File No: NA/517

January 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

UVINUL 5050H

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

UVINUL 5050 H

1. APPLICANT

BASF Australia Ltd of 500 Princes Highway NOBLE PARK VIC 3174 has submitted a limited notification statement in support of their application for an assessment certificate for Uvinul 5050 H.

2. IDENTITY OF THE CHEMICAL

Uvinul 5050 H is considered not to be hazardous based on the nature of the polymer and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, and details of the polymer composition have been exempted from publication in the Full Public Report and the Summary Report.

Other Names:	Light Stabilizer AK-2639
Trade Name:	Uvinul 5050 H

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	yellow to brown granular solid
Melting Point:	104-112°C (see notes below)
Specific Gravity:	994 $kg.m^{-3}$
Vapour Pressure:	not determined
Water Solubility:	< 0.04 $mg.L^{-1}$
Partition Co-efficient (n-octanol/water):	log P_{OW} > 5.98 at 23°C (see notes below)
Hydrolysis as a Function of pH:	not determined (see notes below)

Adsorption/Desorption:	not determined (see notes below)
Dissociation Constant:	pKa = 7.06 (see notes below)
Flash Point:	not determined
Flammability Limits:	not determined
Autoignition Temperature:	not determined
Explosive Properties:	not determined (see notes below)
Reactivity/Stability:	not determined (see notes below)

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines (1) at facilities complying with OECD Principles of Good Laboratory Practice.

The polymer contains a significant proportion of saturated hydrocarbon which will confer significant hydrophobic character on the material. However, the secondary amine in the structure is basic (see further below), and under usual environmental conditions where pH is between 4 and 9, these will be protonated and consequently be positively charged (see further comments on pKa below). This mix of properties is characteristic of surfactants, and the material could be expected to be surface active. While the water solubility is low (less than 0.04 $mg.L^{-1}$), it is possible that the polymer could be dispersed as colloidal aggregates at concentrations significantly higher than that indicated.

The succinimide groups could be expected to be susceptible to hydrolysis under extreme pH conditions, but in the environmental pH region (between 4 and 9) this is expected to be negligible.

P_{ow} was determined as greater than $9.6x10^6$, and was calculated by taking the ratio of the solubility in octanol (greater than 38.3 $g.L^{-1}$ at 23°C) to that in water (0.04 $g.L^{-1}$ at 23°C). From this result Log P_{ow} is calculated as greater than 5.98, and this high value is due to the high content of saturated hydrocarbon in the polymer.

The notifier provided a pKa of 7.06 for the polymer. The listed value may be appropriate for the nitrogen in the succinimide group, but the secondary amine within the substituted moieties will be appreciably basic, and is likely to have a pKa between 10.8 and 11.2 (2). In an aqueous environment these nitrogens would be protonated, giving the polymer a positive charge.

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

The notified polymer is not considered to be reactive. It does not have oxidising properties and does not degrade or decompose under the normal conditions.

The product Uvinul PA Batch ED 8800 which contains 5% of the notified polymer is a yellowish granular solid with a slight odour. The melting point of the formulation Uvinul PA Batch ED 8800 is 184°C.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 98.0%

Toxic or Hazardous Impurities: the notifier claims none detected, but no supporting data included with notification

Non-hazardous Impurities (> 1% by weight):

Chemical name:	Gulftene (a trade name for C_{20}-C_{24} alkenes)
Weight percentage:	1.47%
CAS No.:	93924-10-8

Maximum Content of Residual Monomers: no data provided

Additives/Adjuvants: nil

5. USE, VOLUME AND FORMULATION

The notified polymer will be used as an ultraviolet light stabilising additive for nylon carpets. The carpet is intended for use in automobiles, and in commercial and domestic situations.

Uvinul 5050 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 5050 H will comprise 5% by weight in Uvinul PA Batch ED 8800.

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

Both Uvinul 5050 H and Uvinul PA Batch ED 8800 are formulated as granular solids.

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported in two forms. The “neat” notified polymer is named Uvinul 5050 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 polymer. Uvinul PA Batch ED 8800 is in 25 kg multi-layered kraft paper and polyethylene bags. If Uvinul 5050 H is imported, it will

be formulated into Uvinul PA Batch ED 8800 in Australia.

The vapour pressure for the notified polymer has not been determined. Considering the high molecular weight and the granular formulation, inhalation exposure would be expected to be negligible. The main route of occupational exposure will be through dermal contact.

Transport and storage workers are unlikely to be exposure to the notified polymer except in the event of spillage.

At the formulation site, the notified polymer will be blended dry with other ingredients in a sealed system, heated, extruded, then cooled and granulated. Workers could be exposed to the notified polymer during the process of weighing and adding into the mix vessel. Local exhaust ventilation will be used during the formulation process. Considering the polymer nature and granular formulation of Uvinul 5050 H, the exposure to the notified polymer during formulation is expected to be minimal.

The product Uvinul PA Batch 8800 containing 5% of the notified polymer will be sold as a “masterbatch” to carpet manufacturers. At the carpet manufacturing site, Uvinul PA Batch 8800 will be blended with other ingredients and extruded into nylon fibre for use in carpets. The notified polymer will then constitute 0.25% of the nylon fibre. Workers could be exposed to the notified polymer during mixing and application. However, the exposure is considered to be minimal due to the low concentration of the notified polymer.

7. PUBLIC EXPOSURE

Following import by sea as part of a container lot of mixed chemical products, the notified polymer will be transported by road. Following import, the notified polymer 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 should be disposed according to State legislation.

The notified polymer 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 polymer, 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

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 to 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. Also, 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. Similarly, it is expected that offcuts and trimmings of carpet would be placed into landfill.

The Material Safety Data Sheet (MSDS) gives adequate instructions for actions following a large spillage as a result of transport accidents etc. This involves sweeping up the polymer with a dust binding material followed by disposal into a landfill or incineration.

Following the blending and extrusion operations, the notified material is bound into a polyamide matrix and has little potential for release.

Similarly, when encapsulated within the nylon carpet there is no likelihood of release. However some slow release of the material resulting from breakdown of the carpet after long periods in landfill could be expected.

Fate

The material discarded as a residue in the paper bags, together with that purged from the extrusion equipment would most likely be placed into landfill. 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 biological and abiotic processes would eventually degrade the nylon and the contained stabilising polymer, with concomitant production of water, methane, ammonia and oxides of carbon.

The inherent UV resistance of the compound precludes photochemical degradation, nor is it expected the material would be susceptible to biodegradation. However, very slow degradation through microbial action would probably eventually lead to the compound's destruction. If any polymer was released in a non-degraded form, it is expected that this would adsorb to and become associated with the organic component of soils and sediments.

When carpet containing the polymer 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 5050 H.

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 $mg.kg^{-1}$	(3)
skin irritation	rabbit	not a skin irritant	(4)
eye irritation	rabbit	not an eye irritant	(5)

9.1.1 Oral Toxicity (3)

Species/strain:	rat/Wistar/Chbb: THOM (SPF)
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	the notified polymer suspended in olive oil DAB 10 was given by oral gavage
Clinical observations:	no abnormalities related to the treatment were observed
Mortality:	nil
Morphological findings:	no abnormalities were noted at necropsy
Test method:	based on OECD guidelines (1)
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	the notified polymer was of low acute oral toxicity in rats

9.1.2 Skin Irritation (4)

Species/strain:	rabbit/White Vienna
Number/sex of animals:	3 females
Observation period:	72 hours
Method of administration:	single application (0.5 g solid or semi-solid moistened with aqua bidest) to the intact

	untreated skin with a semiocclusive dressing for 4 hours
Test method:	based on OECD guidelines (1)
Result:	the Draize scores were all zero for erythema and edema from day 1 to 3; the notified polymer was not irritating to the skin of rabbits

9.1.3 Eye Irritation (5)

Species/strain:	rabbit/White Vienna
Number/sex of animals:	2 males, 1 female
Observation period:	72 hours
Method of administration:	single application (33 mg) to the conjunctival sac of the right eyelid
Clinical observation:	the Draize scores were all zero for cornea, conjunctivae (redness, chemosis and discharge) and iris from day 1 to 3
Test method:	based on OECD guidelines (1)
Result:	the notified polymer was not irritating to the eyes of rabbits

9.2 Repeated Dose Toxicity (6)

Species/strain:	rat/Wistar/Chbb: THOM (SPF)
Number/sex of animals:	4 dose groups, each had 20/sex
Method of administration:	dietary
Dose/Study duration::	0, 600, 3 000 and 15 000 ppm for 3 months, 10/sex of each group were sacrificed thereafter and the rest 10/sex were sacrificed after another 4 weeks without treatment (recovery period)
Clinical observations:	no abnormalities related to the treatment were observed
Clinical chemistry/Haematology	some inter-group differences in blood chemistry and reticulocytes were noted,

	however, they were considered to be of no toxicological significance
Histopathology:	no abnormalities related to the treatment were observed
Test method:	based on OECD guidelines (1)
Result:	the notified polymer was of low toxicity in the subchronic dietary toxicity study in rats

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (7)

Strains:	TA 1535, TA 100, TA 1537 and TA 98
Concentration range:	20 - 5 000 μg/plate with or without a metabolising system S-9 (vehicle: tetrahydrofuran)
Test method:	based on OECD guidelines (1)
Result:	the notified polymer was not mutagenic in bacteria either with or without metabolic activation provided by rat liver S-9 fraction under the experimental conditions

9.3.2 Gene Mutation Test in Chinses Hamster Ovary Cells (8)

Species/strain:	Chinese hamster ovary cells (CHO-K1)
Concentration range:	0.005 - 4.64 $\mu g.mL^{-1}$ for tests without S-9 mix; 0.05 - 46.4 $\mu g.mL^{-1}$ for tests with S-9 mix
Method of administration:	4 hours exposure in serum-free medium
Test method:	based on OECD guidelines (1)
Result:	reduced cell densities and cloning efficiencies were found at 1 $\mu g.mL^{-1}$ and above without S-9 mix, and at 10 $\mu g.mL^{-1}$ and above with S-9 mix; no biologically significant increases in mutant frequencies were found in either without or with S-9 mix; the notified polymer did not demonstrate a mutagenic potential under the experimental conditions used in this *in vitro* test system

9.4 Overall Assessment of Toxicological Data

The notified polymer was of low acute oral toxicity (LD_{50} greater than 2 000 $mg.kg^{-1}$) in rats. When tested in rabbits, it was neither a skin nor an eye irritant. The notified polymer showed a low toxicity profile in the 3-month dietary study in rats. In the presence or absence of metabolic activation, the polymer was not mutagenic in bacteria or Chinese Hamster ovary cells. Acute dermal and inhalation toxicity and skin sensitisation data were not provided in the submission. This is acceptable as this is a limited notification and the notified polymer will be imported less than one tonne per annum.

On the basis of submitted data, the notified polymer would not be classified as hazardous in accordance with National Occupational Health and Safety Commission's *Approved Criteria for Classifying Hazardous Substances* (9) in relation to acute lethal effects (oral), irritation effects (skin, eye), and subchronic effects (oral).

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 of the notified chemical on the following ecotoxicological tests.

Test	*Species*	*Results*
Toxicity to Fish (1)	Zebra Fish *Brachydanio rerio*	LC_{50} (96 h) > 10 000 $mg.L^{-1}$ NOEL > 10 000 $mg.L^{-1}$
Immobilisation of Daphnia [EEC directive 79/831/EEC]	*Daphnia Magna* STRAUS	EC_{50} (48 h) > 100 $mg.L^{-1}$
Inhibition of Bacterial Respiration [DIN 38412 part 27]	*Pseudomonas putida*	EC_{50} (30 min.) >10 000 $mg.L^{-1}$

The tests on fish were performed in a continuous flow through tank using un-chlorinated tap water at a temperature of 24±1°C. Test material was added at the following nominal concentrations, 50, 100, 5 000 and 10 000 $mg.L^{-1}$, and no mortality occurred at any of these concentrations over the 96 hour duration of the tests. During the tests the water was cloudy due to the presence of undissolved test material (water solubility less than 0.04 $mg.L^{-1}$), but it can be concluded that the substance is not toxic to zebra fish up to the limits of its solubility.

The immobilisation test with daphnia was performed using a static method at four nominal test concentrations, 12.5, 25, 50 and 100 $mg.L^{-1}$, and four replicate tests were performed for each test concentration. Water temperature was maintained between 19.8 and 21.6°C, while pH was always between 8.2 and 9. The test report did not indicate that the water was cloudy as a result of undissolved test substance, but there were some anomalies in the analysis results for the nominated material, which could be ascribed to inhomogeneous sampling resulting from incomplete

solubilisation. However, the data indicate that the test material is not toxic to daphnia up to the limits of its solubility.

The test material had no detrimental effect on the rate of bacterial respiration. The MSDS provided with the notification also contained some summarised ecotoxicology data, but this data appears to have been derived from a different series of tests from those discussed above. These data are as below, but no test reports are available.

Test	Species	Results
Toxicity to Fish	Ide *Leuciscus idus*	LC_{50} (96 h) > 100 $mg.L^{-1}$
Toxicity to bacteria [DIN 38412 Part 8]	species not specified	LC_{50} (17 h) > 1 000 $mg.L^{-1}$

No test reports detailing the experimental methodology employed in deriving these ecotoxicology data were provided by the notifier.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Only small quantities of the notified material are likely to be released during transportation, and in the formulation and extrusion operations involved in manufacture of the "masterbatch". This material 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 very slow degradation of the residues present in the original packages, discarded "masterbatch" residues and the old (used) nylon carpet could be expected. This may lead to slow release of the notified polymer, but since the material appears to be relatively non toxic to aquatic organisms, the environmental hazard presented by the notified polymer is considered to be small.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

In the animal studies, the notified polymer is of low acute and subchronic oral toxicity. It is not a skin or eye irritant. Two *in vitro* genotoxicity studies in bacteria and animal cells revealed negative results. Based on the available data, the notified polymer is not classified as hazardous according to the NOHSC criteria (9).

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

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

Minor occupational exposure exists for the workers at the formulation site. Formulation of Uvinul PA Batch ED 8800 takes place in an essentially closed system. No handling of the notified polymer is required other than to weigh and mix Uvinul 5050 H with other components prior to the extrusion process. During this process, local exhaust ventilation will be in operation to collect any dust that may be released. The health risk for workers at the formulation site is expected to be low.

Workers at the carpet manufacturing site may be exposed to the notified polymer. However, the occupational health risk for these workers is considered to be minimal because the concentrations of notified polymer in Uvinul PA Batch ED 8800 and nylon fibres are low and the notified polymer 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 polymer is possible following an accident during transport of Uvinul 5050 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 polymer. However, because the notified polymer is fixed in the polymer matrix, the potential for public exposure to the notified polymer during use of carpets incorporating this material is minimal.

13. RECOMMENDATIONS

To minimise occupational exposure to Uvinul 5050 H the following guidelines and precautions should be observed:

- Spillage of the notified polymer 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 polymer was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (10).

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 polymer 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. Organisation for Economic Co-operation and Development 1995-1996, *OECD Guidelines for the Testing of Chemicals on CD-Rom*, OECD, Paris.

2. Weast, R.C., Astle, M.J. & Beyer, W.H. 1985, *Handbook of Chemistry and Physics*, 66 th, CRC Press Inc, Boca Raton, Florida, USA.

3. Gelbke, H.P., Kirsch, Hildebrand & Bahnemann 1994, *Study on the acute oral toxicity of Light Stabilizer Ak-2639 in rats*, Project no., 10A0040/931006, BASF Aktiengesellschaft, Department of Toxicology, Ludwigshafen/Rhein, FRG.

4. Gelbke, H.P., Rossbacher & Kirsch 1994, *Study on the acute dermal irritation of Light Stabilizer AK02639 in the rabbit*, Project no., 18H0040/932013, BASF Aktiengesellschaft, Department of Toxicology, Ludwigshafen/Rhein, FRG.

5. Gelbke, H.P., Rossbacher & Kirsch 1994, *Study on the acute eye irritation of Light Stabilizer AK-2639 in the rabbit*, Project no., 11H0040/932014, BASF Akteingesellschaft, Department of Toxicology, Ludwigshafen/Rhein. FRG.

6. Mellert, W., Deckardt, K., Gembardt & Hildebrand, B. 1995, *Light Stabilizer AK-2639 - Subchronic Oral Toxicity study in Wistar Rats Adminstration in the Diet for 3 Months*, Project no., 57C0040/93050, BASF Aktiengesellschaft, Department of Toxicology,Ludwigshafen/Rhein, FRG

7. Hoffmann, H.D. & Engelhardt, G. 1994, *Study of Lichtschutzmittel AK-2639 in the Ames test*, Project no., 40M0040/934021, BASF Aktiengesellschaft, Department of Toxicology, Ludwigshafen/Rhein, FRG

8. Hoffman, H.D. & Polloth, C. 1994, *Gene Mutation Test in Chinese Hamster Ovary Cells with Light Stabiliser AK-2639*, Project no., 50M0040/934070, BASF Aktiengesellschaft, Department of Toxicology, Ludwigshafen/Rhein, FRG.

9. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra.

10. 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 easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		