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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

HWS-130

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

HWS-130

1. APPLICANT

MBT (Australia) Pty Ltd, 11 Stanton Street, Seven Hills NSW 2147

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, HWS-130, is considered to be non-hazardous. Therefore, the chemical names, molecular and structural formula, molecular weight and chemical purity have been exempted from publication in the Full Public Report and the Summary Report.

Chemical Abstracts Service (CAS) Registry No.: None allocated

Trade names: HWS-130

Method of detection and determination:

HWS-130 and its contaminants can be determined qualitatively using High Performance Liquid Chromatography (HPLC) and semi-quantitatively using gas chromatography (GC). Typical HPLC and GC traces were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Resin like brown liquid.
Odour:	Slight
Freezing Point:	-46°C (the substance solidified rather than froze.)
Boiling Point:	None could be determined.
Density:	1.12 x 10^3 kg/m^3
Vapour Pressure:	25 Pa at 25°C
Water Solubility:	0.56 g/L at 20°C

Fat Solubility: Estimated to be > 5000 mg/100 g solvent. HWS-130 is miscible with standard liquid fat but impurities (probably Na_2SO_4) remain undissolved at the end of the test and prevent determination of the exact solubility.

Partition Co-efficient (n-octanol/water) log $P_{O/W}$: estimated at > 3.3

Hydrolysis as a function of pH: HWS-130 is hydrolytically stable at pH 4 and unstable at pH 7 and 9.

pH	Temperature [°C]	rate constant K_{obs} [hours^{-1}]	Half-life time ($t_{1/2}$) [hours]
7	25	5.86×10^{-5}	1.18×10^{4}
	60	2.53×10^{-3}	274
	70	6.45×10^{-3}	107
9	25	3.36×10^{-3}	206
	40	1.57×10^{-2}	44
	50	4.03×10^{-2}	17

Adsorption/Desorption: Not determined.

Dissociation Constant: Not determined.

Flash Point: 66°C (closed cup).

Flammability Limits: Not determined, but initial handling of HWS-130 did not indicate flammability.

Combustion Products: Oxides of carbon, nitric oxides and other unspecified toxic vapours and fumes.

Pyrolysis Products: Not determined.

Decomposition Temperature: 165°C

Decomposition Products: None under normal storage conditions.

Autoignition Temperature: 345°C

Explosive Properties: Not explosive under influence of thermal or mechanical stress.

Reactivity/Stability:	Not determined. HWS-130 contains no halogens or reactive groups capable of releasing oxygen and is therefore not expected to be an oxidizer. Uncontrolled polymerization may occur in the presence of strong oxidizers and peroxides.
Particle size distribution:	Not relevant for a liquid.
Surface Tension:	51.6 mN/n at 20°C
Viscosity:	100 mPa.s at 20°C

Comments on Physical and Chemical Properties:

During measurement for surface tension the notified chemical was identified as being surface active. The octanol/water partitioning coefficient was estimated as the standard testing methods are not applicable to surface active materials. Estimation was based on the ratio of the solubility in n-octanol to that in water. The test substance was determined to be miscible in n-octanol in a 1:1 ratio. The water solubility was as determined above.

The molecule contains no active hydrogens and is not expected to dissociate. No adsorption/desorption tests were conducted. Exposure to the soil compartment from the proposed use is expected to be very low.

4. INDUSTRIAL USE

HWS-130 is a reactive acrylic monomer which will be used as a binder in construction materials including plaster, mortar, resins and adhesives. It will be blended with other acrylic monomers and marketed as a polymerisable viscous liquid known as Part A of two pack mix. Parts A and B together will consist of resin components, accelerators, fillers and other materials.

Initially HWS-130 will be used as a component in a surface coating for repairing floor coverings. However, corrosion resistant coatings, multi-purpose building plaster and other speciality coatings are expected to be developed.

HWS-130 will not be manufactured in Australia, but will be imported as required in 200L drums. It is currently being notified in several European countries.

5. OCCUPATIONAL EXPOSURE

There will be two categories of workers exposed to HWS-130.

Between one and three people will be involved in resin formulation on probably two occasions each month at a single site in Australia (Sydney). Formulation consists of batch process mixing of ingredients in a 500 L or 1000 L dedicated reactor vessel, followed by the lidding, palletting and transfer to designated storage areas. Local exhaust ventilation and automatic dispensing facilities are intended to be used. The final concentration of HWS-130 in the formulated products will be between 40 and 70% depending on the particular product and its application. All of the formulated products are viscous liquids. The finished product is expected to be packaged as part of a 20 L kit (combined volume of both two-pack components).

An unknown number of construction workers will be expected to use HWS-130 containing products at construction sites. Use will involve mixing HWS-130 with another agent which will polymerize in 4-6 hours. The exact number of people using products containing HWS-130 will depend on the particular material being used, the scope of he job and the degree of market share that MBT (Australia) is able to obtain.

6. PUBLIC EXPOSURE

The formulation product will be used by numerous construction workers, who will mix another substance with the formulation, to polymerize it within 4-6 hours. The public may come into contact with HWS-130 if they are near these construction sites.

7. ENVIRONMENTAL EXPOSURE

. Release

HWS-130 will be formulated into a range of air cured two-pack surface coatings by one company based in Sydney. The end use products are expected to be distributed nationally for use by commercial applicators. The notifier does not intend marketing coatings containing the notified chemical to the public.

The expected total chemical wastage factor resulting from unused residues in the shipping containers, equipment washings, batch residues and spillage has been estimated at < 0.5% per annum. Potential wastage is minimised as formulation and processing is likely to occur only twice per month in a dedicated reaction vessel. Where possible residues containing the notified polymer will be reused in subsequent batches. Otherwise, liquid residues will be collected with other solvent wastes and transported to a liquid waste treatment facility for processing and disposal.

The notified chemical is only intended for use in surface coating formulations used in the construction industry.

Commercial applicators will be required to blend the two components (Part A and Part B) of the surface coating prior to application. Mixing is expected to occur in 20 L pails using a small hand mixer (drill and stirrer blade). Due to the short pot life of the blended coating it is expected that the coating will be applied within 30 minutes of preparation.

Once mixed unused material will be transferred to a suitable waste drum where it will polymerise, prior to disposal in landfill.

. Fate

HWS-130 has moderate water solubility (560 ppm). Therefore leaching from landfill sites may occur if the chemical is released in an uncured form. Incineration of the notified substance is expected to produce oxides of carbon and nitrogen. There is a very low potential for exposure of the unreacted monomer to the environment from the proposed use.

Since it contains ester groups HWS-130 is likely to hydrolyse, either chemically or biologically, under environmentally relevant conditions. Tests indicated that the chemical was unstable at neutral and basic pH. The biodegradation of the notified chemical was measured (28 day) using the modified Sturm test (OECD Guideline 301B) (1) and classified as not readily biodegradable. Under the stringent test conditions, the degree of degradation was indicated as 38% and 26% for concentrations of 10 and 20 ppm respectively. While the chemical did not pass this stringent test, significant levels of biodegradation are likely under environmental conditions.

Based on the molecular structure, relatively high water solubility and hydrolysis/metabolism potential of HWS-130, bioaccumulation is considered unlikely.

The HWS-130 is not expected to be released to the environment until it has been fully cured as part of the coating formulation. Therefore the monomer will be effectively immobilised, chemically bound within the resultant polymer matrix. In the cured form leaching from landfill is not expected.

8. EVALUATION OF TOXICOLOGICAL DATA

8.1 Acute Toxicity

Table 1 Summary of the acute toxicity of HWS-130

Test	Species	Outcome	Reference
Oral	rat	LD50 > 2000 mg/kg	2
Dermal	rat	LD50 > 2000 mg/kg	3
Skin irritation	rabbit	non irritant	4
Eye irritation	rabbit	slight irritant	5
Skin Sensitization	guinea pig	non-sensitizer	6

8.1.1 Oral Toxicity (2)

The study was carried out in accordance with the *OECD Guidelines for testing of Chemicals No: 401*.

Five male and 5 female rats aged 8-10 weeks old were administered a single dose of HWS-130 by oral gavage. Each animal was given 2000 mg/kg of the test substance dissolved in polyethylene glycol. Animals were observed for a period of 15 days after which necropsy was performed.

The only response to the treatment was weight loss in one animal between days 8 and 15 of the study. No clinical signs or macroscopic changes were observed in any animals.

It was concluded that the oral LD_{50} of HWS-130 was > 2000 mg/kg.

8.1.2 Dermal Toxicity (3)

The study was carried out in accordance with the *OECD Guidelines for testing of Chemicals No: 402*.

Five male and five female rats aged approximately 11 weeks old were administered undiluted HWS-130 by dermal application.

On the day prior to exposure an area of 5 x 7 cm on the back of each animal was shaved. On day one of the procedure the test substance was applied to a portion of the shaved area (5 x 5 cm on the males and 3.5 x 5 cm on the females) by application on a gauze patch. This was fixed in place by aluminium foil and a flexible bandage.

Each animal received a single application of 2000 mg/kg of the test substance which remained on the skin for 24 hours after which time it was removed with a water moist tissue. Animals were observed for a period of 15 days after which necropsy was performed.

No mortality occurred during the study. No skin irritation or macroscopic abnormalities were observed. All animals exhibited only slight body weight gain or loss during the first week of the observation period but improved weight gain during the next week.

It was concluded that the dermal LD_{50} of HWS-130 was > 2000 mg/kg.

8.1.3 Skin Irritation (4)

The study was carried out in accordance with the *OECD Guidelines for testing of Chemicals No: 404*.

Two male and one female 15 or 16 week old New Zealand White rabbits were administered a single dose of 0.5 ml of undiluted HWS-130 by dermal application.

On the day prior to exposure an area of approximately 10 x 10 cm on the back of each animal was shaved. On day one of the procedure the test substance was applied to a 6 cm^2 portion of the shaved area and covered with a 3 x 3 cm surgical gauze patch. The dressing was wrapped around the abdomen and anchored with an elastic bandage.

The test substance remained on the skin for 4 hours after which time it was removed with lukewarm tap water. Animals were then observed at 1, 24, 48 and 72 hours after removal of the dressing.

No skin irritation or acute clinical symptoms were observed in any of the animals. The test substance did not cause any staining of the skin.

8.1.4 Eye Irritation (5)

The study was carried out in accordance with the *OECD Guidelines for testing of Chemicals No: 405*.

Two female and one male 15 or 16 week old New Zealand White rabbits were administered a single dose of 0.1 ml of undiluted HWS-130 into the conjunctival sac of the left eye. The eye was held closed for one second to prevent loss of the test substance. The right eye was untreated and used as a control.

Animals were observed at 1, 24, 48 and 72 hours after administration of HWS-130.

Application of the test substance did not result in any staining of the eye. Two animals showed slight diffuse opacity of the cornea, slight reddening and swelling of the conjunctival and nictitating membrane and slight discharge. These symptoms were present 1 hour after treatment and were still present but diminished in one animal after 24 hours. The third animal did not exhibit any eye irritation at any stage during the observation period.

HWS-130 is concluded to be a slight irritant to the eye of the rabbit under the conditions of the study.

8.1.5 Skin Sensitization (6)

The study was carried out in accordance with the *OECD Guidelines for testing of Chemicals No: 406*

The test used was the guinea-pig maximisation test of Magnusson and Kligman.

Preliminary study

To determine the dose level for intra-dermal injection in the main study, 0.1 ml of 1%, 3% and 5% solutions of HWS-130 in ethanol were injected into the clipped flank of two Himalayan spotted guinea-pigs. The resulting dermal reactions were assessed 24 hours later. All three concentrations produced very slight oedema and erythema. A dose of 5% w/v was selected for intra-dermal induction in the main study as this was the highest dose to produce only mild to moderate irritation.

To determine the dose level for topical induction and challenge in the main study, 100, 75, 50 and 25% of HWS-130 in ethanol was applied to the clipped and shaved flanks of 4 guinea-pigs. Filter paper saturated with the test substance was applied to the skin under occlusive bandage. The dressings were removed after 24 hours and assessments made immediately and at 24 hours after removal of the bandage. One animal showed slight erythema 24 hours after treatment with 100% HWS-130. No other responses were observed. A concentration of 75 % (non-irritating) was chosen for the challenge procedure and 100% (irritating) chosen for the induction procedure.

Induction Study

Thirty female guinea-pigs of the Himalayan strain (20 test and 10 control animals) were used.

On day 1 three pairs of intra-dermal injections (volume 0.1 ml) were made into the clipped inter-scapular region of each guinea-pig. The injected solutions were:

- Freund's Complete Adjuvant 50:50 with physiological saline,
- HWS-130 diluted to 5% with ethanol,
- HWS-130 diluted to 5% by emulsion in a 50:50 mixture of ethanol and Freund's Complete Adjuvant: physiological saline (1:1).

Control animals received the same treatment without the test substance.

On day 7 of the test, 24 hours prior to the epidermal application the scapular region was clipped and shaved and pretreated with 10 % sodiumlaurylsulfate (SLS) in petroleum oil. The SLS enhances sensitization by provoking a mild inflammatory reaction. The SLS was massaged into the skin without bandaging.

On day 8 the SLS pretreated area was treated with an occlusive epidermal application of undiluted HWS-130 in the same manner as described above for topical application in the pretest. Control animals were similarly treated but without the use of the test substance. The sites were evaluated 24 and 48 hours after removal of the patches.

Challenge Study

Two weeks after the epidermal induction application, the test and control animals were challenged topically with 75% HWS-130. The test substance was applied to the left flank of each guinea pig and ethanol alone was applied to the right flank. The techniques used were the same as those described above. The bandages remained for 24 hours and assessment was made of the skin reactions at 24 and 48 hours after removal of the bandages.

Results

No skin reactions were observed in test or control animals after challenge. Body weight gains in the test group were generally comparable to those observed in the control group with the exception of one animal which was emaciated between days 8 and 11 of the test. No toxic symptoms were observed in any animals.

During the induction phase, areas around the injection sites of test animals exhibited very slight erythema and oedema. These became necrotic by day 7, encrusted from day 11 and exfoliated until day 25 when the test was terminated.

The results of this study indicate that HWS-130 is not a skin sensitiser in guinea-pigs at the concentrations tested.

8.2 28-Day Repeated Dose Toxicity (7)

The study was carried out in accordance with the *OECD Guidelines for testing of Chemicals No: 407*

In a five day range finding study HWS-130 was administered undiluted by oral gavage to 3 rats per sex per group of Wistar strain rats. Dose levels of 300, 600 or 1000 mg/kg/day were used. As a result of this study dose levels of 0, 50, 200 or 1000 mg/kg/day were chosen for a 28 day study. In the main study it was necessary to dilute HWS-130 with polyethylene glycol to obtain accurate dosing.

The study consisted of four groups of animals, each with 5 animals per sex. There were 5 additional animals per sex for the control and high dose groups. All animals were treated for 28 days, after which necropsy was performed on all but the additional group of animals. These animals were given a 14 day recovery period after which necropsy was performed.

Treatment related effects were observed only in animals given 1000 mg/kg/day. Unless specified otherwise, the effects discussed below were observed at the end of the 4 week study period and prior to commencement of the recovery period.

No clinical signs of toxicity or behavioural changes were noted in any animal that could be attributed to the treatment. Baldness as a result of increased grooming activity was noted in a number of animals but did not show a clear treatment related distribution. No changes to body weight, food consumption or the condition of the eyes were observed that could be attributed to administration of HWS-130.

The only haematological change considered to be of statistical and toxicological significance was a slight increase in prothrombin times in male and female rats (1.1 fold). Two clinical biochemical parameters were altered by treatment with HWS-130. Inorganic phosphate and urea levels were both increased slightly (1.1 - 1.4 fold) in both sexes.

Relative liver and kidney weights were increased in males and females by 1.2 fold. After recovery the kidney ratio continued to be high in females only. All females were found to have pale livers. In addition 2 males and 5 females showed diffuse hepatocellular microvesicular vacuolation. Males only showed periportal and/or diffuse accumulations of mononuclear cells demonstrating microscopic liver damage.

Other minor changes were observed but were not considered biologically relevant as they were in the normal range for animals of the age and sex used.

It can be concluded that the main target organ of HWS-130 was the liver, and that after a 28 day treatment period treatment related effects were reversible.

8.3 Genotoxicity

8.3.1 *Salmonella typhimurium* Reverse Mutation Assay (8)

The study was carried out in accordance with the *OECD Guidelines for testing of Chemicals No: 471*.

HWS-130 was tested for its ability to cause gene mutations in the *Salmonella typhimurium* bacterial reverse mutation assay.

In a preliminary study using *S. typhimurium* strains TA98 and TA100 the concentrations of HWS-130 used were 0, 312.5, 625, 1250, 2500 and 5000 µg/plate. As a result of this study the concentrations selected for the main study were 0, 8, 40, 200, 1000 and 5000 µg/plate. *S. typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 were used, in the presence or absence of liver microsomal S9 activation. Positive controls used in the absence of activation were 4-nitro-o-phenylenediamine and sodium azide. 2-Aminoanthracene was used as the positive control in experiments including the liver S9 mix. All positive controls produced marked increases in the number of revertant colonies within the anticipated range.

No significant increases in the number of revertant colonies of bacteria were recorded for any of the strains of *S. typhimurium* used, at any dose level of the test substance, with or without

metabolic activation. The test substance caused no toxicity to the bacterial lawn at the concentrations used but did cause a weak precipitate at over 5000 µg per plate which did not interfere with the scoring of colonies.

The results indicate that HWS-130 is not genotoxic toward *Salmonella typhimurium*.

8.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (9)

The study was carried out in accordance with the *OECD Guidelines for testing of Chemicals No: 474*.

HWS-130 was investigated for its potential to induce micronuclei in bone marrow polychromatic erythrocytes of 10 week old Charles River strain mice.

Two preliminary experiments involving four animals each were performed to find the maximum tolerated dose. As a result of this initial study the following protocol was followed. A single dose of HWS-130 in polyethylene glycol was administered by oral gavage at 10 ml/kg to animals that had been fasted for 18 hours prior to treatment. At 24 hours or 48 hours after treatment the animals were killed and the bone marrow cells were collected for micronuclei analysis. At the 24 hour preparation time the doses used were 150, 500, and 1500 mg/kg body weight and at the 48 hour preparation interval 1500 mg/kg was used. Six male and six female mice were placed in each treatment group. The undiluted polyethylene glycol was the negative control and cyclophosphamide dissolved in saline administered at 30 mg/kg body weight was the positive control.

Treatment of the mice with the highest dose of HWS-130 resulted in slight toxicity. No cytotoxic effects were observed as indicated by the absence of an increase in the ratio of polychromatic to normochromatic erythrocytes in treated animals compared to controls.No increase in the frequency of micronucleated polychromatic erythrocytes occurred in animals treated with HWS-130 compared to controls. In contrast a distinct increase in the number of micronuclei was noted in animals treated with the positive control cyclophosphamide.

In conclusion, HWS-130 was found not to cause chromosomal damage *in vivo* in bone marrow cells of mice under the conditions of the study.

8.3.3 Chromosome Aberration Assay in Chinese Hamster V79 Cells *in Vitro* (10)

The study was carried out in accordance with the *OECD Guidelines for testing of Chemicals No: 473*.

HWS-130 was investigated for its potential to cause chromosomal aberrations in the V79 line of cells from the Chinese Hamster.

Preliminary experiments were performed in order to determine the toxicity of HWS-130 to the cells. No toxicity was observed in cells in the presence of liver S9 mix up to and including 580 µg/ml. Toxicity was noted in the absence of S9 at 100 µg/ml. Experimental doses were selected with the aim of the highest concentration reducing the plating efficiency by 20-50% and the % cells in mitosis (the mitotic index) by 50 %, and the lowest concentration having no effect on plating efficiency compared to controls. The DMSO solvent and the culture medium were used as the negative controls; ethylmethanesulfonate (8mM final concentration) and cyclophosphamide (15 µM final concentration) dissolved in nutrient medium were the positive controls utilized.

Three experiments were performed using cultures in the absence of S9 metabolic activation and two in the presence of activation. Cells were treated with higher concentrations of HWS-130 in the presence of the S9 based on the results of the preliminary experiments. A single cell suspension of V79 was prepared from 3 day old exponentially growing stock. Cells were subsequently treated for four hours with HWS-130 and chromosomes prepared 18 hours or 28 hours after treatment. Between 18 and 28 hours is considered to be the usual time when the expression of mutagenicity is maximized. Low, medium and high concentrations of HWS-130 were used for the 18 hour interval and high concentrations only for the 28 hour interval. After 48h (28 hour preparation interval) and 55 h (18 h preparation interval) the cell medium was replaced by serum free medium containing HWS-130 without S9 mix or with 50µL/ml S9 mix. After 4 hours the cells were rinsed twice in a salt solution to remove HWS-130 and placed in a complete medium. At 15.5 (28 h) and 25.5 hours (18 h) after addition of HWS-130 colcemid was added to arrest the cells in c-metaphase of mitosis and the cells were then prepared for microscopic analysis. One hundred metaphases per culture were examined for structural chromosomal aberrations including breaks, fragments, deletions, exchanges and chromosomal disintegrations. Only 25 metaphases were examined for the positive control groups.

In experiment 1 after treatment with 300 µg/ml, without S9 mix, and an interval of 28 hours, a statistically significant increase in aberrations was seen to occur. The mitotic index for these cells was 0%. This was not regarded as biologically significant due to the result being within the historical range of control values.

In experiment 2 after treatment with 200 µg/ml without S9 mix and an interval of 18 hours, a statistically and biologically relevant increase in the aberration rate was noted (13.00% compared to the corresponding control of 0.00%). The mitotic index for these cells was 24.3%.

In experiment 3, performed to clarify the results of the previous two experiments, after treatment of cells with 260 µg/ml without S9 mix and an interval of 18 hours, a significant

increase in aberrations (8.5%) occurred, compared to controls (1.5%). No increase in aberrations was noted in cells treated with 200.0 or 220.0 µg/ml. The mitotic index at 260 µg/ml was 39.2%.

The positive control substances both elicited a significant increase in chromosomal aberrations. No biologically relevant increases in the occurrence of polyploid metaphases was noted.

The clastogenic effects of the test substance can be seen to be related to the mitotic index. Only when the mitotic index has been reduced to below 50% was a clastogenic effect observed.

In conclusion, under the conditions of this study HWS-130 can be described as a clastogen at high doses as it induced structural chromosomal aberrations at concentrations reducing the mitotic index to below 50%.

8.4 Overall Assessment of Toxicological Data

HWS-130 was found to have low acute oral and dermal toxicity, to be non-irritating to the skin, and a non-sensitizer but was observed to be slightly irritating to the eyes. It was not mutagenic towards *Salmonella typhimurium*, nor was it clastogenic towards polychromatic erythrocytes of mouse bone marrow *in vivo*. HWS-130 was found to be a clastogen *in vitro* in the V79 cell line of the guinea pig when used in concentrations that reduced the mitotic index to below 50%. In rats, the target organ for toxicity was the liver following repeated dosing for 28 days.

9. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The acute toxicity of HWS-130 to carp (*Cyprinus carpio*) (11) was assessed over 96 hours under semi-static conditions. Testing was in accordance with OECD Guideline 203. To aid dispersion of HWS-130, Tween 80 was used. Test solution was renewed daily to maintain the actual concentration at 80% of nominal. Results indicate a nominal 96 hour LC_{50} between 18 ppm (0% mortality) and 56 ppm (100% mortality) indicating that HWS-130 is slightly toxic to carp. At 32 ppm, 10% mortality was noted. However this result could not be used in the estimation of LC_{50} due to a failure in the aeration equipment resulting in a decreased oxygen concentration in this (32 ppm) test solution.

A 48 hour acute toxicity immobilisation test on *Daphnia magna* using static conditions was reported (12). Testing was in accordance with OECD Guideline 202. Tween 80 was used to aid dispersion of HWS-130. The 24 hour EC_{50} was calculated to be 155 ppm (nominal, 95% confidence interval ranging 21-1060 ppm). The 48 hour EC50 was estimated between 100 and 180 ppm. Deposits of the notified chemical were observed in all test solutions corresponding to toxic concentrations (i.e. Û 180 ppm). HWS-130 may be assessed as slightly to practically non-toxic to daphnia.

No daphnia reproduction or algal growth inhibition tests were reported but this is acceptable due to the low exposure from the proposed use.

10. ASSESSMENT OF ENVIRONMENTAL HAZARD

HWS-130 may be classed as slightly toxic to aquatic species based on the acute toxicity studies on carp and daphnia. The solubility of the monomer is sufficiently high to allow release to the aquatic compartment in the event of inappropriate use. However, the current usage pattern indicates that release of the uncured material to the aquatic compartment is unlikely and the associated hazard is negligible.

When used as indicated above the notified chemical is not expected to be released to the environment until it has been fully cured and chemically bound within a polymer matrix. The ultimate fate of all cured material is landfill. Leaching of the notified chemical from cured material in landfill is not expected due to the chemical and physical bonding which occurs during the surface coating process. The potential for release to the aquatic compartment is minimal.

The low level environmental exposure of the notified chemical as a result of normal use indicate that the overall environmental hazard should be negligible.

11. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is a liquid with a low vapour pressure. It is therefore unlikely to be easily inhaled nor splashed.

Toxicological studies suggest that the risks associated with HWS-130 pertain to its slight eye irritancy and liver damage with repeated oral exposure. These results indicate that care needs to be taken at all times to minimise contact with the substance. A test performed to detect mutagenicity gave negative results. The notified substance had clastogenic effects in an *in vitro* assay using mammalian cells, however these effects were observed only at high cytotoxicity and moreover an *in vivo* clastogenicity assay was negative.

Only a small number of workers will be using the raw product. The formulated products which are resinous in nature will be used by numerous construction workers who will be mixing it with another substance to cure the formulation containing HWS-130. Due to the low vapour pressure, the most likely route of exposure is expected to be dermal. Care will be required to prevent HWS-130 from entering the body via this route.

Provided that reasonable care is taken to avoid skin and eye contact it would appear that HWS-130 will not pose a serious hazard to those who use the product and under normal use conditions would not pose a significant risk to health.

The public will be exposed to HWS-130 in formulated products, mainly in the form of skin, and possibly eye contact, during the mixing and curing process. It is considered that HWS-130 will not pose a significant hazard to health when used in the appropriate manner.

12. RECOMMENDATIONS

To minimise occupational and environmental exposureto HWS-130 the following guide-lines and precautions should be observed:

- If engineering controls and work practices are insufficient to significantly reduce exposure to a safe level, then personal protective devices which conform to and are used in accordance with Australian Standards (AS) for eye protection (AS 1336; AS 1337) (13,14), impermeable gloves (AS 2161) (15) and protective clothing (AS 3765.1 AS 3765.2) (16,17) should be worn.
- Good work practices should be implemented to avoid spillages.
- Good personal hygiene should be adopted.
- A copy of the MSDS for products containing the notified monomer should be easily accessible to employees working with products containing the chemical.
- For best practice, the notified chemical should be polymerised prior to disposal (landfill or incineration).

13. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for HWS-130 was provided in Worksafe Australia format (18). This MSDS was provided by MBT (Australia) Pty Ltd as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of MBT (Australia) Pty Ltd.

14. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of HWS-130 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. A secondary notification will be required if a usage is proposed which will lead to greater exposure of the aquatic compartment. No other specific conditions are prescribed.

15. REFERENCES

1. Ready Biodegradability: Modified Sturm Test with HWS-130, RCC NOTOX Project 068952, RCC NOTOX BV, The Netherlands, 1992.

2. Acute Oral Toxicity with HWS-130 in rats, RCC Project 297404, RCC Research and Consultancy Company AG, Intingen, Germany, 1991.

3. Assessment of Acute Dermal Toxicity with HWS-130 in the rat, RCC NOTOX Project 068906, RCC NOTOX, BV, The Netherlands, 1992.

4. Primary Skin Irritation Study with HWS-130 in rabbits, RCC Project 297426, RCC Research and Consultancy Company AG, Intingen, Germany, 1991.

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