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# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

### **FULL PUBLIC REPORT**

#### **UVINUL 4050H**

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Director Chemicals Notification and Assessment

# **FULL PUBLIC REPORT**

# **UVINUL 4050 H**

#### 1. APPLICANT

BASF Australia Ltd of 500 Princes Highway NOBLE PARK VIC 3174 has submitted a standard/limited notification statement in support of their application for an assessment certificate for UVINUL 4050 H.

#### 2. IDENTITY OF THE CHEMICAL

UVINUL 4050 H is considered not to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, and customers have been exempted from publication in the Full Public Report and the Summary Report.

Other Names: Light Stabiliser 1736

Trade Name: UVINUL 4050 H

# 3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C

and 101.3 kPa:

fine white crystalline powder

Melting Point: 157.3 °C

Specific Gravity: 1 075 kg.m<sup>-3</sup>

**Vapour Pressure:** approximately 10<sup>-8</sup> Pa at 20<sup>o</sup>C

Water Solubility: 13 000 mg.L<sup>-1</sup> at pH 11 (see notes below)

**Partition Co-efficient** Log  $P_{ow}$  = -2 at pH 7 and 25 $^{0}$ C; (n-octanol/water): Log  $P_{ow}$  = 0.8 at pH 9 and 25 $^{0}$ C

Hydrolysis as a Function

of pH:

stable to hydrolytic degradation for 4.3<pH<9.3

(see notes below)

Adsorption/Desorption: not determined (see notes below)

**Dissociation Constant:** not determined (see notes below)

Flash Point: not determined

Flammability Limits: the chemical was found no flammability properties

**Autoignition Temperature:** the chemical did not ignite under the test condition

**Explosive Properties:** not determined (see notes below)

Reactivity/Stability: not determined (see notes below)

**Fat Solubility:** 62 mg per 100 g of standard fat at 37°C.

**Surface Tension:** 65.4 kN.m<sup>-1</sup> at 20<sup>o</sup>C for 1.0 g.L<sup>-1</sup> solution

# **Comments on Physico-Chemical Properties**

Tests were performed according to EEC/OECD test guidelines [Organisation for Economic Co-operation and Development, 1995-1996 #15] at facilities complying with OECD Principles of Good Laboratory Practice, and the relevant test reports were provided with the notification.

The water solubility at pH 11 is appreciable, but could be expected to be even higher under neutral and acid pH conditions when the secondary amino nitrogens in the piperidine rings would protonate giving the molecules a positive charge. This is supported by the oil/water partition coefficient measurements which are discussed below.

Results from a preliminary test on hydrolytic degradation indicated little tendency for hydrolytic decomposition under normal pH conditions, and t<sub>1/2</sub> greater than 560 days at 50°C for all tests conducted between pH 4.3 and 9.3.

The oil/water partition coefficient was determined at pH 7 and at pH 9. This parameter is larger at the higher pH due to partial deprotonation of the molecule (ie removal of positive charge) which will increase the solubility in non polar solvents.

No adsorption/desorption data were provided in the notification. However, the high water solubility and low oil/water partition coefficient indicate the compound will have little tendency to adsorb onto or become associated with organic material in soil or sediments.

The notified chemical contains amino groups which may protonate under normal environmental pH conditions. Although no dissociation data were provided, the pKa for alicyclic secondary amino groups is typically [Weast, 1985 #63] between 10.8 and 11.2. Consequently the material could be expected to be cationic under normal environmental conditions.

The notifier also provided data on fat solubility and surface tension. The modest fat

solubility is a reflection of the effect of the positive charge resulting from protonation of the secondary amine groups.

The material is not surface active, and a 1.0 g.L<sup>-1</sup> solution in water at 20°C had a measured surface tension of 65.4 kN.m<sup>-1</sup>, compared with that of water at 72.6 kN.m<sup>-1</sup>.

The molecular structure of the notified chemical does not indicate an explosion hazard. However, the risk of dust explosion exists as any other organic powders.

The notified chemical has no oxidising properties, and does not degrade or decompose under normal conditions. It is not considered reactive.

# 4. PURITY OF THE CHEMICAL

**Degree of Purity:** 99.8%

# Toxic or Hazardous Impurities:

Chemical name: formamide

Synonyms: methanamide

CAS No.: 75-12-7

Weight percentage: 0.05

Toxic properties: poison by skin contact, an irritant to eye, skin and

mucous membranes [Sax, 1989 #16]

**Non-hazardous Impurities** 

(> 1% by weight): nil

Additives/Adjuvants: nil

# **Comments on Chemical purity**

A gas chromatogram (GC) using ethanol as solvent established the purity of the material at greater than 99.5%, and a subsidiary GC analysis provided a residual formamide content of 0.05%.

The notifier states the material contains two impurities of unknown chemical identity at 0.04% and 0.05% respectively.

# 5. USE, VOLUME AND FORMULATION

Uvinul 4050 H is will be used as an ultra violet light stabiliser of thermoplastic polymers. The major application is to light stabilise fibres in the carpet manufacturing. The carpet is intended for use in automobiles and in commercial and domestic situations.

Uvinul 4050 H will not be manufactured in Australia, but will be imported either alone, or as a component of another solid product called Uvinul PA Batch ED 8800. Uvinul 4050 H will comprise 5% by weight in Uvinul PA Batch ED 8800.

In any case, total annual import quantities of the notified chemical will remain less than 800 kg for the first five years.

Uvinul 4050 H is a fine white crystalline powder and Uvinul PA Batch ED 8800 will be formulated as a granular solid.

#### 6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in two forms. The "neat" notified chemical is named Uvinul 4050 H. It is imported in 25 kg multi-layered kraft paper bags on a shrink wrapped pallet. Another form under the product name of Uvinul PA Batch ED 8800 contains 5% of the notified chemical. Uvinul PA Batch ED 8800 is in 25 kg multi-layered kraft paper and polyethylene bags. If Uvinul 4050 H is imported, it will be formulated into Uvinul PA Batch ED 8800 in Australia.

The vapour pressure for the notified chemical is very low. As the particle size of the powder is not provided, inhalation exposure would be possible. However, the main route of occupational exposure will be through dermal contact.

The transport and storage workers are unlikely to be exposure to the notified chemical except in the incident of spillage.

At the formulation site, the notified chemical will be blended dry with other ingredients in a sealed system, heated and extruded, aand then cooled and granulated. It is estimated that only a few workers will be involved in the formulation process. They could be exposed to the notified chemical during the process of weighting and adding it into the mix vessel.

The product Uvinul PA Batch 8800 containing 5% of the notified chemical will be sold as a "masterbatch" to carpet manufacturer. In the carpet manufacturing site, Uvinul PA Batch 8800 will be blended with more ingredients and extruded into nylon fibre for use in carpets. The notified substance will then constitute 0.25% of the nylon fibre. There are about less than 10 workers will handle the notified chemical in the production of nylon fibres for carpet manufacturing. They could be exposed to the notified chemical during mixing and application.

# 7. PUBLIC EXPOSURE

Following import by sea as part of a container lot of mixed chemical product, the notified chemical will be transported by road. Following import, the notified chemical is only available to industrial processors and not to the general public. In the event of an accident, the spill will be contained and the material will be disposed according to State legislation.

The notified chemical is used as a component of nylon fibres for manufacture of carpets which will be used for a number of applications to which the public will be exposed. However, due to the low toxicity of the notified chemical, its low potential for absorption across biological membranes and its fixation in a polymer matrix once extruded, use of carpets by the public and release of carpet material to the environment are not expected to present any significant public health hazard.

#### 8. ENVIRONMENTAL EXPOSURE

# Release

The notified material is a crystalline solid and some dust is likely to be released during the first blending operation during preliminary weighing and transport procedures. However, this is expected to be minimal, since the intended manufacturing premises are fitted with exhaust systems, and residual dust is collected and disposed of into landfill.

The blending and extrusion operations are performed in sealed equipment which precludes release of the contents.

Residual chemical left in packages is expected to be small (approximately 1 kg per year total) and will be deposited into landfill.

The MSDS gives adequate instructions for actions following a large spillage as a result of transport accidents etc, which involves sweeping up the chemical with a dust binding material followed by disposal into a landfill or incineration.

It is estimated that each year around 3.6 kg of the notified material would be released due to purging the extrusion equipment, and the purged material is also sent to landfill.

Following the blending and extrusion operations, the notified material is bound into a polyamide matrix and has little potential for release. Most of the extruded fibres will be woven into carpet and when encapsulated within the nylon fibres there is no likelihood for release of the chemical. Offcuts and trimmings of carpet would most likely be placed into landfill, as would most old carpet at the end of its useful life, and some slow release of the material resulting from breakdown of the carpet after long periods in landfill could be expected.

#### Fate

The chemical is appreciably soluble in water and so, unless encapsulated within a polymer matrix, could be expected to be mobile in a landfill situation, and may eventually contribute to the dissolved solids in the landfill leachate, and subsequently into the wider aquatic compartment.

However, the fate of most of the notified material will be that of the nylon carpet into which it has been incorporated, and this will be either incineration or deposition into landfill. In a landfill it is expected that very slow degradation of the nylon would take place with concomitant release of the notified chemical.

The inherent UV resistance of the compound precludes photochemical degradation, nor does the material appear susceptible to biodegradation. The MSDS indicates that the material is not readily biodegradable, with less than 20% reduction in Dissolved Organic Carbon according to OECD Test 302 B. However, slow degradation through microbial action would probably eventually lead to the compound's destruction.

By the same token, given the low oil/water partition coefficient, there is little potential for bioaccumulation in fatty tissue of aquatic organisms.

When carpet containing the chemical is incinerated the notified compound would decompose to carbon dioxide, water and oxides of nitrogen.

#### 9. EVALUATION OF TOXICOLOGICAL DATA

# 9.1 Acute Toxicity

Summary of the acute toxicity of Uvinul 4050.

Test	Species	Outcome	Referenc e
acute oral toxicity	rat	LD <sub>50</sub> > 2 200 mg.kg <sup>-1</sup>	[Gelbke, 1992 #75]
acute inhalation toxicity	rat	$LC_{50} > 5 \text{ mg.L}^{-1}.4 \text{ hours}^{-1}$	[Gamer, 1992 #76]
skin irritation	rabbit	not a skin irritant	[Gelbke, 1992 #78]
eye irritation	rabbit	a moderate eye irritant	[Gelbke, 1992 #77]
skin sensitisation	guinea pig	not a skin sensitiser	[Gelbke, 1992 #79]

# **9.1.1 Oral Toxicity** [Gelbke, 1992 #75]

Species/strain: rat/Wistar/Chbb: THOM (SPF)

Number/sex of animals: 3/sex

Observation period: 14 days

Method of administration: the notified chemical in olive oil DAB 9 was

administrated by oral gavage

Clinical observations: no abnormality

Mortality: nil

Morphological findings: no pathologic findings related to the treatment

were observed

Test method: similar to OECD guidelines [Organisation for

Economic Co-operation and Development,

1995-1996 #15]

 $LD_{50}$ : > 2 200 mg.kg<sup>-1</sup>

Result: the notified chemical was of low acute oral

toxicity in rats

# 9.1.2 Dermal Toxicity

The acute dermal toxicity study was not provided. This is acceptable for a limited notification.

# 9.1.3 Inhalation Toxicity [Gamer, 1992 #76]

Species/strain: rat/Wistar/Chbb: THOM (SPF)

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: fine powder with a mass median aerodynamic

diameter of 2.9 µm of the notified chemical was administered for 4 hours in rats via a head-nose inhalation system INA 20

Clinical observations: accelerated respiration and bloody nasal crust

formation were observed and became normal

from day 4 onward

Mortality: nil

Morphological findings: no macroscopic pathologic findings related to

the treatment were observed

Test method: based on OECD guidelines [Organisation for

Economic Co-operation and Development,

1995-1996 #15]

 $LC_{50}$ : > 5.0 mg.L<sup>-1</sup>.4 hours<sup>-1</sup>

Result: the notified chemical was of low acute

inhalational toxicity in rats

# **9.1.4 Skin Irritation** [Gelbke, 1992 #78]

Species/strain: rabbit/White Vienna

Number/sex of animals: 2 male, 1 female

Observation period: 72 hours

Method of administration: applied in a single dose (0.5 g, moistened with

distilled water) to the intact untreated skin with

a semiocclusive dressing for 4 hours

Test method: based on OECD guidelines [Organisation for

Economic Co-operation and Development,

1995-1996 #15]

Result: the Draize scores were all zero for both

erythema and edema formations at day 1, 2 and 3; the notified chemical was not irritating

to the skin of rabbits

### **9.1.5 Eye Irritation** [Gelbke, 1992 #77]

Species/strain: rabbit/White Vienna

Number/sex of animals: 1 male, 2 female

Observation period: 15 days

Method of administration: single application (24 mg) to the conjunctival

sac of the right eyelid

Draize scores [Draize, 1959 #4]:

#### Time after instillation

Animal	•	1 da	y	2	day	/S	3	day	'S	8	day	'S	1	5 da	ys
Cornea	Oª	é	a <sup>b</sup>	O <sup>a</sup>	ŧ	a <sup>b</sup>	O <sup>a</sup>	a	l <sup>b</sup>	O <sup>a</sup>	а	b	Oª	ê	l <sup>b</sup>
1	<sup>1</sup> 1	1		0	C	)	0	C	)	0	0	)	0	C	)
2	1	1		1	1		1	1		0	0	)	0	C	)
3	1	1		1	1		1	1		1	1		0	C	)
Iris															
1		1			1			1			0			0	
2		1		1		1 0			0						
3		1		1 1				0			0				
Conjunctiva	rc	Cd	<b>d</b> e	rc	Cd	<b>d</b> e	rc	Cd	<b>d</b> e	rc	Cd	<b>d</b> e	rc	Cd	<b>d</b> e
1	2	1	2	2	1	1	2	1	1	1	0	0	0	0	0
2	2	1	2	2	1	1	2	0	1	1	0	0	0	0	0
3	2	2	2	2	2	1	1	1	1	1	0	0	0	0	0
		1	see A	ttachr	nent	1 for	Draiz	e sca	ales						

a opacity b area c redness d chemosis e discharge

Test method: similar to OECD guidelines [Organisation for

Economic Co-operation and Development,

1995-1996 #15]

Result: the average Draize score (day 1 to 3) for

irritation was calculated to be 0.8 for corneal opacity, 1.0 for iris, 1.9 for conjunctivae redness, 1.1 for chemosis and 1.3 for

discharge; the notified chemical was moderate irritating to the eyes of rabbits under the test

conditions

# **9.1.6 Skin Sensitisation** [Gelbke, 1992 #79]

Species/strain: guinea pigs/Pirbright White, Dunkin Hartley

HOE DHPK [SPF-LAC] BÖ

Number of animals: 15 female (5 control, 10 test)

Induction procedure: Day 0: 3 pairs of intradermal injections:

0.1 mL of Freund's complete adjuvant

(FCA) and isotonic saline (1:1)

0.1 mL of the notified chemical (5%) in

olive oil DAB 9

0.1 mL of the notified chemical (5%) in FCA and isotonic saline (1:1)

Day 7: occluded application of filter paper strips containing the notified chemical (25%) in olive oil DAB 9 for 48 hours

Challenge procedure: Day 21: occluded application of filter paper

strips containing the notified chemical (10%) in olive oil DAB 9 for 24 hours

#### Challenge outcome:

Challanga	Test a	nimals	Control animals		
Challenge concentration	24 hours*	48 hours*	24 hours	48 hours	
10%	**0/10	0/10	0/5	0/5	

time after patch removal

Test method: similar to OECD guidelines [Organisation for

Economic Co-operation and Development,

1995-1996 #15]

Result: the notified chemical was not sensitising to the

skin of guinea pigs

#### Repeated Dose Toxicity [Kirsch, 1992 #80] 9.2

rat/Wistar/Chbb: THOM (SPF) Species/strain:

Number/sex of animals: 4 groups, 5/sex each

Method of administration: oral gavage

Dose/Study duration: 100, 300 and 1 000 mg.kg<sup>-1</sup> for 4 weeks (21

administrations)

Clinical observations: no abnormalities in food consumption, body

weight and other clinical observations

Clinical

a slight decrease of total protein and albumin chemistry/Haematology concentration was found in the serum of the

high-dose females, however, a slight increase

was observed in males

no significant differences in organ weights; no Histopathology:

treatment related gross lesions or microscopic

findings

<sup>\*\*</sup> number of animals exhibiting positive response

Test method: similar to OECD guidelines [Organisation for

Economic Co-operation and Development,

1995-1996 #15]

Result: the notified chemical was of low toxicity at the

dose levels of 100, 300 and 1 000 mg kg-1 in

rats during the 28-day oral study

### 9.3 Genotoxicity

### 9.3.1 Salmonella typhimurium Reverse Mutation Assay [Hoffmann, 1992 #81]

Strains: TA 1535, TA 100, TA 1537 and TA 98

Concentration range: 20 - 5 000 μg/plate with or without rat liver

metabolising system S-9

Test method: similar to OECD guidelines [Organisation for

Economic Co-operation and Development,

1995-1996 #15]

Result: a reduced his- background growth was

observed with TA 98 in the preincubation test without S-9 mix at 5 000  $\mu$ g/plate; no increase in the number of his+ revertants was observed

in the standard plate test and in the

preincubation test either with or without S-9 metabolising system; the notified chemical was not mutagenic in the Ames test under the

experimental conditions

# 9.3.2 Chromosome Aberration Test in Chinese Hamster Lung (CHL) Cells [Wright, 1996 #82]

Species/strain: CHL cell line

Doses: 250 - 2 000 μg.mL<sup>-1</sup> for 6 and 24-hour

exposure groups, and 62.5 - 2 000 μg.mL<sup>-1</sup> for

48-hour exposure groups

Method of administration: in the absence of metabolic activation, CHL

cells were exposed 24 or 48 hours

continuously to the notified chemical prior to

cell harvest

in the presence of metabolic activation, CHL cells were exposed 6 hours to the notified chemical; then a phosphate buffered saline

wash and a further 18 hours in treatment-free

media prior to cell harvest

Test method: Safepharm Standard Method Number JMOL

03 [Safepharm Laboratory Limited, #83]

Result: the notified chemical did not induce any

statistically significant, dose-related increases in the frequency of cells with chromosome aberrations either in the presence or absence of a liver enzyme metabolising system or after

various exposure times in CHL cells

# 9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse [Hoffmann, 1992 #84]

Species/strain: mouse/NMRI

Number and sex of animals: 30/sex

Doses: 300, 600 and 1 200 mg.kg<sup>-1</sup> body weight

Method of administration: single oral administration

Test method: based on OECD guidelines [Organisation for

Economic Co-operation and Development,

1995-1996 #15]

Result: there were no significant differences in the

frequency of erythrocytes containing

micronuclei either between the control and the 3 dose groups (300, 600 and 1 200 mg.kg<sup>-1</sup>) or between the various sacrifice intervals (16, 24 and 48 hours); the notified chemical had no clastogenic effect nor does it lead to any impairment of chromosome distribution in the

course of mitosis

# 9.4 Overall Assessment of Toxicological Data

The notified chemical showed low acute oral (LD<sub>50</sub> greater than 2 200 mg.kg<sup>-1</sup>) and inhalation toxicity (LC<sub>50</sub> greater than 5 mg.L<sup>-1</sup>.4 hours<sup>-1</sup>) in rats. When tested in rabbits, it was not a skin irritant but a moderate eye irritant. The notified chemical was not a skin sensitiser in guinea pigs. The notified chemical showed a low toxicity profile in the 28-day repeat oral dose study. In the presence or absence of metabolic activation, the chemical was not mutagenic in bacteria, and did not produce either chromosome aberrations in CHL cells or clastogenic effect in mouse micronucleus assay. No acute dermal toxicity study was provided.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with National Occupational Health and Safety Commission's *Approved Criteria for Classifying Hazardous Substances* in relation to acute lethal effects (oral, inhalation), skin irritation and skin irritation effects. However, based on the iris lesion scores presented in the submitted eye irritancy test, the chemical would be classified as hazardous.

#### 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although not required for materials to be imported in quantities less than one tonne per annum, the notifier provided data and test reports on the following ecotoxicological tests.

TEST	SPECIES	RESULTS
Toxicity to Fish	Zebra Fish	EC <sub>50</sub> (96 h) > 10.0 mg.L <sup>-1</sup>
[EEC directive	Brachydanio rerio	NOEL > 100 mg.L <sup>-1</sup>
84/449/EEC]		
Immobilisation of	Daphnia Magna	EC <sub>50</sub> (48 h) = 92.1 mg.L <sup>-1</sup>
Daphnia	STRAUS	
[EEC directive		
79/831/EEC]		
Inhibition of Bacterial	Pseudomonas putida	$EC_{10}$ (16 h) = 305 mg.L <sup>-1</sup>
Respiration		$EC_{50}$ (16 h) = 455 mg.L <sup>-1</sup>
[DIN 38412 part 8]		EC <sub>90</sub> (16 h) = 675 mg.L <sup>-1</sup>

The tests on fish were performed in a continuous flow through tank using unchlorinated tap water. Test material was added at 50 and 100 mg.L<sup>-1</sup> nominal concentration, and the water temperature was constant at 21°C, while the pH was always between 7.5 (min) and 8.9 (max). No mortality occurred at any of these concentrations over the 96 hour duration of the tests, and on the basis of these results the material is regarded as non toxic to this species.

The immobilisation tests with *daphnia* were performed in a 48 hour static test using seven concentrations of test material over the nominal concentration range between 1.56 and 100 mg.L<sup>-1</sup>. Four replicate tests were performed for each test concentration, and water temperature was maintained at 21°C, while pH was between 7.9 (min) and 9.4 (max). The data indicate that the test material is slightly toxic to *daphnia*.

The test on inhibition of bacterial respiration (*Pseudomonas putida*) performed in medium buffered near neutral pH material had small detrimental effect. However, remarks in the test report indicate that at higher pH the material has a very strong inhibitory effect on bacterial respiration.

The MSDS provided with the notification also contained some values for ecotoxicology data. While the results for bacterial respiration are in accord with the report provided with this notification as discussed above, the data on toxicity to fish

appears to have been derived for a different species. This data is as below, but note the relevant report for this fish test is not available.

Test	Species	Results
Toxicity to Fish	Ide	LC <sub>50</sub> (96 h) >100 mg.L <sup>-1</sup>
	leuciscus idus	
Inhibition of Bacterial	Species not specified in	EC <sub>10</sub> (17 h) = 305 mg.L <sup>-1</sup>
Respiration	MSDS	$EC_{50}$ (17 h) = 455 mg.L <sup>-1</sup>
[DIN 38412 part 8]		

#### 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Only small quantities of the notified chemical are likely to be released during transportation, and in the formulation and extrusion operations involved in manufacture of the "masterbatch". This chemical would be deposited into landfill.

Since the material is encapsulated in a polyamide "masterbatch" matrix, there is virtually no possibility of release to the environment during the secondary extrusion operations involved in manufacture of the carpet product. Small amounts of material may be discarded (either to landfill or incineration) as a result of periodic cleaning of the extrusion equipment.

In a landfill slow degradation of the residues present in the original packages, discarded "masterbatch" residues and the old (used) nylon carpet is expected. This would lead to slow and very dispersed release of the notified chemical, but since the material appears to be of low toxicity to aquatic organisms, the environmental hazard presented by the notified chemical is considered to be small.

# 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical has a NAMW of approximately 455 and the notifier claims that as such it would be expected to be poorly absorbed across biological membranes. The notifier states that no observations of health problems or adverse symptoms in humans exposed to this chemical have been reported.

In the animal studies, the notified chemical is of low acute oral and inhalation toxicity, and no skin irritation and sensitisation effects. It showed low toxicity in a 28-day repeat dose study. Three in vivo and in vitro studies did not reveal any notified genotoxic effects induced by the chemical in bacteria, CHL: cells and mice. The notified chemical is classified as hazardous based on its irritating effects in iris in the eye irritation study.

There is an impurity of formamide in Uvinul 4050 H. Formamide is on the NOHSC's *List of Designated Hazardous Substances*. NOHSC has established an exposure standards for formamide of 10 ppm or 18 mg.m<sup>-3</sup> (TWA). Formamide is poisonous by skin contact and subcutaneous routes. It is an irritant to eye, skin and mucous

membranes. Although the concentration of formamide in Uvinul 4050 H is low (0.05%), it may contribute some in the irritancy property of the product.

The toxicity of the product, Uvinul PA Batch ED 8800, containing 5% of the notified chemical is expected to be low. Once the notified chemical is incorporated into Uvinul PA Batch ED 8800, the notified chemical becomes unavailable as it is bound into a polymer matrix.

The occupational health risk is negligible for the transport and storage workers except in the events of accidents.

A low occupational health risk exists for the workers at the formulation site. The mixing takes place in a sealed blender. The formulation of Uvinul PA Batch ED 8800 is in an essentially closed system. No handling of the notified chemical is required other than to weigh and mix Uvinul 4050 H with other components prior to the extrusion process. Dust may generate and dermal contact is possible during weighing and adding the notified chemical into mixing vessel. Eye protection is considered to be necessary for workers handle this chemical during these processes, although local exhaust ventilation is in operation to collect any dust that may be released.

Workers at the carpet manufacturing site may be exposed to the notified chemical. However, the occupational health risk for these workers is minimal because the concentrations of notified chemical in Uvinul PA Batch ED 8800 and nylon fibres are low and the notified chemical becomes unavailable after it is bound into a polymer matrix

Under normal conditions of transport, handling and end-use, the likelihood of public exposure to this material is very low. While public exposure to the notified chemical is possible following an accident during transport of Uvinul 4040 H, the likelihood is low in view of the clean up and disposal measures. There may be widespread public contact with finished carpets that contain the notified chemical. However, because the notified chemical is fixed in the polymer matrix, the potential for public exposure to the notified chemical during use of carpets incorporating this material is minimal.

#### 13. RECOMMENDATIONS

To minimise occupational exposure to UVINUL 4050 H the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 [Standards Australia, 1994 #21] to comply with Australian/New Zealand Standard (AS/NZS) 1337 [Standards Australia/Standards New Zealand, 1992 #23];
- Industrial clothing should conform to the specifications detailed in AS 2919
   [Standards Australia, 1987 #18] and AS 3765.1 [Standards Australia, 1990 #19];

- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

#### 14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* [National Occupational Health and Safety Commission, 1994 #13].

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

#### 15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

#### 16. REFERENCES

- 1. Weast, R.C., Astle, M.J. & Beyer, W.H. 1985, *Handbook of Chemistry and Physics*, 66 th, CRC Press Inc, Boca Raton, Florida, USA.
- 2. Sax, N.I. & Lewis, R.J. 1989, *Dangerous Properties of Industrial Materials*, Van Nostrand Reinhold, New York.
- 3. Organisation for Economic Co-operation and Development 1995-1996, OECD Guidelines for the Testing of Chemicals on CD-Rom, OECD, Paris.
- 4. Gelbke, H.P., Kirsch, Hildebrand & Freisberg 1992, Study on the acute oral Toxicity of Lichtschutzmittel 1736 in rats, Project no., 10A0470/911137, BASF Aktiengesellschaft, Department of Toxicology, Ludwigshafen/Rhein, FRG.
- Gamer, A.O., Kirsch, P. & Freisberg, K.O. 1992, Study on the acute inhalation toxicity LC50 of Lichtschutzmittel 1736 as a dust aerosol in rats 4hour exposure, Project no., 13I0470/917038, BASF Aktiengesellschaft, Deepartment of Toxicology, Ludwigshafen, FRG.
- 6. Gelbke, H.P., Rossbacher & Kirsch 1992, Study on the acute dermal irritation/corrosion of Lichtchutzmittel 1736 in the rabbit, Project no.,

- 18H0470/912268, BASF Aktiengesellschaft, Department of Toxicology, Ludwigshafen, FRG.
- 7. Gelbke, H.P., Rossbacher & Kirsch 1992, Study on the acute eye irritation of Lichtschutzmittel 1736 in the rabbit, Project no., 11H0470/912269, BASF Aktiengesellschaft, Department of Toxicology, Ludwigshafen/Rhein, FRG.
- 8. Gelbke, H.P. & Kirsch 1992, On the Maximization Test for the sensitizing potential of Lichtschutzmittel 1736 in guinea pigs, Project no., 30H0470/912236, BASF Aktiengesellschaft, Department of Toxicology, Ludwigshafen/Rhein, FRG.
- 9. Draize, J.H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, vol. 49, pp. 2-56.
- 10. Kirsch, P., Deckardt, K., Gembardt & Hildebrand, B. 1992, Study of the oral toxicity of Lichtschutzmittel 1736 in Wistar rats administration by gavage over 4 weeks (21 administrations), Project no., 34S0470/91076, BASF Aktiengesellschaft, Department of Toxicology, Ludwigshafen/Rhein, FRG.
- 11. Hoffmann, H.D. & Engelhardt, G. 1992, *On the study of Lichtschutzmittel* 1736 in the Ames test, Project no., 40M0470/914303, BASF Akteingesellschaft, department of Toxicology, Ludwigshafen/Rhein, FRG.
- 12. Wright, N.P. 1996, *Uvinul 4050H: Chromosome aberration test in CHL cells in vitro*, Project no., 660/004, Safepharm Laboratory Limited, Derby, UK.
- 13. Safepharm Laboratory Limited , 'Safepharm Standard Method Number JMOL 03'.
- 14. Hoffmann, H.D. & Engelhardt, G. 1992, Cytogenetic study in vivo of Lichtschutzmittel 1736 in mice micronucleus test single oral adminstration, Project no., 26M0470/914312, BASF Aktiengesellschaft, Department of Toxicology, Ludwigshafen/Rhein, FRG.
- 15. Standards Australia 1994, Australian Standard 1336-1994, Eye protection in the Industrial Environment, Standards Association of Australia, Sydney.
- 16. Standards Australia/Standards New Zealand 1992, Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.
- 17. National Occupational Health and Safety Commission 1994, National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)], Australian Government Publishing Service, Canberra.

# **Attachment 1**

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	Rating	Oedema Formation	Rating	
No erythema	0	No oedema	0	
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1	
Well-defined erythema	2	Slight oedema (edges of area well- defined by definite raising	2	
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3	
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4	

The Draize scale for evaluation of eye reactions is as follows:

# **CORNEA**

Opacity	Rating	Area of Cornea involved	Rating
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

# CONJUNCTIVAE

Redness	Rating	Chemosis	Rating	Discharge	Rating
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
easily discernible  Diffuse beefy red	3	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and	3 severe
	severe	Swelling with lids half-closed to completely closed	4 severe	hairs and considerable area around eye	

# IRIS

Values	Rating
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe