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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Dynasylan 9116

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Plastral Pty Ltd. (ABN 68 000 144 132)
11b Lachlan St.
Waterloo NSW 2017

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
- CAS Number
- Molecular Formula
- Structural Formula
- Molecular Weight
- Import Amounts
- Composition Including Purities, Impurities and By product
- Identity of Sites
- Used Details

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

- Hydrolysis
- Dissociation constant
- Absorption/Desorption
- Octanol-Water partition coefficient
- Flammability
- Autoignition temperature
- Explosive properties
- Reactivity
- Acute inhalation toxicity test
- Acute dermal toxicity test
- Subacute toxicity test
- Ames-test
- Biodegradation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, Canada, Korea, China, EU, Philippines.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Hexadecyltrimethoxysilane
n-Hexadecyltrimethoxysilane
AY 43-216MC

Dynasylan 9116
Si 116
Silane 116
Silane Si 116

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 be imported as a component (1-5%) of a polyethylene plastic compound (pellet form) in 500 kg or 1000 kg cardboards.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	30-100	30-100	30-100	30-100	30-100

USE
The notified chemical will be used as an additive for polyethylene to make plastic articles.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Imported polymer compound containing the notified chemical will be received by the notifier and stored at third party warehouse(s) in Victoria.

TRANSPORTATION AND PACKAGING
Imported polymer compound containing the notified chemical will be imported in 500 kg or 1000 kg plastic lined and sealed cardboard (also called "Octabins") which will be transported from wharf by road and stored at a site in VIC before they are distributed to manufacturers in Australia. Local distribution will be by road.

5.2. Operation description

Reformulation/manufacturing
The plastic compound containing the notified chemical will be imported in a form suitable for the direct feeding into an automated extrusion line. No repackaging of the imported product will be carried out in Australia.

The polymer compound containing the notified chemical will be automatically fed into an enclosed extrusion machine and be extruded to form plastic article. The newly formed article will then be subjected to a humid environment which will cause the notified chemical to permanently and irreversibly bond to the polymer substrate. All manufacturing operations will be performed in an enclosed and automatic system.

End use
Articles made from the polymer will find use in a variety of both industrial and domestic purposes.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Waterside and Transport	10	1-2	10
Warehouse	3	2	24
Manufacturing	2	1	365

Exposure Details

Waterside, transport and warehouse workers will not open imported containers of the polymer compound containing the notified chemical. The possibility of exposure to the notified chemical on breaching the containers is minimal as the notified chemical has a very low vapour pressure and is encapsulated in the polymer compound. Workers will routinely wear protective overalls and safety footwear.

Worker exposure during manufacturing is unlikely as the polymer compound containing the notified chemical will be automatically fed into an enclosed extrusion machine. All manufacturing operations will be performed in an enclosed and automatic system. The possibility of worker exposure to the notified chemical on spilling of imported polymer compound containing the notified chemical is minimal as the notified chemical has a very low vapour pressure and is encapsulated in the polymer compound. In addition, personal protective equipment will be routinely used and will include safety glasses, gloves, protective coveralls and safety footwear.

No worker exposure is possible during end uses as the notified chemical is totally transformed and permanently bonded to the polymer carrier during the manufacturing process.

5.4. Release

RELEASE OF CHEMICAL AT SITE

A polymer in pellet form encapsulates the notified chemical which is automatically fed into an enclosed extrusion machine and is extruded to form plastic articles. The chemical will undergo hydrolysis when exposed to humid conditions to permanently bond to the polymer compound. In the event of spills it would be expected that the chemical be reused to the extent practicable. The pellets containing the notified chemical are expected to be easily physically removed from the packaging. Residue in packaging is expected to be approximately 20 g per 500 kg “octabin” resulting in a wastage rate of 0.004%. Therefore, up to 4 kg will be disposed per annum.

RELEASE OF CHEMICAL FROM USE

The notified chemical is totally transformed and permanently bonded to the polymer carrier during the manufacturing process. No release to the environment is possible.

5.5. Disposal

Residues from empty containers will be disposed to landfill.

5.6. Public exposure

No public exposure is possible during use of plastic articles for industrial and domestic use as the notified chemical is totally transformed and permanently bonded to the polymer carrier during the manufacturing process.

The public may be exposed to the notified chemical in the unlikely event of an accident during transportation of the polymer compound containing the notified chemical.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Colourless liquid

Melting Point/Freezing Point 1.4 ºC

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Using differential scanning calorimetry (DSC)
TEST FACILITY Infracor GmbH (2003a)

Boiling Point 350°C at 100.5 kPa

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Using differential scanning calorimetry (DSC)
TEST FACILITY Infracor GmbH (2003b)

Density 890 kg/m^3 at 20ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
TEST FACILITY Infracor GmbH (2003c)

Vapour Pressure 0.133 kPa at 25ºC

METHOD MPBPWIN Program, Version 1.40
U.S. Environmental Protection Agency, 2000
TEST FACILITY Degussa (2003)

Water Solubility Not applicable

Remarks It is reactive and unstable in water.

Hydrolysis as a Function of pH Not applicable

Remarks Hydrolyses in water, with spontaneous hydrolysis at any pH other than 7.

Partition Coefficient (n-octanol/water) Not applicable

Remarks Spontaneous hydrolysis of the notified chemical does not allow measurement of O/W partition coefficient.

Adsorption/Desorption Not applicable

Remarks The notified chemical will undergo hydrolysis upon contact with moisture or water to release methanol and reactive silanols. The silanols will irreversibly become chemically bonded to siliceous and other oxides in soils. It is expected that the adsorption to soil will be near 100%.

Dissociation Constant Not applicable

Remarks The notified chemical does not contain functional groups which are likely to dissociate. Spontaneous hydrolysis of the notified chemical does not allow measurement of dissociation constants in water.

Flash Point 165 °C

METHOD DIN 51758
TEST FACILITY Degussa , Germany (no test report was provided)

Flammability Limits Not determined

Remarks The notified chemical is classified as a combustible liquid. However, the product is not expected to reach a temperature high enough to form combustible vapours in

air.

Autoignition Temperature Not determined, but estimated to be > 165 °C

Remarks No test data is available.

Explosive Properties Not determined

Remarks The notified chemical has no potential to detonate as a result of heat, shock or friction.

Reactivity Not determined

Remarks The notified chemical has no oxidising properties. It will undergo hydrolysis in the presence of water, and methanol is a product of this reaction (this will not occur with the imported product).

ADDITIONAL TESTS

Viscosity 7 mPas at 20°C

METHOD DIN 53015
Remarks The test report is not available.

7. TOXICOLOGICAL INVESTIGATIONS

The notified chemical produces methanol after hydrolysis. Some of the toxicity studies were conducted using analogous chemicals that are considered to be acceptable analogues of the notified chemical:

Analogue chemical 1 – Silane, trimethoxy- : this substance is similar to the notified chemical in that it has three methoxy groups on one of its constituent silanes. The end alkl group is replace by a hydrogen atom. This analogue is significantly more volatile. It is claimed that because of the higher volatility, this chemical would have more adverse toxicity and can be considered as the worse case effect.

Analogue chemical 2 - Silane, octyltrimethoxy-: this substance is similar to the notified chemical. The only difference is that the alkyl group is C5 instead of C3.

The two analogues are considered suitable for this assessment.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral (LD_{50} >5002mg/kg bw)	Low toxicity
Rat, acute dermal	Moderately to severely irritating to the skin
Rat, acute inhalation	Not performed
Rabbit, skin irritation	Moderately irritating
Rabbit, eye irritation	Slightly irritating
Guinea pig, skin sensitisation - adjuvant test	No evidence of sensitisation
Rat, inhalation repeat dose toxicity - 28 days	NOAEL not established
Genotoxicity - bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro chromosomal aberration	Non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.
- Species/Strain: Rat/ Bor: WISW (SPFCpb)
- Vehicle: None, undiluted test substance

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5002	None

- LD50: >5002 mg/kg bw
- Signs of Toxicity: None
- Effects in Organs: None

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

TEST FACILITY ASTA Pharma AG (1989a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Analogue chemical 1 (Silane, trimethoxy-)

METHOD No Test Guidelines was indicated.
- Species/Strain: Rabbit/New Zealand White
- Vehicle: None, untitled test substance
- Type of dressing: Occlusive
- Exposure period: 24 h

Remarks – Method	The study was conducted to evaluate nephrotoxic potential. Ttest substance was applied to the clipped and intact skin of the trunk. Doses used 4 and 12 mL/kg. Observations for skin reactions were made at 1h, 7 days and 14 days after removal of patches. Body weights were recorded before dosing, 7 days and 14 days after dosing. At death or sacrifice, each animal was subjected to gross pathologic evaluation. Only the kidneys and urinary bladders were evaluated microscopically. No individual observations for skin reactions and body weight were provided in the study report.

RESULTS

Group	*Number and Sex of Animals*	*Dose*	*Mortality*
1	4 females	12 mL/kg	4/4
2	4 females	4 mL/kg	1/4

Signs of Toxicity - Local	Cutaneus effects at both doses - erythema, edema, necrosis, ecchymoses, fissuring, desquamtion, alopecia and scabs. In addition, the dosed area of each rabbit had a leather-like texture.
Signs of Toxicity - Systemic	Sluggishness, prostration, discharge around nose at both doses.
Effects on kidneys and urinary bladder	Necropsy of rabbits that died revealed dark red lungs, pale tan lungs with dark red areas (in 1 animal), gas-filled intestines (in 1) and a trace amount of blood in the urine (in 1). Necropsy of rabbits that survived revealed maroon and dark red lungs (in 1) and dark red kidneys (in 1). The only microscopical lesions observed in the kidneys were moderate focal tubular dilation in one animal at 12 mL/kg and minimal multifocal mineralization in I animal at 4 mL/kg.
CONCLUSION	The test substance was moderately to severely irritating to the skin.
TEST FACILITY	Bushy Run Research Centre, (1991)

7.3. Acute toxicity – inhalation

TEST SUBSTANCE	Not performed

7.4a. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/White Russian (Albino)
Number of Animals	3 males
Vehicle	None
Exposure Period	4 h
Observation Period	10 days
Type of Dressing	Occlusive patch

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	3	2	3	4	9 days	0
Oedema	2	2	3	4	9 days	0

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

Remarks – Results

Well defined erythema, slight to severe edema; also observed escharosis and formation of skin scales. The Primary Irritation Index is 3.6. Systemic toxic effects did not occur after exposure. The general condition of the test animals was not affected.

CONCLUSION

The notified chemical is moderately irritating to the skin.

TEST FACILITY

ASTA Pharma AG (1989b)

7.4b. Irritation – skin

TEST SUBSTANCE

Analogue chemical 1 (Silane, trimethoxy-)

METHOD

No Test Guidelines was indicated.

Species/Strain: Rabbit/New Zealand White

Number of Animals: 6 (3 males and 3 females)

Vehicle: Water

Observation Period: 14 days

Type of Dressing: Occlusive

Remarks – Method: 0.5 mL test substance was applied to the clipped and intact skin under a gauze patch and was loosely covered with impervious sheeting. The exposure duration is inconsistent in the study report provided – it states 4 hours in the test procedures, but is 1 hour and 3 minutes in the Result tables. Skin reactions were scored by the method of Draize at 1 hour, 2, 3, 7, 10 and 14 days after dosing.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
1 hour exposure				
Erythema/Eschar	1.9	2.0	7 days	0
Oedema	2.1	2.2	7 days	0
3 min. exposure				
Erythema/Eschar	1.6	1.8	7 days	0
Oedema	1.7	2.0	3 days	0

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

Remarks – Results

Skin reactions after 1 hour exposure:

Moderate erythema and oedema were observed in all animals up to 72 hours after exposure, with 3 animals showing slight erythema and oedema on day 7. All erythema and oedema were clear by day 10.

Other effects were also observed including ecchymoses, narcosis, ulceration, fissuring, desquamation, alopecia, scabs, and sloughing of skin from dose site, most of which occurred from day 3.

Skin reactions after 3 minutes exposure:

Erythema and oedema were observed in all animals that are similar to the 1 hour exposure but slightly minor in severity. Fissuring, desquamation, and alopecia were observed from day 3.

CONCLUSION: No conclusions were made by the study author(s). Based on the description of the test result, the test substance is considered moderately irritating.

TEST FACILITY: Bushy Run Research Centre, (1991)

7.5. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain: Rabbit/White Russian (Albino)
Number of Animals: 3 (2 males, 1 female)
Observation Period: 6 days

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	0.7	1	1	4 days	0
Conjunctiva: chemosis	1	1	1.3	2	4 days	0
Conjunctiva: discharge	0.3	0	0.3	1	1 day	0
Corneal opacity	0	0	0	0		0
Iridial inflammation	0	0	0	0		0

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

REMARKS: The primary irritation index was 6. Hyperemia, crimson discoloration, and slight swelling with partial eversion of the lids was observed.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: ASTA Pharma AG (1989c)

7.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 406 Skin Sensitisation – Buehler Test.
EC Directive 96/54/EC B.6 Skin Sensitisation – Buehler Test.
Species/Strain: Guinea pig/Dunkin-Harley, females
PRELIMINARY STUDY: Maximum Non-irritating Concentration:
topical: 20% test substance in corn oil
MAIN STUDY
Number of Animals: Test Group: 20 Control Group: 10
INDUCTION PHASE: Induction Concentration:
topical application 50% test substance in corn oil
Signs of Irritation: A slight to moderate erythema was observed in test group animals at the first induction following 6 hours topical exposure to the test substance at 50% concentration. A slight erythema was noted in 2 of 20 test animals following the second induction. No reaction was observed in any animals following the third induction.

CHALLENGE PHASE

1st challenge	Topical application: 20% test substance in corn oil.
Remarks – Method	Body weight was observed at Day 1 and termination of the study.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	20% test substance in corn oil	0	0	NA	NA
Control Group	corn oil	0	0	NA	NA

Remarks – Results	Body weight changes were similar between the treated and control groups.
CONCLUSION	No evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	RTC Research Toxicology Centre (2004)

7.7. Repeat dose toxicity - inhalation

TEST SUBSTANCE	Analogue chemical 1 (Silane, trimethoxy-)
METHOD	No test guidelines were indicated. In accordance with GLP regulations
Species/Strain	Rats/Sprague-Dawby (Albino)
Route of Administration	Inhalation – whole body
Exposure Information	Total exposure days: 20 days Dose regimen: 5 days per week for 4 weeks Duration of exposure (inhalation): 7 hours/day Post-exposure observation period: No
Physical Form	Vapour
Remarks – Method	All groups of animals were treated concurrently except for group IV (high dose) due to high mortality rate occurred in this group.

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration ppm*		*Mortality*
		Nominal	*Actual*	
I (control)	10 male/10 female	0		0
II (low dose)	10 male/10 female	0.5 ppm		0
III (mid dose)	10 male/10 female	5 ppm		4 male/ 4 female
IV (high dose)	10 male/10 female	10 ppm		10 male/10 female

Mortality:
Four of 10 rats of each sex of the mid dose group and all animals of the high dose group were found dead or sacrificed in a moribund condition during the course of treatment.

Clinical observations:
Clinical symptoms in the mid and high dose groups consisted primarily of lung congestion during the first week of treatment with nose discharge and a general weakness developing during week 2, leading to eventual death. No abnormalities were observed in the low dose group.

Significant dose dependent reduction in body weights of treated male and female rats. The magnitude of this reduction was greatest in the high dose group, less in the intermediate dose group and only marginally different from the controls in the low dose males. Bodyweight did not differ from the control group for females in the low dose group.

Significant dose-dependent reduction in absolute food consumption of treated male and female rats. The magnitude of this reduction was greatest in the high dose group, less in the intermediate dose group and only marginally different from the controls in the low dose group.

Haematology:
A decreased leucocyte count was observed in females of the low dose group. In mid and high dose animals a dose dependent increase in erythrocyte count, haemoglobin, and haematocrit was accompanied by a dose dependent decrease in leucocyte count and the proportion of lymphocytes and an increase in the proportion of segmented neutrophils.

Blood Chemistry
There was no effect on blood chemistry parameters in treated animals of the low and mid dose group compared to the control group. Abnormal blood chemistry parameters were observed in surviving animals of the high dose group.

Urinalysis
There was no effect on the urinary parameters in treated animals of the low and mid dose group compared to the control group. High mortality in the high dose group precluded analysis.

Morphological findings:
Gross Pathology
All animals had diffuse congestion of the lung and focal reddening in the gastrointestinal tract however, the incidence and severity was greater in treated animals. Findings in mid and high dose animals included areas of atelectasis and focal reddening in the lung and a failure of the lung to collapse when removed from the thoracic cavity.

Organ Weight
Increased lung weight in males of the mid and high dose groups.

Histopathology
High dose animals had pulmonary lesions consisting of bronchitis and bronchiolitis in the large and medium sized bronchii as well as smaller bronchioles. This was accompanied by, in severe cases, complete desquamation of the bronchial epithelium with replacement by mixed inflammatory cells and obliteration of the bronchial lumina with a mucopurulent exudate. Mucous metaplasia of the bronchial epithelium was revealed in several cases and this change extended sometimes to the submucosal glands.
No treatment related findings were observed in low dose group animals.
Examination of bone marrow smears revealed in high dose animals marked change with general reversal of the myeloid-erythroid ratio (which correlated with the changes in erythocyte and leucocyte counts found in the peripheral circulation), hypocellularity and general changes associated with moribund condition of the animals. Abundant megakaryocytes were noted in low dose animals.
Histopathological evaluation was not conducted on mid dose animals.

CONCLUSION
Inhalation of trimethoxysilane over 4 weeks resulted in chronic inflammatory changes to the lung, dose related changes in haematological indices and morphological changes to the bone marrow in treated rats. Changes in leucocyte counts were seen in females at the lowest dose tested a No Observed Adverse Effect Level (NOAEL) cannot be determined for this study. A No Observed Adverse Effect Level (NOAEL) was not established

TEST FACILITY Bio Research Laboratories LTD. (1980)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Analogue chemical 2 (Silane, octyltrimethoxy-)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	S 9 liver microsome fraction
Concentration Range in Main Test	a) With metabolic activation: 33.3 to 5000µg/plate. b) Without metabolic activation: 33.3 to 5000µg/plate.
Vehicle	Ethanol

RESULTS

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

CONCLUSION	The test substance is not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Anawa BIOSERVICE Scientific Laboratories GmbH (1996).

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.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	Ovary cells
Metabolic Activation System	S 9 liver microsome fraction
Vehicle	Ethanol

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Present			
Test 1	325 to 1300*	3 hours	20 hours
Test 2	Not conducted[#]		
Absent			
Test 1	325 to 1300*	3 hours	20 hours
Test 2	10.2 to 40.6*	20 hours	20 hours

*Cultures selected for metaphase analysis. [#] Due to negative results obtained in Test 1.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	NA	1300, 650	1300, 650	Negative
Test 2	NA	NA	NA	NA
Absent				
Test 1	NA	1300	-	Negative
Test 2	NA	10.2 - 1300	-	Negative

NA, not applicable.

CONCLUSION The notified chemical was not clastogenic to Chinese hamster ovary cells treated in vitro under the conditions of the test.

TEST FACILITY RTC Research Toxicology Centre (2005)

8. ENVIRONMENT

8.1. Environmental fate

The ready biodegradability was conducted using an analogous chemical that is considered to be acceptable analogue of the notified chemical. It is n-Hexadecyltriethoxysilano (Analogue Chemical 3).

8.1.1. Ready biodegradability

TEST SUBSTANCE Analogue chemical 3 (n-Hexadecyltriethoxysilano)

METHOD Method for Testing Biodegradability of Chemical Substances by micro-organisms stipulated in the "Testing Methods for New Chemical Substances (13 July 1974, Kangpogyo No.5 Planning and Coordination Bureau, Environment Agency, Yakuhatu No. 615, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare and 49 Kikyoku No. 392, Basic Industries Bureau, Ministry of International Trade and Industry, Japan. The test method is similar to OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).

Inoculum	Activated Sludge prepared from ten sites: Fukogawa city sewage plant, Fukashiba industry sewage plant, Nakahama city sewage plant, Ochiai city sewage plant, Kitakami river, Shinano river, Yoshino river, Lake Biwa, Hiroshima bay, Dookai bay.
Exposure Period	28 Days
Auxiliary Solvent	None specified
Analytical Monitoring	Biochemical Oxygen Demand (BOD), HPLC for test substance and GC for ethanol as a decomposition product.
Remarks - Method	The inoculum comprised of old and fresh activated sludge. Triplicate analysis was performed on 30 mg of test substance added to 300 mL of 100 mg/L activated sludge (vessels 1- 3). A control was run with 300 mL of purified water and no activated sludge (vessel 6). A control blank was run containing 300 mL of inoculum but no test substance or reference substance (vessel 5). A reference was also run using 30 mg (29.5 µL) of aniline (Vessel 4). Temperature 25 ± 1 °C

RESULTS

Biodegradation of test substance and reference substance as determined by BOD and HPLC

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
28	43 (BOD)	28	70
28	74 (HPLC)	28	79

Biodegradation of test substance as determined by BOD

Test	Day 7		Day 14		Day 21		Day 28	
	BOD (mg)	% Deg	BOD (mg)	% Deg	BOD (mg)	% Deg	BOD (mg)	% Deg
Vessel 1	2.5	0	13.9	12	35.5	36	50.8	53
Vessel 2	1.9	0	17.4	16	39.8	41	46.1	47
Vessel 3	1.8	0	4.6	1	10.2	5	30.5	29
Vessel 4	65.7	70	75.8	79	77.4	79	78.4	79
Vessel 5	2.3	-	4.1	-	5.8	-	6.9	-
Vessel 6	0.0	-	0.0	-	0.0	-	0.0	-

Deg = degradation

Biodegradation of expected intermediate silanol compound

Test	BOD – B (mg)	Sw – Ss (mg)	Ethanol Amount Theor. (mg)	TOD Ethanol (mg)	Silanol Amount Theor. (mg)	TOD Silanol (mg)	(BOD- B) Less TOD Ethanol (mg)	% Biodeg silanol
Vessel 1	43.9	27.2	9.7	20.2	21.3	54.7	23.7	43
Vessel 2	39.2	24.1	8.6	17.9	18.9	48.6	21.3	44
Vessel 3	23.6	13.4	4.8	10.0	10.5	27.0	13.6	50

The BOD of vessel 5 = B
The residual amount of vessel 5 less the residual of the average of the amounts of vessels 1- 3 = S_w - S_s
Biodeg = biodegradation;
Theor = Theoretical amount if all notified chemical underwent hydrolysis.
TOD = Theoretical Oxygen Demand when the test substance is completely oxidised.

Remarks - Results	The test substance is likely to be degraded in a two-step process. Firstly to ethanol and silanol. The ethanol is expected to be rapidly biodegraded, with the silanol undergoing slow degradation. The average degradation of the silanol is estimated as 46% after 28 days. The test substance in water only, as analysed by HPLC, showed that 98% of the test substance remained after 28 days. No ethanol was present in the GC analysis. The test substance was not dissolved at the initiation of the culturing and was white and cloudy at the termination of the culturing.
CONCLUSION	The test substance is not considered readily biodegradable, although the HPLC analysis demonstrates that the analogue degrades to intermediates likely to be ethanol and silanol.
TEST FACILITY	Karume Research Laboratories (1994)

8.1.2. Bioaccumulation

Not Tested. The notified chemical is unlikely to bioaccumulate as it hydrolyses rapidly in humid conditions and will permanently bond to mineral substances, rendering it biologically unavailable.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test Limit Test semi-static.
Species	Brachiodanio rerio
Exposure Period	96 hours
Auxiliary Solvent	Nil
Water Hardness	210 mg $CaCO_3$/L
Analytical Monitoring	Observations for mortality and abnormal behaviour at 24, 48, 72 and 96 hours.
Remarks – Method	A range finding test was conducted using four replicates of ten fish subjected to nominal concentration of 1000 mg/L prepared as Water Available Fraction (WAF) of test substance. Four control tests were also run. Temperature 25 ± 1°C. pH 7.6 – 8.0 Dissolved Oxygen mg/L 6.1 – 8.1

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0		40	0	0	0	0
1000		40	0	0	0	0

LC50	> 1000 mg/L at 24 hours. > 1000 mg/L at 48 hours. > 1000 mg/L at 72 hours. > 1000 mg/L at 96 hours.
NOEC (or LOEC)	= 1000 mg/L at 96 hours.
Remarks – Results	No sign of harm to any fish. Oil like substance was seen on the surface of the test solutions. Not toxic to limits of test substance's solubility.
CONCLUSION	The notified chemical is practically non- toxic to fish.
TEST FACILITY	TNO (1990a)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static
Species	*Daphnia magna*
Exposure Period	24 hours
Auxiliary Solvent	Nil
Water Hardness	210 mg $CaCO_3$/L
Analytical Monitoring	Observations for mortality and abnormal behaviour at 24 and 48 hours.
Remarks - Method	A solution of 1000 mg/L of test substance was prepared by vigorously stirring for 24 hours. WAFs were drawn off after 24 hours and 48 hours of settling. Four replicates of 5 daphnia were subjected to WAF of nominal concentration of 1000 mg/L of test substance drawn at 24 and 48 hours. Controls were also run. Temperature 25 ± 1°C. pH 7.8 – 8.0

Dissolved Oxygen mg/L 7.7 – 8.8

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*
Nominal	*Settling Time hours*		*24 h*
0	-	20	0
1000	24	20	0
0	-	20	0
1000	48	20	0

LC50 > 1000 mg/L at 24 hours

Remarks - Results Although a surface layer of the test substance was not visible to the naked eye, the observations of the daphnia in the WAF prepared after 24 hours indicated that a surface layer was present. The daphnia in the WAF prepared at 24 hours swam on the surface and were slower and paler than the control. No adverse effects were shown to the daphnia in the WAF prepared at 48 hours. Not toxic to limits of test substance's solubility.

CONCLUSION The notified chemical is practically non- toxic to daphnia.

TEST FACILITY TNO (1990b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified Chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
Species Scenedesmus subspicatus
Exposure Period 96 hours
Concentration Range Nominal: 0.01 – 31.8 mg/L (methanol)
Nominal: 0.009 – 29.5 mg/L (tertiary butanol)
Auxiliary Solvent Methanol; tertiary butanol (TBA)
Water Hardness Not determined
Analytical Monitoring Microscopic examination of cells/ electronic particle counting.
Remarks - Method A range finding test was conducted by subjecting an algae test medium containing approximately 10^4 cells per mL to 0.0007, 0.007, 0.07, 0.60 and 8.0 mg/L of test substance using tertiary butanol as auxiliary solvent. Two preliminary inhibition tests were conducted by subjecting an algae test medium containing approximately 10^4 cells per mL to 0.003, 0.010, 0.032, 0.056, 0.10, 0.32, and 1.0; and 0.0032, 0.010, 0.032, 0.10, 0.32, 1.0, 3.2 and 10 mg/L of test substance using tertiary butanol as auxiliary solvent. Duplicate controls were run using algae and solvent only. A test substance without algae was run to determine the background count for the electronic particle count. The morphology of the algae was examined microscopically. The preliminary test showed that inhibiting effects could be expected at concentrations above 0.007 mg/L.
A test was conducted by subjecting duplicate algae test media containing approximately 10^4 cells per mL 0.01, 0.03, 0.10, 0.32, 1.0, 3.2, 10 and 32 mg/L using methanol and tertiary butanol as auxiliary solvent. A further test was conducted by subjecting duplicate algae test media containing approximately 10^4 cells per mL 0.009, 0.029, 0.094, 0.29, 0.94, 2.9, 9.4 and 29.5 mg/L using tertiary butanol as auxiliary solvent. A test substance without algae was run to determine the background count for the electronic particle count. The morphology of the algae was examined microscopically.

Temperature 23 ± 1°C.

Light intensity 60 – 120 µmol/sec/m^2

RESULTS

Preliminary Test

Biomass EbC50 (mg/L at 96 h)	*Growth ErC90 (mg/L at 96 h)*
> 10	> 10

Inhibition Test Using Methanol and TBA as Auxiliary Solvents.

Biomass EbC50 mg/L at 96 h	*Growth ErC50 mg/L at 96 h*
> 31.8 (methanol) > 29.5 (TBA)	> 31.8 (methanol) > 29.5 (TBA)

Remarks - Results	No abnormalities were noted. 31.8 and 29.5 mg/L were the highest tested concentrations using methanol and TBA, respectively.
CONCLUSION	The notified chemical is slightly to practically non- toxic to algae.
TEST FACILITY	TNO (1992)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is encapsulated in a polymer matrix. During use to form plastic articles it is reacted to irreversibly bond to the polymer compound. No release of the notified chemical to the environment is expected from this route.

It is expected that up to 4 kg of the notified chemical will be disposed to landfill from packaging residue. The chemical is encapsulated in a polymer matrix. It is expected that the polymer matrix will eventually undergo in-situ degradation. When the notified chemical is exposed to the atmosphere it is likely to react and irreversibly bond with the polymer matrix. No release to the aquatic environment is expected from this route.

9.1.2. Environment – effects assessment

No toxic effects up to the limits of solubility of the notified chemical in tests to fish and daphnia were shown. It is expected that the chemical underwent hydrolysis followed by condensation to form an insoluble oil layer, with methanol as the by-product. Methanol is practically non – toxic to aquatic organisms. Auxiliary solvents were used to dissolve the notified chemical for the algae test. No toxic effects were shown to algae to the highest concentration tested. The following is a summary of the ecotoxicity results.

Organism	Duration (hour)	End Point	Toxicity (mg/L)
Fish	96	LC50	>1000
Daphnia	24	LC50	>1000
Algae (methanol)	96	EbC50 & ErC50	>31.8
Algae (TBA)	96	EbC50 & ErC50	>29.5

No end point was established so a PNEC cannot be calculated. However it will be above 295 µg/L.

9.1.3. Environment – risk characterisation

There is unlikely to be any release of the chemical to the aquatic environment. Although an exact Predicted Environmental Concentration (PEC) cannot be calculated from the use pattern and the reactivity of the chemical with water, the PEC will be effectively zero. In addition, the notified chemical showed no toxicity to aquatic organisms to extent tested. Therefore, the notified chemical is not expected to pose an unacceptable risk to the environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported as a component (1-5%) of a polyethylene plastic compound. During transport and storage, the possibility of exposure to the notified chemical on breaching the containers is minimal as the notified chemical has a very low vapour pressure and is encapsulated in the polymer compound.

Worker exposure during manufacturing is unlikely due to use of an enclosed and automatic system and the notified chemical will be imported in a form suitable for the direct feeding into an automated extrusion line. In addition, personal protective equipment will be routinely used to reduce exposure.

No worker exposure is possible during end uses as the notified chemical is totally transformed and permanently bonded to the polymer carrier during manufacturing.

9.2.2. Public health – exposure assessment

No public exposure is expected during use of plastic articles for industrial and domestic use as the notified chemical is totally transformed and permanently bonded to the polymer carrier during the manufacture of the articles. The public may be exposed to the notified chemical in the unlikely event of an accident during transportation of the polymer compound containing the notified chemical. However, the possibility is minimal due to very low vapour pressure and encapsulation of the notified chemical in the polymer compound.

9.2.3. Human health – effects assessment

Some of the toxicity studies provided were conducted using analogous chemicals that are considered to be acceptable analogues of the notified chemical.

The notified chemical is of low acute toxicity via oral exposure (LD50 > 5002 mg/kg/bw).

A number of signs of severe dermal irritation were seen in two skin irritation studies, one using the notified chemical and following OECD TG and one using an analogue chemical and not conducted with OECD TG. The signs of irritation persisted in all animals for more than 24 hours. Based on this evidence, the notified chemical is classified in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004) as:

R38 – irritating to skin

Eye irritation and skin sensitisation (Buehler Test) studies using the notified chemical and following OECD TG showed slight eye irritation and negative allergic reaction.

A 28-days repeated dose inhalation study was conducted using an analogue chemical resulted in chronic inflammatory changes to the lung, dose related changes in haematological indices and morphological changes to the bone marrow in treated rats. Changes in leucocyte counts were seen at the lowest dose tested (0.5 ppm) and no NOAEL can be determined for this study. It is not expected that the notified chemical will display effects more adverse than those observed with trimethoxysilane (analogue 1) in this repeat dose inhalation study. Further testing on the notified chemical would be required for a satisfactory assessment of effects from repeated exposure. Based on this study the notified chemical is likely to be irritating to respiratory system.:

R37 Irritating to respiratory system

There was no evidence of genotoxicity based on bacterial reverse mutation test (using an analogue chemical) and *in vitro* mammalian chromosome aberration test (using the notified chemical).

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical will be imported in pellet forms at 1-5%. Inhalation exposure is not likely as the notified chemical is incorporated into the plastic compound. Considering that manufacturing processes are enclosed and automated and that the notified chemical is contained in the polyethylene plastic compound at a maximum of 5%, the risk of adverse health effects is low. However, respiratory and skin protection is required if workers are likely to handle the product containing the notified chemical.

9.2.5. Public health – risk characterisation

Due to the negligible exposure expected and low health concern, the risk of adverse effects to the public is considered to be insignificant.

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 hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R37/38 – Irritating to respiratory system and skin

As a comparison only, the classification of 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
Irritant	2	Causes skin irritation

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is No Significant Concern to public health based on the reported use pattern.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was assessed in accordance with the

NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is (They are) 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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following hazard classification for the notified chemical:
  - R37/38 Irritating to respiratory system and skin
- The following risk phrases for products/mixtures containing the notified chemical apply:
  - ≥20% R37/38 Irritating to respiratory system and skin
- Products containing ≥20% notified chemical should carry the following warnings on the label:
  - S24 Avoid contact with skin
  - S25 Avoid contact with eyes
  - S36 Wear suitable protective clothing
  - S37 Wear suitable gloves

CONTROL MEASURES
Occupational Health and Safety

- 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 by authorised landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical collection for reuse of the spilled material to the extent practicable or disposal.

12.1. Secondary notification

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

(1) Under Section 64(2) of the Act:

– if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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