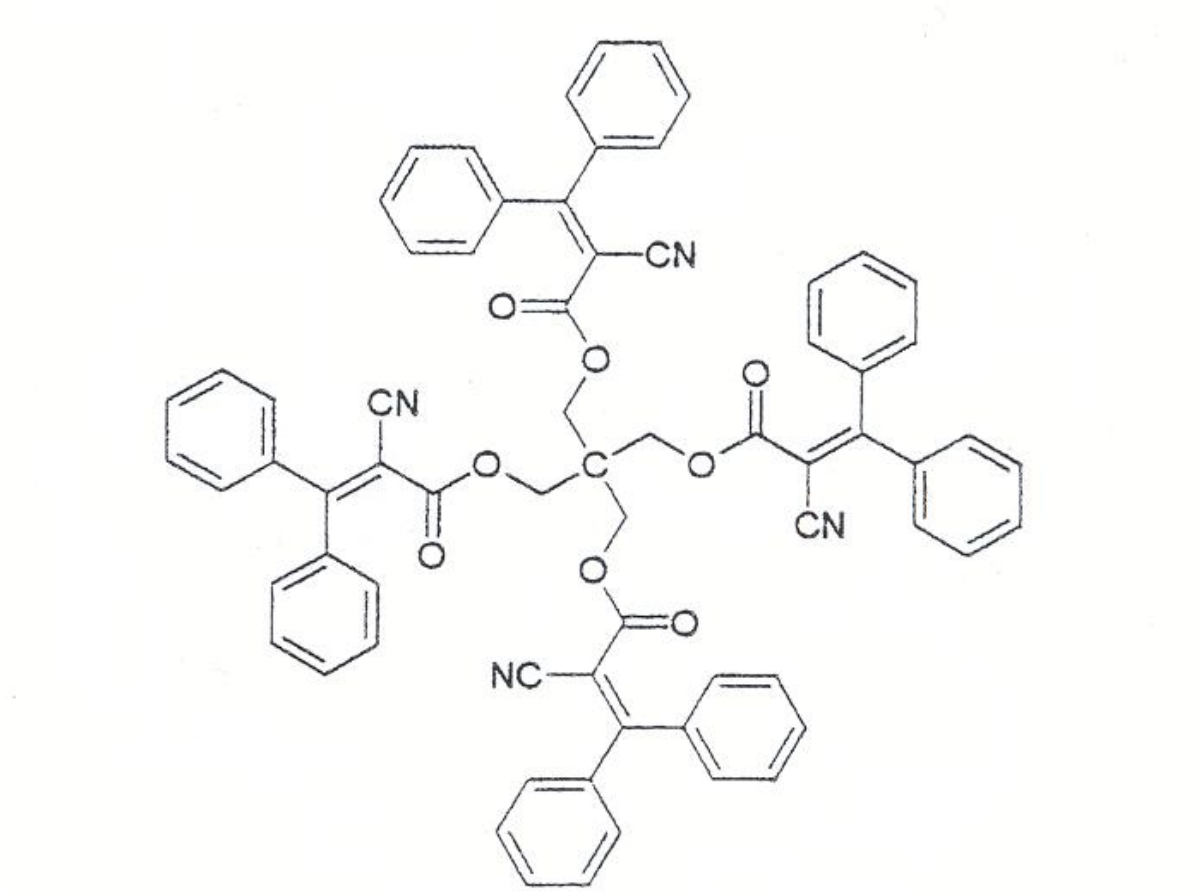
OTHER NAME(S)
1,3-Bis[(2-cyano-3,3-diphenylacryloyl)oxy]-2,2-bis[[(2-cyano-3,3-diphenylacryloyl)oxy]methyl]propane
Pentaerythritol tetrakis(2-cyano-3,3-diphenylacrylate)
Cyanoacrylate absorber

MARKETING NAME(S)
Uvinul 3030
Uvinul ED 8738

CAS NUMBER
178671-58-4

MOLECULAR FORMULA
$C_{69}H_{48}N_4O_8$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
1061.1 g/mol

SPECTRAL DATA

METHOD	UV/VIS, IR and ^{1}H-NMR
Remarks	UV/VIS spectrum: λmax = 307 nm, ε = 48368, conc. = 11.14 mg/L in acetonitrile
	IR peaks: 3417, 3056, 2221, 1721, 1583, 1559, 1489, 1466, 1445, 1395, 1330, 1248, 1182, 1161, 1096, 1029, 1001, 967, 932, 783, 764, 748, 699, 665, 619, 611, 455 cm^{-1}
	NMR spectrum: The signals correspond to the expected structure of the notified chemical.
TEST FACILITY	BASF (2002)

3. COMPOSITION

DEGREE OF PURITY
99.0-99.4%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	Benzene, 1,3-dimethyl-		
CAS No.	108-38-3	*Weight %*	0.017
Chemical Name	Benzene, 1,2-dimethyl-		
CAS No.	95-47-6	*Weight %*	0.011
Chemical Name	Benzene, 1,4-dimethyl-		
CAS No.	106-42-3	*Weight %*	0.004

Hazardous Properties	At Concentrations equal to or more than 20%: Harmful (Xn): R20/21 - Harmful by inhalation and in contact with skin; R38 - Irritating to skin. At Concentrations equal to or more than 12.5% and less than 20%: Harmful (Xn): R20/21 - Harmful by inhalation and in contact with skin.

Chemical Name	Benzene, ethyl-		
CAS No.	100-41-4	*Weight %*	0.004
Hazardous Properties	At Concentrations equal to or more than 25%: Harmful (Xn): R20 - Harmful by inhalation.		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)
None.

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported in effectively pure crystalline form.

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

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

USE
As a UV absorber for plastics used in the manufacturing industry to produce plastic fittings for cars, plastic sheetings for roofs, etc.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
GE Plastics (Australia) Pty Ltd, Dandenong VIC

TRANSPORTATION AND PACKAGING
Uvinul 3030 will be shipped into Australia by sea in 25 kg cartons, transported by road to Patrick Intermodal warehouse, Laverton North VIC, and then to GE Plastics production plant for processing. Storage will be in appropriate areas with adequate spill containment and in accordance with state legislation.

5.2. Operation Description

Shipments of the notified chemical will be unloaded and loaded at dockside with the aid of a forklift, then transported to the Patrick Intermodal warehouse prior to delivery to the GE Plastics production plant.

At the customer plastics processing plant, a storeperson will transfer the unopened cartons of Uvinul 3030 by forklift to various work areas as required, for example, warehouse, batch making area, and processing equipment area. The batchmaker will weigh Uvinul 3030 according to formulation and transfer all weighed raw materials to an enclosed mixer (1-5 tonnes capacity) for producing polymer compounds. The laboratory technician will perform testing and adjustment to the formulation if necessary. The extruder operator then will transfer the resulting mixtures (including approximately 2-4% w/w notified chemical) to an extruder. It is also an enclosed machine that melts all raw materials

and produces polymer stands that cool in water, being cut into small granules/pellets, which will be packaged into bags or bulk containers by automatic means for subsequent sale as a masterbatch for use by plastics processors.

Downstream sales of the polymer compound are plastics processors who extrude or mould the compound into items that are used by manufacturing industry and consumers, for example, plastic fittings for cars, plastic sheeting for roofs, etc. At this point, the notified chemical is encapsulated within the polymer matrix.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Waterside, transport and warehouse workers	5-12	short period	
Store personnel at production plant	1	short period	
Mixing and extrusion plant operators	2	short period	3 hours/month
Laboratory technician	1	short period	5 days/year
Plant maintenance workers	<5	short period	

Exposure Details

It is anticipated that waterside, transport and warehouse workers would only be exposed to the notified chemical in the event of an accidental spill. Should a spill occur, it is expected to be contained and collected using dust binding materials, and placed into suitable containers for recovery or disposal in accord with the MSDS and official regulations.

In the mixing, extrusion and moulding plants, the potential routes of worker exposure to the notified chemical will be dermal contact and inhalation. Spillages and dust generation during weighing, transferring, mixing, moulding, maintenance, and cleaning operations may also result in exposure to the eyes, skin, nose, throat and mucous membranes. Results of a particle size distribution study for Uvinul 3030 (test report not provided) indicates that although the majority of dust particles are in the inhalable range (10-100 μm), almost none are in the respirable range (<10 μm). High dust concentrations within the plastics processing plant have a potential for combustion or explosion. The notifier indicates that adequate ventilation will be in place to prevent workers from breathing dust and particulates. Local exhaust ventilation will be employed at all work areas when required.

During extrusion, at the formulation plant and during downstream use, the polymer compounds are heated at high temperatures for an extended period, and harmful fumes and vapours can evolve. It is expected that these fumes will be captured and scrubbed. Cross contamination will be avoided by thorough cleaning of the extruder and other processing equipment with purging compound prior to product changeover. Any incidents of accidental spillages will be contained and removed by mechanical means such as vacuuming or sweeping. It is intended that dust formation will be avoided and the release will be kept out of water supplies and sewers.

Plastics production plant operators will wear appropriate respirators, dust masks and safety glasses with side-shields/chemical goggles. Protective clothing and gloves will also be worn at all times. Copies of the MSDS will be readily accessible in all work areas.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Environmental exposure associated with the manufacture of the notified chemical will not occur in Australia. Release of the notified chemical to the environment during the mixing and moulding/extrusion processes is expected to be minimal. The concentration of the new chemical in the formulated additive mix is expected to be 2-4%. A maximum of one carton (25 kg) per annum may be released due to accidental damage and loss of product.

Up to 25 kg per annum of the imported notified chemical is expected to remain as residue in import cartons, which will be sent to landfill. There is a potential for release during measuring out the notified chemical or during transfer of the formulations into various equipment. Airborne fumes, other than

from accidental release, would not be expected due to the very low vapour pressure of the chemical.

Approximately 0.5% of the imported notified chemical is expected to be released per annum when the extruder is cleared of off-grade polymer by a periodic purging process. The purged polymeric material would be recycled or disposed of in landfill. Based on a worst-case scenario of zero recycling, up to 25 kg of the notified chemical is estimated to be released per annum due to the purging process.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be used in manufacturing industry only. The notifier did not provide details on the manufacture of plastic items using the polymer product containing the notified chemical. It is assumed that this involves standard moulding processes and that the release of the notified chemical to the environment during the manufacture of the final products to be less than 2% (maximum of 100 kg), which will be landfilled. The majority of the products containing the notified chemical will be disposed of to landfill at the end of their useful lives though some may be recycled.

5.5. Disposal

Waste containing the notified chemical generated during the formulation and extrusion/moulding processes and manufacture of the plastic articles will be disposed of to landfill.

5.6. Public exposure

Uvinul 3030 will not be available to the public except in the form of finished articles. There is potential for extensive public exposure through dermal contact with articles including plasticisers containing the notified chemical. Indirect exposure via air and water contamination will be negligible taking into account the physicochemical characteristics of the new chemical such as high molecular weight, low vapour pressure and water solubility.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White crystalline powder with no odour

Melting Point 170-178°C

METHOD	OECD TG 102 Melting Point/Melting Range.
Remarks	With the differential scanning calorimetry method, the average of melting peaks is 170.2°C. With the Kofler hot bar method, the notified chemical starts with converting to a melt at about 178.
TEST FACILITY	BASF (1999a)

Density 1198 kg/m^3 at 20°C

METHOD	OECD TG 109 Density of Liquids and Solids (Oscillating density meter) for the densities of displacement liquids. EC Directive 92/69/EEC (Pycnometer).
Remarks	Displacement liquids: petroleum and silicon oil AP100.
TEST FACILITY	BASF (1999a)

Vapour Pressure $<10^{-9}$ kPa at 20°C

METHOD	EC Directive 92/69/EEC – Effusion Method
Remarks	Above 255°C the colour of the notified chemical had changed to black. Thermal decomposition led to high measuring error and the poor reproducibility of the data. The notified chemical is slight volatile (Mensink et al., 1995).
TEST FACILITY	BASF (1999a)

Water Solubility $<1x10^{-4}$ g/L at 20°C

METHOD	EC Directive 92/69/EEC – Column Elution Method (with levelling vessel).
Remarks	HPLC analysis was used with pH of the test solution ranging 6.98-7.59. The notified chemical is slightly soluble (Mensink et al., 1995).

TEST FACILITY BASF (1999a)

Hydrolysis as a Function of pH Not determined

Remarks It was considered the hydrolytic decomposition of the notified chemical is unlikely to be significant.

Partition Coefficient (n-octanol/water) log Pow = 8.0
log Pow = 13.4 (estimated)

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks HPLC Method was used. Estimation of log Pow was based on theoretical calculation using KOWWIN v.1.51, Syracuse Research Corp.
The high log Pow is consistent with the low water solubility indicating the notified chemical is likely to partition into the octanol phase.
TEST FACILITY BASF (1999a)

Adsorption/Desorption Not determined

Remarks The low water solubility and high log Pow indicate strong adsorption to and low mobility in soils.

Dissociation Constant Not determined

Remarks Due to the low water solubility of the notified chemical, determination of its dissociation constant was not technically feasible. There are no groups likely to dissociate.

Particle Size

Range (μm)	*Mass (%)*
<20	0.0
20-100	71.4
200-800	28.6

Remarks Full test report not provided.

Flash Point Not determined

Remarks The notified chemical is solid at room temperature.

Flammability Limits Not considered highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical does not burn.
TEST FACILITY BASF (1998a)

Autoignition Temperature No self ignition to 400°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The notified chemical was tested in its commercial form and no self-heating was observed to 400°C. At the end of the test the wire basket was empty.
TEST FACILITY BASF (1998a)

Explosive Properties Not considered explosive

Remarks The notified chemical is not expected to be explosive, based on structure; however, it may be a dust explosion hazard.

Reactivity Stable under normal environmental conditions

Remarks The decomposition process of the notified chemical at elevated temperatures is indicated by a sharp endothermic peak at about 370°C and a broad exothermic peak at about 400°C in DSC measurements (BASF 1999a).

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	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation (10% notified chemical)
Rat, repeat dose oral toxicity - 28 days	NOAEL = 15000 ppm
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	non genotoxic
Genotoxicity – in vivo gene mutation test	non genotoxic
Pharmacokinetic/Toxicokinetic studies	no data available
Developmental and reproductive effects	no data available
Carcinogenicity	no data available

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 96/54/EC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain Rat/Wistar chbb:thom

Vehicle 0.5% Tylose CB 30.000 (cleaned sodium carboxymethylcellulose) in aqua bidest

Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 males	2000	0/3
II	3 females	2000	0/3

LD50 >2000 mg/kg bw

Signs of Toxicity No mortalities or clinical signs of toxicity.
Animal weight gain as expected.

Effects in Organs No macroscopic abnormalities observed at necropsy of animals at the end of the study.

Remarks - Results None.

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

TEST FACILITY BASF (1998b)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD OECD TG 402 Acute Dermal Toxicity.

	EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/Wistar chbb:thom
Vehicle	0.5% Tylose CB 30.000 in aqua bidest
Type of dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	No local effects noted.
Signs of Toxicity - Systemic	No mortalities or systemic signs of toxicity. Animal weight gain as expected.
Effects in Organs	No macroscopic abnormalities observed at necropsy of animals at the end of the study.
Remarks - Results	None.

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

TEST FACILITY — BASF (1999b)

7.3. Acute toxicity – inhalation

Remarks — Test was not conducted.

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
Number of Animals	1 male, 2 females
Vehicle	Moistened with aqua bidest
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	1	1 h	0
Oedema	0	0	0	0	0 h	0

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

Remarks - Results	Slight erythema observed in 1 animal was reversible within 24 h post treatment. Primary irritation index = 0.08 (slightly irritating).

CONCLUSION — The notified chemical is slightly irritating to skin.

TEST FACILITY — BASF (1998c)

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
Number of Animals	3 females
Observation Period	72 hours
Remarks - Method	A single animal was treated initially, followed by another two animals due to the lack of severe findings in the first animal.

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	1.0	0.7	0.3	2	48 h	0
Conjunctiva: chemosis	0.3	0.0	0.0	1	24 h	0
Conjunctiva: discharge	0	0	0	1	1 h	0
Corneal opacity	0	0	0	0	0 h	0
Iridial inflammation	0	0	0	0	0 h	0

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

Remarks - Results	Signs of irritation were reversible within 72 h post treatment.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	BASF (1998d)

7.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation – Maximisation Test. EC Directive 96/54/EC B.6 Skin Sensitisation – Maximisation Test.
Species/Strain	Guinea pig/Dunkin Hartley Crl:(HA)BR
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 5% test substance in vehicle topical: 10% test substance in vehicle (vehicle = 1% Tylose CB 30.000 in aqua bidest) (adjuvant = 1:1 Freund's adjuvant/0.9% NaCl)
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 5% test substance in vehicle or in adjuvant topical: 25% test substance in vehicle
Signs of Irritation	After intradermal induction, moderate and confluent erythema and swelling were observed at the injection sites of all control and test animals (excluding vehicle control animals). Animals injected with a 50% mixture of vehicle with adjuvant showed the same skin reactions. After percutaneous induction, all animals (including vehicle control animals) exhibited incrustation, partially open (caused by the intradermal induction) in addition to the above erythema and swelling effects.
CHALLENGE PHASE	
1st challenge	topical: 10% test substance in vehicle
Remarks - Method	No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*	
		24 h	*48 h*
Test Group	10%	0/10	0/10
Control Group	10%	0/5	0/5

Remarks - Results: No skin reactions were observed in control and test animals. A separate positive control study with alpha-hexyl-cinnamaldehyde (techn. 85%) confirmed the sensitivity of the test system.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test (10% notified chemical).

TEST FACILITY: BASF (1998e)

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).
Japan MHW Repeated Dose (28 Days) Toxicity in Mammalian Species.

Species/Strain	Rat/Wistar chbb:thom
Route of Administration	Oral – diet
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 2 weeks
Vehicle	None
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose ppm*	*Mortality*
I (control)	5 males, 5 females	0	0/5
II (low dose)	5 males, 5 females	600	0/5
III (mid dose)	5 males, 5 females	3000	0/5
IV (high dose)	5 males, 5 females	15000	0/5
V (control recovery)	5 males, 5 females	0	0/5
VI (high dose recovery)	5 males, 5 females	15000	0/5

Mortality and Time to Death
No mortalities were noted during the study.

Clinical Observations
No abnormal clinical signs were observed. Detailed clinical observations, functional observational battery as well as measurement of motor activity did not reveal any signs of neurotoxicity. No statistically or biologically relevant changes in food/water consumption, food efficiency and body weight were observed.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There were no treatment related changes in haematology, clinical chemistry, and urine parameters

Effects in Organs
There were no remarkable gross lesions or microscopic findings in any of the organs investigated in the animals of the main and recovery groups. The microscopic findings were either single observations, or they occurred in control animals only, or they were recorded at comparable incidence and graded severity in control and high dose males and/or females. Hence, they were all regarded to be unrelated to treatment.

After a 2-week recovery period, the mean absolute and relative adrenal weights of the high dose males were significantly decreased. There were no other indications of an affection of the organs of the central or peripheral nervous system, the reproductive system, and the immune system by the test chemical, based on weight parameters, or based on the gross lesions or microscopic findings in these organs.

Remarks – Results

Effects in the adrenal glands in males of the high dose recovery group were not regarded to be treatment related as there were no significant deviation in the respective weights in females of the recovery groups; no significant deviations in the absolute and relative weights in males or females of the main groups; and no morphologic alteration that may account for the weight increase.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 15000 ppm (equivalent to 1304 and 1405 mg/kg bw in males and females, respectively), which is the highest dose tested in this study.

TEST FACILITY BASF (1998f)

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.
Plate incorporation procedure/Pre-incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA.
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	a) Plate incorporate (±S9): 0, 20, 100, 500, 2500, 5000 µg/plate. b) Pre-incubation (±S9): 0, 4, 20, 100, 500, 2500 µg/plate.
Vehicle	DMSO
Remarks - Method	Two independent experiments were performed in triplicate: the first by the plate incorporate procedure and the second by the pre-incubation procedure.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	Not performed	≥500	≥500	Negative
Test 2	Not performed	≥500	≥500	Negative
Present				
Test 1	Not performed	≥500	≥500	Negative
Test 2	Not performed	≥500	≥500	Negative

Remarks – Results

Precipitation was found at ≥500 µg/plate. A weak bacteriotoxicity decrease in the number of revertants (plus decrease in the titer) was occasionally observed at ≥500 µg/plate, especially in TA 1537 (plate incorporation test), and in TA 1535, TA1537, TA98 (pre-incubation test) with and without metabolic activation. The vehicle, negative and positive controls responded appropriately.

CONCLUSION

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

TEST FACILITY BASF (1998g)

7.9a. Genotoxicity – in vitro (Chromosomal Aberration Assay)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test. EC Directive 92/69/EEC B.10 Mutagenicity - In vitro Mammalian Cytogenetic Test.
Cell Type/Cell Line	V79 Chinese hamster
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Vehicle	DMSO
Remarks - Method	Depending on cytotoxicity only one dose (100 µg/mL) was evaluated without S9 at the additional harvest time of 28 h.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Preliminary Test	1, 5, 10, 50, 100, 200	4 h	18 h
Test 1	5*, 20*, 100*	4 h	18 h
Test 2	5*, 20*, 100*	18 h	18 h, 28 h
Present			
Preliminary Test	1, 5, 10, 50, 100, 200	4 h	18 h
Test 1	5*, 20*, 100*	4 h	18 h
Test 2	5*, 20*, 100*	4 h	28 h

*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	>200	>100	≥20	Negative
Test 2	--	>100	≥20	Negative
Present				
Test 1	>200	>100	≥20	Negative
Test 2	--	>100	≥20	Negative

Remarks - Results	An increase in the number of chromosomal aberrations including and excluding gaps was observed towards high dose treatments either with or without metabolic activation in the two independent tests. However, the types and frequencies of aberrations were within the range of the concurrent negative control values at both sampling times and within the range of the historical data. Statistical significances occasionally observed for chromosomal aberrations including gaps were not considered to be an indication for a clastogenic activity of the test chemical as they are based only on an increase in the number of gaps which generally are not regarded as a suitable criterion for demonstrating clastogenic events; the values observed are within the historical range; or they are due to the low spontaneous mutation rate. No suppression of the mitotic activity and no growth inhibition were observed at any test conditions. The vehicle, negative and positive controls responded appropriately.
CONCLUSION	The notified chemical was not clastogenic to V79 cells treated in vitro under the conditions of the test.
TEST FACILITY	BASF (1998h)

7.9b. Genotoxicity – in vitro (HPRT Locus Assay)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 476 In vitro Mammalian Cell Gene Mutation Test. EC Directive 87/302/EEC B.10 Mutagenicity - In vitro Mammalian Cytogenetic Test.
Cell Type/Cell Line	Chinese hamster ovary (CHO)
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Vehicle	DMSO
Remarks - Method	

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Preliminary Test	5, 10, 50, 100, 500, 1000, 2500, 5000	4 h	--	--
Test 1	8*, 40*, 200*, 1000*, 5000*	4 h	7 days	7 days
Test 2	8*, 40*, 200*, 1000*, 5000*	4 h	7 days	7 days
Present				
Preliminary Test	5, 10, 50, 100, 500, 1000, 2500, 5000	4 h	--	--
Test 1	8*, 40*, 200*, 1000*, 5000*	4 h	7 days	7 days
Test 2	8*, 40*, 200*, 1000*, 5000*	4 h	7 days	7 days

*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	≥5000	≥5000	≥50	Negative
Test 2	≥5000	≥5000	≥50	Negative
Present				
Test 1	≥5000	≥5000	≥50	Negative
Test 2	≥5000	≥5000	≥50	Negative

Remarks - Results	The notified chemical did not lead to an increase in the number of mutant colonies at any test concentrations with or without metabolic activation. The vehicle, negative and positive controls responded appropriately.
CONCLUSION	The notified chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test.
TEST FACILITY	BASF (1999c)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301F Ready Biodegradability-Manometric Respirometry Test. EC Directive 92/69/EEC ISO Standard 9408.
Inoculum	Activated sludge from a municipal wastewater treatment plant
Exposure Period	28 days
Auxiliary Solvent	None

Analytical Monitoring	Biochemical Oxygen Demand (BOD)
Remarks - Method	In addition to the test substance (100 mg/L), samples containing a reference substance (aniline at 10 and 100 mg/L) and a test assay containing the test substance and demineralised water were investigated.

RESULTS

	% degradation	
Day	*Test substance*	*Sodium benzoate*
7	0	62
14	0	70
21	0	74
28	0	76

Remarks - Results	The degradation of the test substance was less than 20% indicating its poor biodegradability. Degradation of the reference substance up to 76% validates the test system.
CONCLUSION	The test substance is not readily biodegradable according to the OECD criteria.
TEST FACILITY	BASF (2000a)

8.1.2. Bioaccumulation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 305 Bioconcentration: Flow-through Fish Test. MITI/MHW Japan 1998
Species	Common carp (*Cyprinus carpio*)
Exposure Period	Exposure: 42 days Depuration: 16 days
Auxiliary Solvent	Cremophor RH 40 (hardened castor oil) was used as a dispersion.
Concentration Range	
Nominal	0, 0.1 and 1.0 mg/L (these were selected based on the results of the fish acute toxicity tests that are summarised under 8.2.2).
Analytical Monitoring	By reverse phase HPLC with UV-detection.
Remarks - Method	A 10% homogenous dispersion of the test substance was prepared with 10% test substance, 20% Cremophor RH 40 and 70% bidistilled water. Fish and water samples were obtained on 9 occasions during the uptake phase and on 4 occasions during the depuration phase and analysed for test substance.
RESULTS	
Bioconcentration Factor	31.0 (mean of the bioconcentration factors for both test concentrations)
CT50	Not reported
Remarks - Results	No mortalities or changes in appearance or behaviour were observed throughout the study. The concentration of the test substance in water was generally within a range of ±20% of the nominal concentration in both test concentrations. The concentration in fish reached steady state after about 14 days in both test groups. In the depuration period, more than 50% of the test substance in the fish was excreted within 1 to 2 days and concentrations decreased until the end of the uptake period. While 95% of the test substance was excreted after approximately 16 days in the 1.0 mg/L group, that level was not reached in the lower concentration group within 16 days.
CONCLUSION	The BCF is estimated to be 31.0 indicating a low potential for bioaccumulation in fish.

TEST FACILITY	BASF (2000b)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish – Zebra fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static. EC Directive 84/449/EEC (Updated Dec 92) C.1 Acute Toxicity for Fish.
Species	Zebra fish (*Brachydanio rerio* Ham. and Buch.)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Unfiltrated and filtrated samples were analysed by reverse phase HPLC with UV detection.
Remarks – Method	Based on the results of two preliminary tests (96 hour LC50 >10000 mg/L) four test concentrations ranging from 50 to 10000 mg/L were selected. The test solutions were prepared using an ultra-turrax stirrer. Oxygen content, pH and temperature were all satisfactorily maintained. The measured concentrations of the unfiltered samples ranged from 2.7% to 12.0% and between 1.0% to 2.5% of the nominal concentration at the beginning and after about 96 hours, respectively. The analytical recovery in the filtered samples was less than the detection limit of the test of 0.2 mg/L. Undissolved test substance was visible at the water surface and on the bottom of all test vessels and the solutions above 100 mg/L appeared to be milky. Both these effects increased with increasing test concentrations. The fish in the high concentration assays were directed towards the front pane of the vessel to determine mortality and sublethal effects.
RESULTS	
LC50	
(based on nominal concentrations)	>10000 mg/L at 96 hours.
(based on measured concentrations)	>245 mg/L at 96 hours.
NOEC	
(based on nominal concentrations)	10000 mg/L at 96 hours.
(based on measured concentrations)	245 mg/L at 96 hours.
Remarks – Results	No mortalities or substance related sublethal effects were observed at any of the test concentrations.
CONCLUSION	The test substance is not toxic to fish up to the limit of its water solubility.
TEST FACILITY	BASF (1998i)

8.2.2. Acute toxicity to fish – Common carp

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish. Japanese Industrial Standard JIS K0102 – 1986.

Species	Common carp (*Cyprinus carpio*)
Exposure Period	96 hours
Auxiliary Solvent	Cremophor RH 40 (hardened castor oil) was used as a dispersion.
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Samples obtained from the middle of the test vessels were analysed by HPLC with UV detection.
Remarks – Method	Test concentrations (100 and 1000 mg/L, plus a dispersant control) were selected based on the results of the study summarised under 8.2.1. A 10% homogenous dispersion of the test substance was prepared with 10% test substance, 20% Cremophor RH 40 and 70% bidistilled water. Test solutions showed a white turbidity. The measured test concentrations were within the range of ±10% and decreased to 64.5% to 71% of nominal values at beginning and the end of the study, respectively. The mean measured concentration in the highest test concentration (1000 mg/L) was 815 mg/L. The fish in assays ≥100 mg/L were directed towards the front pane of the vessel to determine mortality and sublethal effects. The pH and temperature were satisfactorily maintained. The oxygen content measured at 24 hours was below 60% of the air saturation value in the 100 and 1000 mg/L concentrations. This was considered not to have affected the results since no mortality was observed in these concentrations.

RESULTS

LC50 (based on nominal concentrations)	>1000 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	No mortalities were observed at any test concentrations. The only sublethal symptom recorded was swimming near water surface at the 1000 mg/L concentration (3 or 4 fish were observed at 1, 4, 24, 48, 72 and 96 hours after start of exposure).

CONCLUSION	The test substance is not toxic to fish up to the limit of its water solubility.
TEST FACILITY	BASF (2001)

8.2.3. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 92/32/EEC C.2 Acute Toxicity for Daphnia – Static.
Species	*Daphnia magna* STRAUS 1820
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Standard medium was used.
Analytical Monitoring	By reverse phase HPLC with UV detection.
Remarks - Method	The test substance was stirred in M4 medium for about 20 hours at approximately 20 ± 2°C. Undissolved test substance was removed by centrifugation at about 17700 G for approximately 20 minutes. The four test concentrations (12.5, 25, 50 and 100 mg/L) were prepared by diluting the eluate (with a nominal concentration of 100 mg/L) with M4 medium. The concentration control analysis was performed on the test solutions of 0, 12.5 and 100 mg/L. Samples from vessels without daphnids were analysed at the start of the test and samples from vessels with and without

daphnids were analysed at the end of the test. Oxygen content, pH and temperature were all satisfactorily maintained.

RESULTS

LC50	>100 mg/L at 48 hours
NOEC (or LOEC)	100 mg/L at 48 hours (the highest concentration tested)
Remarks - Results	No immobilised daphnia were observed. The analytical recovery rates in all analysed test solutions were below the detection limit. Test substance precipitation or physical effects were not reported.

CONCLUSION — The test substance is not toxic to *Daphnia magna* up to the limit of its water solubility.

TEST FACILITY — BASF (1998j)

8.2.4. Algal growth inhibition test

TEST SUBSTANCE — Notified chemical

METHOD — EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Scenedesmus subspicatus* CHODAT SAG 86.81
Exposure Period	72 hours
Concentration Range	
Nominal	0, 12.5, 25, 50 and 100 mg/L
Auxiliary Solvent	None
Water Hardness	Standard medium was used
Analytical Monitoring	Samples with nominal concentration of 0, 50 and 100 mg/L and the stock solution of 125 mg/L were analysed by reverse phase HPLC with UV detection.
Remarks - Method	The test substance was stirred in demineralised water for about 20 hours at 20 ± 2°C. Undissolved test substance was removed by centrifugation at about 17700 G for approximately 20 minutes. The four test concentrations were prepared by diluting the eluate (with a nominal concentration of 125 mg/L) with demineralised water. The concentration control analysis was performed on the test solutions of 0, 50, 100 and 125 mg/L. Samples from replicates with no algal cells were analysed at the start of the test and samples from vessels with and without algal cells were analysed at the end of the test. The pH and temperature were satisfactorily maintained.

RESULTS

Biomass		*Growth*	
E_bC50	*NOEC*	*E_rC50*	*NOEC*
mg/L at 72 h	*mg/L at 72 h*	*mg/L at 72 h*	*mg/L at 72 h*
>100	100*	>100	100*

* 95% significance level

Remarks - Results — The analytical recovery rates (after 0 and 72 hours) in all analysed test solutions were below the detection limit of 0.1 mg/L.

CONCLUSION — The test substance is not toxic to algae up to the limit of its water solubility.

TEST FACILITY — BASF (1998k)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Up to 200 kg of the notified chemical may be placed into landfill each year with waste resulting from formulation and manufacture of polymer masterbatches as well as from the manufacture of end use plastic articles. At the end of their useful lives the plastic articles containing the notified chemical would also be placed into landfill. If some articles are incinerated the notified chemical will be destroyed with production of water vapour and oxides of carbon and nitrogen.

Once incorporated into polymer articles the chemical is bound into the polymer matrix with little potential for release during the useful life of the articles. However, once placed in landfill, the polymer matrix is expected to slowly degrade and break down due to slow abiotic and biological processes. If the notified chemical is released during this process it is expected to be immobile in soil. Although not ready biodegradable, it is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified chemical to water and oxides of carbon and nitrogen.

While the low water solubility and high partition coefficient indicate a high potential for bioaccumulation, the notified chemical is not expected to cross biological membranes and bioaccumulate due to its high molecular weight. This is supported by the experimental BCF of 31.0, indicating a low potential to bioaccumulate.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below.

Organism	*End Point*	*mg/L*
Fish (*Brachydanio rerio*)	LC50	>245*
Fish (*Cyprinus carpio*)	LC50	>1000
Daphnia	EC50	>100
Green algae	E_bC50	>100
	E_rC50	>100

* Based on measured concentrations.

A predicted no effect concentration (PNEC - aquatic ecosystems) of >1mg/L (1000 µg/L) has been derived by dividing the lowest end point value of >100 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels).

9.1.3. Environment – risk characterisation

Almost all of the chemical imported will eventually be disposed of to landfill including wastes from the masterbatch and plastics manufacturing processes, residues in empty containers and the injection moulded and extruded articles at the end of their useful lives. In landfill, the notified chemical can be expected to be immobile and eventually degrade to give water vapour and oxides of carbon and nitrogen.

The use pattern of the notified polymer will result in limited exposure to the aquatic environment, and hence a PEC value could not be determined. However, the available ecotoxicity information indicates that the chemical is not toxic to aquatic organism at any trophic level (up to the limit of its water solubility).

Due to the limited release to water, it is unlikely that the chemical would exist at levels which could accumulate and pose a threat to aquatic organisms or to bioaccumulate. Based on the proposed use pattern, the release of the notified chemical to the environment is expected to be very low. Abiotic or slow biotic processes are expected to be largely responsible for the eventual degradation of the notified chemical as it is not readily biodegradable. The notified chemical is not expected to present a risk to the environment when used as a UV absorber for plastic products.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During transport and storage, workers are unlikely to be exposed to the notified chemical. In the event of an accident, spills will be removed in accord with the MSDS and government regulations.

Inhalation, dermal and ocular exposure will potentially occur during weighing and mixing procedures, prior to incorporation of the notified chemical in a polymer matrix, due to spillages. However, exposure to significant amounts of the notified chemical is limited because of the engineering controls and personal protective equipment worn by workers. Employers are responsible for maintaining the level of atmospheric nuisance dust below the NOHSC exposure standard of 10 mg/m^3 TWA (NOHSC, 1995). Following incorporation of the notified chemical in masterbatches or articles, it is encapsulated in a polymer matrix where the bioavailability will be low and therefore negligible exposure is expected. Personal protective equipment (impervious gloves, dust/vapour respirators, safety glasses and protective clothing) is also required for protection of workers against hot processes.

9.2.2. Public health – exposure assessment

Although the notified chemical can be used as a UV absorber for paints, the notifier has no intention of offering it to the paint industry. It is intended for use in the plastic manufacturing industry only. It will not be sold to the public except in the form of finished articles, which is inert, chemically stable and unlikely to be bioavailable. The public exposure is therefore determined to be low.

9.2.3. Human health - effects assessment

The notified chemical has a low acute oral and dermal toxicity in rats (LD50>2000 mg/kg/bw). It is slightly irritating to the skin and eyes of the rabbit. It shows no sensitising activity at 10% solution in an adjuvant study in guinea pigs. The NOAEL was established to be 15000 ppm (equivalent to 1304 and 1405 mg/kg bw in males and females, respectively) in a 28-day repeat dose oral study in rats. Reduction in adrenal weights of the high dose males (15000 ppm) was considered unrelated to treatment. The notified chemical was not mutagenic in a bacterial reverse mutation assay, and did not reveal any genotoxic potential in vitro.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002). However, the MSDS indicates that dust and/or mist generated from processing of the notified chemical may cause mechanical irritation to the eyes and respiratory tract if inhaled. Repeated or prolonged skin contact with the chemical may result in mild irritation.

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low, given the low hazard of the chemical, the automated process and engineering controls, the good work practices and safety measures including use of appropriate personal protective equipment by workers.

The notified chemical may be present in formulations containing hazardous ingredients. If these formulations 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.

9.2.5. Public health – risk characterisation

Members of the public may make dermal contact with plastics articles containing the notified chemical. However, the risk to public health will be negligible because the notified polymer is bound within a matrix, resistant to degradation and unlikely to be bioavailable.

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 a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

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 in the proposed manner.

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

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to dust and mist of the notified chemical:
  - Enclosed and automated processes at the mixing and moulding/extrusion sites, including enclosed and automatic transfer lines/pumps for loading and emptying of the mixing and cooling vessels;
  - Adequate local exhaust ventilation for the plant operators.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to dust and mist of the notified chemical:
  - Safety glasses;
  - Industrial standard protective clothing and gloves;
  - Dust masks or appropriate respirators if high levels of dust are present.

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

- Occupational exposure to dust or decomposition products during formulation and extruding articles made from the notified chemical should be maintained below the NOHSC and ACGIH Exposure Standards (10 mg/m^3 TWA for nuisance dust and 3 mg/m^3 for respirable dust, respectively).

- 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.

Disposal

- The notified chemical waste and contaminated packaging should be disposed of to an approved waste disposal facility in accordance with official regulations. Treatment options include incineration or secured landfill disposal.

- Uncontaminated packaging may be reused.

Emergency procedures

- Spills/release of the notified chemical should be prevented from entering drains, surface and ground water, or contaminating firefighting water.

- Small spills should be picked up with suitable appliances while large spills contained with dust binding material prior to disposal in accordance with official regulations.

12.1. Secondary notification

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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