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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**FM-450**

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Director
Chemicals Notification and Assessment

**FULL PUBLIC REPORT**

**FM-450**

## 1. APPLICANT

Konica Business Machines Australia Pty Ltd, 22 Giffnock Avenue, North Ryde, NSW 2113.

## 2. IDENTITY OF THE CHEMICAL

| | |
|---|---|
| Chemical Abstract Service Registry Number (CAS No): | not available |
| Other name: | Halogen substitution-modified methyl methacrylate |
| Trade name: | FM-450 |
| Number-average molecular weight: | 2.53 x 105 + 2.0 x 104<br>lowest number-average molecular weight is 2.33 x 105 |
| Weight-average molecular weight: | 5.35 x 105 + 3.2 x 104 |
| Maximum percentage of low molecular weight species (<1000): | not more than 0.1% w/w |

Monomers:

| Chemical name | CAS No: | Weight percentage (% w/w) |
|---|---|---|
| 2-propenoic acid, 2-methyl -2,2,3,3,3-pentafluoropropyl ester | 45115-53-5 | 59.9 |
| 2-propenoic acid, 2-methyl -2,2,3,3-tetrafluoropropyl ester | 45102-52-1 | 20.0 |
| 2-propenoic acid, 2-methyl -methyl ester | 80-62-6 | 20.0 |

FM-450 is classified as a non-hazardous chemical to human health as it is not likely to cross biological membranes with a number-average molecular

weight of 2.53 x 105. For this reason, its chemical name, empirical formula and structural formula have been granted exemption from publication in the Full Public Report and Summary Report.

## 3. METHOD OF DETECTION AND DETERMINATION

Fourier Transform Infra Red Spectroscopy

Infra Red spectral data were provided for assessment.

## 4. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| Appearance: | the notified chemical is a colourless transparent solid but the formulated carrier is a dense brown powder |
| Vapour pressure: | estimated to be negligible as the notified chemical is a high molecular weight polymer |
| Water solubility: | insoluble in water |
| Solubility in organic solvent: | 700 g/L in methyl ethyl ketone @ 23oC |
| Hydrolysis: | stable in aqueous buffer solutions of pH = 1.2-9; on strong heating with acid or base, hydrolysis may occur producing carboxylic acids and alcohols. |
| Partition coefficient: | not provided as the notified chemical is insoluble in water |
| Adsorption/Desorption: | not provided as the notified chemical is insoluble in water |
| Dissociation constant: | not provided as the notified chemical is insoluble in water |
| Flash point: | not provided as the notified chemical has negligible vapour pressure |
| Flammability: | combustible |
| Combustion products: | toxic organic fumes such as carbon dioxide, carbon monoxide, hydrogen halide such as hydrogen fluoride and halogenated hydrocarbons |

| | |
|---|---|
| Autoignition temperature: | not provided as the notified chemical has negligible vapour pressure |
| Decomposition temperature: | 270oC |
| Decomposition products: | as for Combustion products |
| Explosive properties: | not provided as the notified chemical has negligible vapour pressure |
| Reactivity: | non-oxidising; stable under ambient conditions; hydrolysis may occur on strong heating with acid or base, producing carboxylic acid and alcohols |
| Particle size: | the formulated carrier containing the chem--ical has a particle size range of 40-150 µm |

**Comments on physico-chemical properties**

Attempts were made to test the solubility of the polymer by non-specific TOC measurement, and tests of stability (pH 1.2-9) showed that dissolved organic carbon was hardly present. (Residue was subjected to infra-red spectral measurement and the results were the same as those for the original substance). Literature supports that polyesters of this type are highly insoluble and difficult to hydrolyse.

No data were provided for Partition Coefficient, Adsorption/Desorption and Dissociation Constant. This is acceptable as the measurement and interpretation of results for these properties would be difficult. Such polymers are also likely to be immobile in soil.

## 5. PURITY

Degree of purity: 98.94% w/w

Toxic or hazardous impurities:

a) Chemical name: 2-propenoic acid, 2-methyl-methyl ester

Synonyms: acrylic acid, 2-methyl-,methyl ester; methyl methacrylate; methyl à-methylacrylate; methyl 2-methyl-2-propenoate; 2-methyl-2-propenoic acid methyl ester

CAS No: 80-62-6

Maximum residual content: 0.2% w/w

Toxic properties: tumorigen; mutagen; reproductive affector; skin and eye irritant (1)

b) Chemical name: L-dodecanethiol

Synonyms: dodecyl mercaptan; m-dodecyl mercaptan; 1-dodecyl mercaptan; lauryl mercaptan; m-lauryl mercaptan; 1-mercaptododecane

CAS No: 112-55-0

Maximum residual content: 0.05% w/w

Toxic properties: mutagen (1)

c) Chemical name: propanenitrile, 2,2'-azobis(2-methyl)

Synonyms: azobisisobutylonitrile; azobisisobutyronitrile; ?,?'-azobisisobutylonitrile; 2,2'-azobis(isobutyronitrile); 2,2'-azobis(2-methylpropionitrile); azodiisobutyronitrile; ?,?'-azodiisobutyronitrile; 2,2'-azodiisobutyronitrile; azodiisobutyronitrile; 2,2'-dicyano-2,2'-azopropane

CAS No: 78-67-1

Maximum residual content: 0.01% w/w

Toxic properties: not listed; oral LD50 in rats: 670 mg/kg (1)

Other impurities: (<1% w/w)

a) Chemical name: 2-propenoic acid, 2-methyl-2,2,3,3,3-pentafluoropropyl ester

CAS No: 45115-53-5

Maximum residual content: 0.6% w/w

b) Chemical name: 2-propenoic acid,2-methyl-2,2,3,3-tetrafluoropropyl ester

CAS No: 45102-52-1

Maximum residual content: 0.2% w/w

Additives/ Adjuvants: none

Maximum content of
residual monomers: 0.8% w/w

## 6. INDUSTRIAL USE

FM-450 will be imported as a formulated image carrier to be used in office photocopying machines. It will be used as a resin for the iron core carrier and will be present as a minor component (2-3% w/w) in the coating of the iron core carrier. Less than one tonne will be imported per year in the first five years.

## 7. PUBLIC EXPOSURE

Under normal use conditions, the potential for public exposure to FM-450 will be low. FM-450 will be present as a minor component of the image carrier and will be contained within the photocopier during its functional life thus not coming in contact with the photocopying paper. Used image carrier containing FM-450 will be disposed to landfill.

## 8. OCCUPATIONAL EXPOSURE

The notifier states that FM-450, a minor component (2-3% w/w) in a formulated image carrier, will be imported in 750 g plastic sachets packed 12 to a batch in 2 ply honeycomb cardboard boxes weighing 10 kg. Significant risk of exposure to the notified chemical during transport and storage is unlikely even in the event of an accident due to its low level in the formulated carrier and the limited amount (<1 tonne/year) imported.

No reweighing or repackaging will be carried out after importation. Office personnel who use the photocopiers do not recharge them when the formulated carrier needs replacing. The notifier states that only service engineers who replace the used formulated carrier in office photocopying machines may be exposed to the notified chemical.

The duration of exposure of the service engineers to the notified chemical is estimated to be 15 hours/service engineer/year. Approximately 140 service engineers could be involved with this process which is expected to take place up to twelve times a year and about 10 minutes for each change. If good work practices to minimise dust generation, and personal protection measures are not implemented, the service engineers may come into direct contact with the notified chemical. The major route of direct contact will be dermal as little airborne dust is anticipated because of the high specific gravity (s.g.) of the carrier (s.g.=3-7) as compared to that of air (s.g.=1). In the event of an exposure, the extent of exposure of these workers to the notified chemical is expected to be very low as it is present as a minor component (2-3% w/w) in the coating of the formulated carrier and moreover, it is insoluble in water and is non-volatile.

The notifier states that the notified chemical will be contained within the photocopier during its functional life and will not come in contact

with the paper during photocopying. Therefore, office workers who handle the photocopies will not be exposed to the notified chemical.

## 9. ENVIRONMENTAL EXPOSURE

### 9.1 Release

Significant release of the notified chemical during transport and storage is unlikely as the image carrier will be securely packaged in preweighed units. Environmental release during use is also unlikely as the image carrier will be well contained within the photocopier. However, during use, limited environmental release is possible during the loading and unloading of the image carrier but, the notifier asserts that service engineers who perform this task will implement good work practices to minimise such releases. As the image carrier does not come into contact with the photocopying paper, there will be no environmental release via this route. Therefore, the major route of environmental release is likely to be through the used image carrier discarded at landfill.

### 9.2 Fate

Any changes undergone by the notified polymer or the image carrier containing the notified polymer during the operation of the photocopier are not known. Thus it is assumed that the waste material discarded at landfill will contain the unchanged polymer.

Stability of the notified chemical over a range of pH values (pH 1.2-9) likely to be encountered at landfill suggests that it is unlikely to undergo abiotic degradation. Even though biodegradability data are not available, it is unlikely that microbial activity will degrade the notified chemical to any significant extent.

The large molecular weight, negligible water solubility and lack of hydrolysis of the notified chemical suggest that it is likely to remain soil-bound and leaching is unlikely to be significant.

## 10. EVALUATION OF TOXICOLOGICAL DATA

### 10.1 Genotoxicity

#### 10.1.1 Salmonella typhimurium and Escherichia coli reverse mutation assays (2)

FM-450 at concentrations of 10000, 3200, 1000, 320, 100 and 0 æg/plate was tested for gene mutation according to Ames (3) using Salmonella typhimurium strains TA100, TA1535, TA98 and TA1537, and Escherichia coli strain WP2 uvrA, both in the presence and absence of microsomal activation. Positive controls used were 2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide, sodium azide, 9-aminoacridine and 2-aminoanthracene. No dose-related increase in the number of revertant colonies was observed in any of the strains exposed to the FM-450 both in the presence or absence of microsomal activation. In contrast, the positive controls showed marked increases in the number of revertant colonies.

The results of this study suggest that FM-450 was not mutagenic under the experimental conditions reported.

### 10.2 Overall assessment of toxicological data

As the notified chemical will be imported at no more than one tonne in any one year, according to the Industrial Chemicals (Notification and Assessment) Act 1989, toxicological data specified in Part C of the Schedule are not required to be submitted for assessment. One genotoxicity study was submitted (2) and the results from this study suggest that FM-450 is not genotoxic.

## 11. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of number-average molecular weight >1000, according to the Industrial Chemicals Notification and Assessment Act 1989.

## 12. ASSESSMENT OF ENVIRONMENTAL HAZARD

Environmental exposure from the disposal of the used image carrier at landfill is unlikely to pose a hazard since the notified chemical is likely to remain soil-bound and unchanged.

The notified chemical, due to its high molecular weight and limited environmental release is unlikely to pose a significant environmental hazard.

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

FM-450 has a very high molecular weight (number-average molecular weight of 2.53 x 105 + 2.0 x 104) and as a result is not likely to cross biological membranes. Therefore it is expected to pose a very low health hazard. The notifier estimates that low molecular weight polymers (<1000) will amount to no more than 0.1% w/w, a concentration which is considered to be too low to present any hazardous concerns to humans (4). The notified chemical contains very low amounts of impurities (0.01 - 0.2% w/w) of which tumorigenic, mutagenic, teratogenic, skin sensitising or eye and skin irritant effects have been reported in animal studies (1). Each of these impurities are present at levels below their concentration cut-offs values for classification as a hazardous substance (4, 5) and are therefore not expected to present any hazardous concerns to humans. Similarly, as each residual monomer is present at <1% w/w, they are not expected to be hazardous to humans (4). A mutagenicity study (2) suggests that FM-450 is not genotoxic. However, due to the lack of toxicological data on this chemical and as it has only been used for approximately 18 months in Japan, prevention of direct contact with the notified chemical is recommended. To date, the notifier states that no adverse effects have been reported with the handling and use of this chemical overseas.

FM-450 is stable under ambient conditions, is insoluble in water, has negligible vapour pressure and is not explosive nor autoignitable. Therefore, it should not present any significant acute safety hazard to workers in the work environment. However FM-450 is combustible, producing toxic fumes such as carbon dioxide, carbon monoxide, hydrogen halides and halogenated hydrocarbons.

## 14. ASSESSMENT OF MATERIAL SAFETY DATA SHEETS

The Material Safety Data Sheet (MSDS) for FM-450 (Attachment 1) was provided in Worksafe Australia format (6). This MSDS was provided by Konica Business Machines 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 Konica Business Machines Australia Pty Ltd.

## 15. RECOMMENDATIONS FOR THE CONTROL OF PUBLIC AND WORKER EXPOSURE

To minimise public and worker exposure to FM-450, the following guidelines and precautions should be observed:

- as good work practice, photocopiers should be located in well ventilated areas to control the accumulation of dusts, gases and fumes;
- a copy of the MSDS should be easily accessible to all personnel who may be exposed to the chemical;
- service engineers who may come into contact with the chemical should:
    - wear appropriate gloves (for eg. cotton or impervious gloves) which comply with Australian Standard 2161 (7);
    - avoid the generation of a dust cloud; and
    - observe good personal hygiene practices;
- used formulations should be disposed in compliance with local regulations

Note: Guidance on general working practices associated with the operation of office copying machines is detailed in Worksafe Australia Guide on Office Copying Machines (8).

## 16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Industrial Chemicals (Notification and Assessment) Act 1989, secondary notification of FM-450 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

## 17. REFERENCES

1. Registry of Toxic Effects of Chemical Substances (RTECS) database, 1991.

2. Konica Corporation, Japan, "Microbial Metabolic Activation Test to Assess the Potential Mutagenic Effect of 13F (FM-450)". Data on file, Protocol No: 90-33-M, 1991.

3. Ames, B.N., McCann, J. and Yamasaki, E., Mutation Res. vol. 31, 1975, pp.347-364.

4. National Occupational Health and Safety Commission, Guidance Note for Determining and Classifying a Hazardous Substance, AGPS, Canberra, 1991.

5. National Occupational Health and Safety Commission, Consolidated List of Hazardous Substances, (in print).

6. National Occupational Health and Safety Commission, Guidance Note for the Completion of a Material Safety Data Sheet, 2nd. Edition, AGPS, Canberra, 1990.

7. Australian Standard 2161 - 1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves), Standards Association of Australia Publ., Sydney, 1978.

8. National Occupational Health and Safety Commission, Office Copying Machines, AGPS, Canberra, 1989.