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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Millad 3988

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For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Millad 3988

1. APPLICANTS

Ciba Geigy Australia Ltd, 235 Settlement Road, Thomastown Vic 3074

Harcros Chemicals Pty Ltd, 74 Henderson Road, Clayton North Vic 3168

Hoechst Australia Ltd, 606 St Kilda Road, Melbourne Vic 3004

ICI Australia (Operations) Pty Ltd, 1 Nicholson Street, Melbourne Vic 3001

Shell Chemical (Australia) Pty Ltd, 1 Spring Street, Melbourne Vic 3000

Tupperware Australia Pty Ltd, Lysterfield Road, Ferntree Gully Vic 3156

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, Millad 3988, is considered to be non-hazardous. Therefore, the chemical name, CAS number, molecular formula, structural formula, molecular weight and spectral data have been exempted from publication in the Full Public Report and the Summary Reports.

Trade name: Millad 3988

Method of detection and determination:

The chemical may be estimated by HPLC with UV detection.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white powder
Melting Point/Range:	261-265°C
Density:	725 kg/m^3 at 22°C
Vapour Pressure:	1.23 x 10^{-9} kPa at 25°C
Water Solubility:	4.76 x 10^{-5} g/L at 22°C
Fat Solubility:	4.49 x 10^{-3} g/100g fat at 37°C
Surface Tension (at 24.5°C)**:**	72.4 mN/m (63% saturated) 72.3 mN/m (42% saturated) 72.2 mN/m (21% saturated)
Partition Co-efficient (n-octanol/water) log $P_{O/W}$:	3.37

Hydrolysis as a function of pH:	pH 4, $t_{1/2}$ = 1.78 h (50°C) pH 7, $t_{1/2}$ > 5 days (50°C) pH 9, $t_{1/2}$ > 5 days (50°C)
Flammability Limits:	non-flammable; does not react with moisture leading to development of flammable gas
Autoignition Temperature:	>420°C
Explosive Properties:	non-explosive when subjected to heat, shock or friction
Dust Explosion Properties:	forms explosive dust clouds in air
Explosion severity:	weak (Kst: 194 bar.m/s)
Minimum ignition energy:	6-10 mJ
Minimum ignition temperature:	410°C
Minimum explosible concentration:	15 g/m^3
Electrostatic risk:	high resistivity
Reactivity/Stability:	exhibits oxidising properties
Particle size distribution:	100% > 38 µm 67% > 300 µm

Comments on physico-chemical data:

Soil adsorption/desorption and dissociation tests were not performed on the basis that the chemical will be encapsulated in a polymer matrix from which it will not significantly leach.

4. PURITY OF THE CHEMICAL

The notified chemical contains no hazardous impurities. Therefore, information on the purity of the polymer has been exempted from publication in the Full Public Report and the Summary Report.

5. INDUSTRIAL USE

Millad 3988 will be imported into Australia for use as a clarifying agent during polypropylene homopolymer production. The polypropylene will be used in the manufacture of articles such as housewares, bottles, syringes and take away food containers. Approximately 10-100 tonnes of Millad 3988 will be imported per annum during the first five years.

6. OCCUPATIONAL EXPOSURE

Millad 3988 powder will be imported from the USA in palletised Tyvek bags (10 kg net) and transported to wholesalers and/or manufacturers. Worker exposure during transportation should only result in the event of an accident.

The chemical will be blended into an additive mixture before use in the manufacture of polypropylene granules. Companies which may be involved in manufacture of the additive mixture include ICI Australia (Botany NSW), Hoechst Australia (Melbourne Vic) and Ciba-Geigy Australia (Thomastown Vic). The submitted information suggests that Shell Chemical will receive blended Millad 3988 from Ciba-Geigy. Harcros Chemicals (Clayton North Vic) may also import Millad 3988, but only to supply to other joint applicants. Tupperware Australia (Ferntree Gully Vic) has been included as one of the joint applicants as there is a possibility they may import the encapsulated form of the polypropylene granule directly.

A total of ~150 workers will be involved in the manufacture of the additive and/or granule throughout Australia.

Manufacture of additive

At the Ciba-Geigy plant, imported Millad 3988 will be debagged into a bulk bag from which it will be automatically fed (computer controlled), along with other ingredients, into an enclosed paddle mixer (via screw feeders set up on weight cells) and finally passed into another bulk bag for distribution to the granulator (Shell). All vessels and lines will be connected to a dust collection system. A total of 19 personnel are anticipated to be involved in the blending process, including ~10 operators potentially exposed for 12 days/year. Operator exposure is likely to occur during bag emptying. Maintenance personnel may be exposed during maintenance of additive dosing equipment while cleaners will be potentially exposed in the event of a spill. Ciba-Geigy state that during all these operations workers will wear overalls, PVC gloves, a dust mask (half dust mask fitted with a P1 filter level 2) and eye protection, however maintenance personnel may remove their gloves to 'obtain a better "feel" while doing the job'. An operating 8 hour TWA of 5 mg/m^3 is observed at Ciba-Geigy with regular dust monitoring.

Blending procedures will be similar at ICI and Hoechst.

Manufacture of polypropylene granules

During polypropylene granule manufacture, additive will be mechanically discharged from bulk bags into a closed system. At Shell, the bags will be manoeuvred using an electric hoist which will position them against the pan edge where they will be automatically cut and the powder emptied into the pan. Exposure of operators may result during bag emptying or during the lowering of the bag back to ground level. Operator exposure (1 day/year at Shell) will be minimised by the use of a dust extraction system to minimise discharge of the mixture to the surrounds and by the use of personal protective equipment including cotton overalls, PVC gloves, antifog goggles and 3M 9920 dust, mist and fume respirators Class P2 (Shell).

Similar handling procedures will be used at the other plants.

Once Millad 3988 has been encapsulated into polypropylene granules (2 kg/tonne), the potential for worker exposure should be negligible. No personal protective equipment are stipulated by the applicants for handling of polypropylene granules.

Polypropylene granules will be transported to customers in 1 tonne bulker box containers which will be recycled. The granules will be converted into finished articles by injection for blow moulding and thermoforming. This process encapsulates Millad 3988 within the polymer matrix.

7. PUBLIC EXPOSURE

There is low potential for public exposure during manufacturing processes, which take place within closed vessels connected to dust collection systems. Any spilled or wasted dust will be bagged and disposed of to landfill, while waste polypropylene granules or moulded polypropylene can be disposed of in garbage or recycled. Virtually all Millad 3988 will enter the public domain in finished articles, but at this stage the notified chemical will be incorporated into the polypropylene matrix, from which significant quantities are unlikely to be absorbed by dermal contact.

There is potential for widespread public exposure to low doses of Millad 3988 in the diet, caused by migration from polypropylene food and drink containers. In extraction studies performed with polypropylene containing 0.4% of the notified chemical, maximum concentrations of Millad 3988 were 0.74 ppm in acidic and aqueous foods and 4.59 ppm in alcoholic and fatty foods. A daily intake of 0.00195 mg/kg/day has been estimated, assuming 60 kg bodyweight and that 2% of the diet comes into contact with polypropylene containing the notified chemical. Additional exposure may arise from

injectable solutions following contact with polypropylene syringes containing the notified chemical. This aspect has not been addressed by the notifiers but is likely to result in only low, infrequent exposure.

. Release

Millad 3988 will be imported from USA in 10 kg palletised Tyvek bags, and then used to prepare the masterbatch. ICI estimates that less than 1 kg per annum of waste Millad 3988 will be generated during incorporation into polypropylene; at Ciba-Geigy (who will prepare the masterbatch for Shell) there is an estimated 20 kg of waste and at Hoechst while no figure for waste generated was given but as any waste is swept up and placed back in the process, an estimate in the range 1 to 20 kg appears reasonable. The empty Tyvek bags will be contaminated with Millad 3988, estimated at 10 g per bag. All of these waste, including the Tyvek bags, will be disposed of by secure landfill. The total for the unencapsulated waste will be between 32 and 122 kg of Millad 3988 per annum.

Most of the polypropylene containing Millad 3988 will be disposed of with domestic garbage, encapsulated in polypropylene. Any granules that are spilled will be swept up and disposed of by landfill, estimated at 200 kg per annum. During manufacture of the finished articles, any trimmings or runner will be recycled or sold to a recycler. The articles at the end of their use are likely to be disposed of in the domestic garbage, which is normally disposed of by landfill or by incineration. Incineration of Millad 3988 will produce oxides of carbon and water.

. Fate

Most of the Millad 3988 imported into Australia will be encapsulated into the polypropylene before eventual disposal by landfill or by incineration. In this form there is unlikely to be any significant release of Millad to the environment. As part of this submission a report made to the US Food and Drug Administration was included on the extraction of Millad 3988 from polypropylene with 8% ethanol at 212°F (100°C) in a pressure reactor for 2 hours, then for 24 h at 120°F (48.9°C). Under these forcing conditions there was <1% extraction. Therefore in landfill there is unlikely to be any significant extraction from the polypropylene matrix.

A 28 day degradation study was performed according to OECD test guideline TG 301 B, at a nominal concentration of 10 and 20 mg/L. The result showed degradation of Millad 3988 of 28% at both concentrations. Although Millad 3988 is not readily biodegradable according to the test guidelines, it should slowly degrade and not persist in the environment.

The unencapsulated material that is disposed of by landfill or from the manufacturing process should not significantly leach due to the suspected strong adsorption as demonstrated by the high P_{OW} and low water solubility.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1Summary of the acute toxicity of Millad 3988

Test	Species	Outcome	Reference
Oral toxicity	Rat	LD_{50} >5000 mg/kg	(1)
Dermal toxicity	Rat	LD_{50} >2000 mg/kg	(2)
Skin Irritation	Rabbit	slight irritant	(3)
Eye irritation	Rabbit	slight to moderate irritant	(4)
Skin sensitisation	Guinea pig	non-sensitising	(5)

9.1.1 Oral Toxicity (1)

This study was conducted in accordance with OECD guideline No: 401 (6).

Millad 3988 was administered to 10 Crl:CD®BR rats (5/sex) by oral gavage, at a single dose of 5000 mg/kg in corn oil (25 ml/animal). Clinical observations were made over a 14-day period.

No deaths occurred during the observation period. All rats were sacrificed on day 14 and necropsy performed. Bodyweight gains of the treated animals were unaffected by treatment. Clinical signs of toxicity included soft stool in 2 females on the day of treatment. Necropsy on sacrificed animals revealed no treatment-related macroscopic lesions.

Results of this study indicate an acute oral LD_{50} of >5000 kg/mg in rats of both sexes for Millad 3988.

9.1.2 Dermal Toxicity (2)

This study was conducted in accordance with OECD guideline No: 402 (7).

A single dose (2000 mg/kg) of Millad 3988, prepared as a 47%(w/w) paste in sterile Codex liquid paraffin, and was applied (at a volume of 4 ml/kg) by the cutaneous route to Sprague-Dawley rats (5/sex). Clinical observations were made over a 15 day period.

There were no significant changes in behaviour or clinical signs over the observation period. Desquamation was observed in 1 male from day 5 to 7. No deaths occurred during the observation period. All rats were sacrificed on day 15 and necropsy performed. Bodyweight gains of the treated animals were unaffected by treatment. Necropsy on sacrificed animals revealed no treatment-related macroscopic lesions.

Results of this study indicate an acute dermal LD_{50} of >2000 kg/mg in rats of both sexes for Millad 3988.

9.1.3 Inhalation Toxicity

Inhalational toxicity data were not provided. This is acceptable as the particle size of the chemical is > 38 μm and non-respirable.

9.1.4 Skin Irritation (3)

This study was conducted in accordance with OECD guideline No: 404 (8).

A single dose of 0.5 g Millad 3988 (prepared as a paste with 0.46 g of sterile Codex liquid paraffin) was applied by semi-occlusive application to the intact skin of 6 male New Zealand white rabbits for 4 hours. The dressings were removed four hours later and the treated sites wiped clean. Skin reactions were assessed 1, 24, 48 and 72 hours after dressing removal.

Well defined erythema was observed in 1 animal at 1 hour, lessening to very slight erythema by the 24 hour observation. The remaining 5 animals all showed very slight erythema at 1 hour, which persisted through to 24 hours in 2 animals and 48 hours in another 2. No oedema was observed in any of the animals during the course of the study. No corrosive effects occurred on the skin of any of the animals.

Results of this study indicate that Millad 3988 is a slight skin irritant in rabbits.

9.1.5 Eye Irritation (4)

This study was conducted in accordance with OECD guideline No: 405 (9).

A single dose of 0.1 ml of Millad 3988 was instilled in the conjuctival sac of the right eye of each of 6 male New Zealand white rabbits. The left eye served as the control. The eyes were examined 1, 24, 48 and 72 hours as well as 7 days after treatment.

Slight corneal opacity was observed in one animal at 24 hours only. Conjunctival chemosis was reported at 1 hour in all animals (2 with obvious and 4 with slight effects), persisting through to 24 hours as slight chemosis in 4 of these animals. Conjuctival redness was observed in all animals at 1 and 24 hours, persisting in 3 animals to 48 hours and 1 animal to 72 hours. No corrosion was observed. All animals showed circumcorneal injections of the iris at 1 and 24 hours with 5 of these animals also showing congestion of the iris at 1 hour. All animals showed no effects on photomotor reflex during the study.

The results of this study suggest that Millad 3988 is a slight to moderate eye irritant in rabbits.

9.1.6 Skin Sensitisation (5)

This study was conducted in accordance with OECD guideline No: 406 (10).

The Magnusson-Kligman Maximisation Test was used. Test animals were albino Hartley guinea pigs.

Induction

In a preliminary study 0.1% Millad 3988 was shown to produce moderate to severe irritation with a "burnt" appearance at the injection site. Topical application of 0.5 ml Millad 3988 produced moderate irritation.

On day one, 20 test animals (10/sex) were injected intradermally (in duplicate) with:

. 0.1 ml Freund's Complete Adjuvant diluted 50:50 in isotonic solution (50:50 FCA),

. 0.1 ml Millad 3988 (0.1% w/w suspension) in absolute ethanol, and

. 0.1 ml mixture of Millad 3988 (0.2% w/w suspension) and 50:50 FCA.

Similar injections were made in the control animals (5/sex) however test material was excluded.

On day 8, topical applications with 0.5 ml Millad 3988 (50% w/w paste in absolute ethanol) were made to the injection sites of all test animals and occluded for 48 hours. Control animals were treated as above with the omission of Millad 3988. Skin reactions were assessed by the Draize method 24 and 48 hours after patch removal.

Challenge

After an 11 day rest period both test and control animals were challenged with topical applications of both 0.5 ml Millad 3988 (50% w/w paste in absolute ethanol) and vehicle alone. Patches were occluded for 24 hours. Sensitisation reactions were assessed 24 and 48 hours after patch removal.

After 24 and 48 hours, all animals (test + control) showed no sensitisation reactions (erythema or oedema) at either Millad 3988 or vehicle challenge sites. Other skin anomalies were reported in test animals only. These included "burnt" aspects of the skin (7/20) and slight desquamation of the epidermis (7/20).

The results of this study suggest that Millad 3988 is not a skin sensitiser in guinea pigs.

9.2 Repeated Dose Toxicity (11)

A 13-week oral toxicity study was conducted in accordance with OECD guideline No: 408 (12).

Millad 3988 was administered daily in food to Sprague-Dawley rats at 0 (control group), 2000 (low dose), 6500 (mid dose) or 20000 (high dose) mg/kg powdered diet for 13 weeks. These doses corresponded to an average of 0, 123.1, 406.5 or 1261.3 mg/kg/day in male rats and 0, 146.9, 478.5 or 1479.2 mg/kg/day in female rats. A total of 80 rats were used for the toxicity test (10/sex/dose). An additional 20 rats (5/sex at the 0 and high doses) were observed for a further 4 weeks without exposure in a recovery test.

All animals survived to scheduled necropsy and there were no treatment-related clinical signs, changes in food consumption, haematological or ophthalmic effects reported during the study.

Significant body weight changes were observed in the form of decreased body weight gain in mid and high dose males throughout the treatment period, and in high dose females after 1 month of treatment. This effect was reversible after 4 weeks without treatment.

No treatment related changes in blood clinical chemistry were apparent at the termination of treatment (all parameters) or after the recovery period (blood urea nitrogen measured only).

Pathology conducted at 13 and 17 weeks revealed no treatment-related effects on organ weights.

Microscopic examination showed no treatment-associated effects.

Under the conditions of this study Millad 3988 exhibited low toxicity in the rat after 13-week oral administration.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium and Escherichia coli Reverse Mutation Assays (13)

This study was conducted in accordance with OECD guideline No: 471 (14) and OECD guideline No: 472 (15).

Millad 3988 was tested in the *Salmonella typhimurium* test strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538, as well as *Escherichia coli* strain WP2*uvr*A, with or without metabolic activation.

Two experiments were conducted (total of 3 plates/strain/dose) at doses of 0, 100, 250, 500, 1000, 2500 or 5000 µg/plate. The reference mutagens sodium azide (TA 100, TA 1535; - S9), 2-nitrofluorene (TA 98, TA 1538; - S9), ICR-191 (TA 1537; - S9), 4-nitroquinoline-N-oxide (WP2*uvr*A; - S9) and 2-aminoanthracene (all strains; + S9) were used as positive controls.

No increases were noted in revertant colonies in the presence of Millad 3988, with or without metabolic activation, at any of the tested concentrations. All positive controls showed an increase compared to the negative control.

The results of this study indicate that Millad 3988 is not mutagenic against *Salmonella typhimurium* or *Escherichia coli* in this test.

9.3.2 Mouse Lymphoma Mutagenicity Test (16)

This study was conducted in accordance with OECD guideline No: 476 (17).

Millad 3988 was assessed for its potential to induce point mutations at the *Tk* locus (5-trifluorothymidine) in cultured mouse lymphoma L5178Y cells, both in the presence and absence of S9 mix prepared from Aroclor-induced rat liver.

Two experiments were conducted. Cells were treated with 0, 6.25, 12.5, 25 or 50 µg/ml Millad 3988 for 2 days, and then plated for determination of viability and mutant frequency. In both experiments precipitation of the test compound was observed at the high dose.

Millad 3988 did not produce statistically significant increases in mutation frequency in mouse lymphoma L5178Y cells under the conditions of the assay. The positive controls (4-nitroquinoline 1-oxide, -S9; benzo(a)pyrene, +S9) induced clear increases in mutation frequency.

Under the experimental conditions described Millad 3988 was unable to demonstrate any mutagenic activity.

9.3.3 Chromosome Aberrations in Human Peripheral Blood Lymphocytes (18)

This study was conducted in accordance with OECD guideline No: 473 (19).

Human peripheral blood lymphocytes were exposed to Millad 3988 with and without exogenous metabolic activation. Experiments were conducted in duplicate. In the first experiment concentrations of 0, 3.754, 5.006, 6.674, 8.899, 11.87, 15.82, 21.09, 28.13, 37.50 or 50.00 µg/ml were incubated with S9 mix for 3 hours and cells harvested after a 17 hour recovery period. Cultures without S9 mix were treated with the same concentrations for 20 hours with no recovery period. In the second experiment concentrations of 0, 20.48, 25.60, 32.00, 40.00 and 50.00 µg/ml were tested with S9 mix (3 h treatment, 17 h recovery; 3 h treatment, 41 h recovery) and in the absence of S9 mix (20 h treatment, no recovery; 3 h treatment, 17 h recovery; 44 h treatment, no recovery), additional concentrations). Cultures were also treated with appropriate reference mutagens (cyclophosphamide in the presence of S9 or 4-nitroquinoline-1-oxide without). Stained chromosome preparations were examined for chromosomal aberrations (100 metaphases per treatment group).

In the absence and presence of metabolic activation Millad 3988 produced no significant increases in cells with structural aberrations at any of the dose levels tested. The positive controls showed marked increases in the number of cells with structural aberrations.

Under the conditions of this test Millad 3988 is not clastogenic *in vitro*.

9.4 Overall Assessment of Toxicological Data

Animal tests suggest that Millad 3988 has low acute oral and dermal toxicity (rat LD_{50}s >5000 and >2000 mg/kg respectively). It was a slight skin and eye irritant in rabbits but did not show any sensitisation potential in guinea pigs. After 90 days of oral administration with 406.5 or 1261.3 mg/kg/day of Millad 3988 a significant decrease in body weight gain was observed in rats. No other significant effects were noted.

Genotoxicity studies indicated that the chemical does not cause point mutations in bacteria (*Salmonella typhimurium* and *Escherichia coli*) or in mammalian cells (mouse lymphoma L5178Y cells), and is not clastogenic in human peripheral blood lymphocytes.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following tests were performed according to OECD guidelines (1984) except for the algae test which was amended in 1987 (EEC 87/302 Part C).

Species	Test OECD	Result*
Zebra Fish, *Brachydanio rerio*	96 hour acute TG 203	NOEC >0.05 mg/L, maximum solubility
Daphnia, *Daphnia magna*	48 hour immobilisation TG 202	NOEC >0.05 mg/L
Algae, *Scenedesmus subspicatus*	72 hours, TG 201	NOEC > 0.05 mg/L

* Concentrations are actual

The above results show that Millad 3988 is practically non-toxic to fish, daphnia and algae at the limit of water solubility. Based on these results, chronic effects would not be expected at the maximum environmental concentrations possible and the lack of daphnia reproduction tests results is acceptable. There is unlikely to be any effects on aquatic organisms from the proposed use.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

There is unlikely to be significant environmental hazards associated with the product when use as indicated by the applicants. When Millad 3988 is encapsulated in the polypropylene, it will not leach into the environment and thus not be biologically available. Further, most of the encapsulated Millad 3988 will be disposed of by landfill or incineration when articles are disposed of with the domestic garbage. The unencapsulated waste from the manufacturing process will be disposed of at a secured landfill and it is unlikely to leach to the surrounding environment.

Because of the low environmental exposure and encapsulation in polypropylene, the environmental hazard can be assessed as being negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Millad 3988 powder may form explosive dust clouds in air (minimum explosible concentration of 15 g/m^3). The Australian exposure standard for nuisance dusts is 10 mg/m^3 inspirable (20) and Ciba-Geigy state that they will observe a 5 mg/m^3 limit. The control measures stated by the applicants to be in place during manufacturing processes, as well as conformation to the exposure standard should eliminate any explosion risk

The toxicity profile of Millad 3988 suggests the main toxicological hazard to workers to be due to the chemical's possible skin and eye irritant effects. During manufacture of Millad 3988 additive mixture or polyethylene granules, the most likely routes of worker exposure are by skin and eye contact as well as inhalation of dust. However, the particle size distribution (100% > 38 μm), indicates that no Millad 3988 should be respirable. The use of appropriate personal protective equipment should minimise skin and eye exposure.

Therefore, under normal use conditions, when appropriate personal protective equipment is worn, the risk to occupational health and safety should be minimal.

There is potential for widespread public exposure to the notified chemical resulting from migration into food, with the estimated daily intake of Millad 3988 being 0.00195 mg/kg/day. Applying a 2000-fold safety factor to the NOEL of 123 mg/kg/day in the 90-day rat study would yield an ADI of 0.0615 mg/kg/day, which is approximately 30-fold greater than the estimated daily intake of Millad 3988. There may be minor additional exposure via injectable solutions contacting syringes incorporating the notified chemical, but no quantitative estimate can be made from existing data.

Based on the above information, it is considered that Millad 3988 will not pose a significant hazard to public health arising from manufacturing processes or in finished products not intended for food or medical use.

13. RECOMMENDATIONS

To minimise occupational exposure to Millad 3988 the following guidelines and precautions should be observe.

. Special precautions must be taken to avoid the generation of dust. Atmospheric concentrations of Millad 3988 should be kept below the recommended exposure standard for nuisance dusts:

TWA 10 mg/m^3 (20);

. The notified chemical should be stored in sealed anti-static containers away from sources of heat or ignition;

. Engineering controls such as enclosed systems should be used where possible;

. The work place should be well ventilated and if necessary local exhaust ventilation should be used;

. If work practices and engineering methods are insufficient to reduce exposure to the notified chemical to a safe level the following personal protection equipment which comply with Australian Standards should be worn:

  . dust mask (AS 1715, AS 1716) (21,22);

  . goggles as appropriate (AS 1336, AS 1337) (23,24);

  . PVC gloves (AS 2161) (25);

  . protective clothing (AS 3765.1, AS 3765.2) (26,27);

. Good housekeeping and maintenance should be practised. Spills should be cleaned up promptly. Personal protective equipment should be worn during cleaning;

. Good personal hygiene practices, such as washing of hands prior to eating food, should be observed; and

. A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

MSDS for Millad 3988 were provided in Worksafe Australia format (28) by Ciba Geigy Australia Ltd (Attachment 1), Hoechst Australia Ltd (Attachment 2) and ICI Australia (Operations) Pty Ltd (Attachment 3) as part of their notification statement. They are reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Ciba Geigy Australia Ltd, Hoechst Australia Ltd and ICI Australia (Operations) Pty Ltd.

Harcros Chemicals Pty Ltd, Shell Chemical (Australia) Pty Ltd and Tupperware Australia Pty Ltd may import Millad 3988, or mixtures containing Millad 3988, at a later date. At such time each of these companies will be required to submit their MSDS.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Millad 3988 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

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3. Report No. 13493. *Test to Evaluate the Acute Primary Cutaneous Irritation and Corrosivity, in the Rabbit*. Pharmacon Europe, 1993.

4. Report No. 13593. *Test to Evaluate Acute Ocular Irritation and Reversibility, in the Rabbit*. Pharmacon Europe, 1993.

5. Report No. 13693. *Test to Evaluate Sensitizing Potential in the Guinea-Pig: Guinea-Pig Maximization Test*. Pharmacon Europe, 1993.

6. OECD Guidelines for Testing of chemicals - *Acute Oral Toxicity* No: 401, 1981.

7. OECD Guidelines for Testing of chemicals - *Acute Dermal Toxicity* No: 402, 1981.

8. OECD Guidelines for Testing of Chemicals - *Acute Dermal Irritation/Corrosion* No: 404, 1981.

9. OECD Guidelines for Testing of chemicals - *Acute Eye Irritation/Corrosion* No: 405, 1987.

10. OECD Guidelines for Testing of chemicals - *Skin Sensitisation* No: 406, 1981.

11. Report No. 837/003. *Millad 3988 - 13 week oral (dietary admixture) toxicity study in the rat followed by a 4 week treatment-free period*. Pharmacon Europe, 1993.

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13. HWA Study No.: 15238-0-409R. *Mutagenicity Test on [Millad 3988] in the* Salmonella-Escherichia coli*/Mammalian-Microsome Reverse Mutation Assay with Confirmatory Assay*. Hazleton Washington, Inc., 1992.

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15. OECD Guidelines for Testing of chemicals - Escherichia coli, *Reverse Mutation Assay* No: 472, 1983.

16. HUK Study No.: 1054/4. *Study to Determine the Ability of Millad 3988 to Induce Mutations at the Thymidine Kinase (tk) Locus in Mouse Lymphoma L5178Y Cells Using a Fluctuation Assay*. Hazleton Washington, Inc., 1993.

17. OECD Guidelines for Testing of chemicals - In vitro Mammalian Cell Gene Mutation No: 476, 1984.

18. HUK Study No.: 1054/6. *Study to Evaluate the Chromosome Damaging Potential of Millad 3988 by Its Effects on Cultured Human Peripheral Blood Lymphocytes Using an* in vitro *Cytogenetics Assay.*. Hazleton Washington, Inc., 1993.

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