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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Eastman Carboxymethylcellulose Acetate Butyrate

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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Holder of the original assessment certificate (No. 1646, LTD/1065):

Eastman Chemical LTD (ABN: 40 003 039 405) of Level 8, 15 Talavera Road, NORTH RYDE NSW 2113.

Applicant for an extension of the original assessment certificate:

Multichem Pty Ltd (ACN: 006 115 886) of Suite 5, 400 High Street, KEW VIC 3101.

NOTIFICATION CATEGORY

Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical name, CAS number, molecular and structural formula, molecular weight, spectral data, purity and impurities, analytical methods of detection and determination, import volumes and specific use.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Absorption/desorption coefficient, dissociation constant, flash point, explosive properties and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

A PMN has been made in the USA for this substance (submitted July, 1999)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Eastman Carboxymethylcellulose Acetate Butyrate

CMCAB

SPECTRAL DATA

ANALYTICAL The notified polymer can be identified by IR, UV/Vis or NMR. The notifier has provided

METHOD copies of the spectra.

3. COMPOSITION

DEGREE OF PURITY

High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

None

ADDITIVES/ADJUVANTS

None

POLYMER CONSTITUENTS

The polymer is comprised of monomers that are listed on AICS.

DEGRADATION PRODUCTS

The notified polymer is expected to be stable under normal conditions.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES No information available.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS The notified polymer is imported as a powder in 20 kg bags or drums.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	1	2	3	4	5
Tonnes	<10	<10	<10	< 30	< 30

USE

Component of surface coating for metal, plastic, and wood substrates.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Not known.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 20 kg bags or drums and transported to the notifier's warehouse. It will be transported by road to customer sites.

5.2. Operation Description

Manufacture

The notified polymer will not be manufactured in Australia.

Reformulation

The polymer is charged to a tank where it is mixed with solvents, pigments, other additive and water to form a coating, which is packed off on automatic filling lines into various-sized metal containers. The notified polymer is present in the final formulated coating at up to 20%, but typically 2-7%.

Application

The surface coating will be applied by spraying, rolling or brushing on wood, metal, plastic or other substrates, however, it is expected that the principal method of application will be by spray.

5.3. Occupational exposure

Number and Category of Workers

The transport and storage of the notified polymer will involve a maximum of four workers. At each customer site, between 20 and 80 workers will be exposed to the polymer.

Exposure Details

Exposure to the notified polymer during transport and storage is not anticipated except in the unlikely

event of an accident where the packages containing the notified polymer may be breached.

Dermal and inhalation exposure to the polymer may occur when the workers are weighing and introducing the polymer to the tank and during application of the coating. The reformulation and application operations are carried out under local exhaust ventilation.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Formulation of the coatings containing the notified polymer may occur at up to ten customer sites. Release during formulation and in container residues is expected to be less than 1% (equating to up to 300 kg at market maturity) as the powder residues are expected to be reused. Waste powder not reused is expected to be collected and disposed of by incineration or in landfill. Used containers will be recycled.

RELEASE OF CHEMICAL FROM USE

The coatings containing the notified polymer will only be used in a factory setting in industrial application. No DIY use is anticipated. It is anticipated that nearly 100% of the coatings will be applied by spray. We expect spray applications to take place in spray booths fitted with scrubbers to collect overspray.

The notifier indicates that an overall material loss rate of below 0.5% (150 kg at market maturity) will be required to be disposed of in the application process for the manufactured articles. The notifier expects the customer to properly dispose of wastes according to applicable environmental and industrial regulations, most likely by incineration or in landfill.

5.5. Disposal

Waste will be collected and disposed of by landfill or incineration.

5.6. Public exposure

The notified polymer will be used in industrial applications and will not be available for DIY use. The notified polymer will only become publicly available once cured on coated articles.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Solid, white powder

Melting Point 142°C

METHOD OECD TG 102 Melting Point/Melting Range.

EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.

Remarks

TEST FACILITY SafePharm (2001a)

Density $1253 \text{ kg/m}^3 \text{ at } 21^{\circ}\text{C}$

METHOD OECD TG 109 Density of Liquids and Solids.

EC Directive 92/69/EEC A.3 Relative Density.

Remarks

TEST FACILITY SafePharm (2001a)

Vapour Pressure $<1.3 \times 10^{-4} \text{ Pa at } 25^{\circ}\text{C}.$

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.

Remarks The vapour pressure was determined using a vapour pressure balance system. It

was measured over a temperature range to enable extrapolation to 25°C. Linear

regression analysis was used to calculate the vapour pressure at 25°C.

The result indicates that the notified polymer is very slightly volatile (Mensink et

al 1995).

TEST FACILITY SafePharm Laboratories (2001b)

Water Solubility <1 mg/L at 20°C

METHOD OECD TG 105 Water Solubility.

EC Directive 92/69/EEC A.6 Water Solubility (Shake-flask method).

Remarks The test substance (0.001 g) was added to 1 L of water in flasks and ultrasonicated

for 10 minutes at approximately 20°C. The water solubility of test samples was assessed visually to be clear and colourless with excess material present. No analysis could be performed as no method of recovery of the test material from aqueous media could be developed. Using WSKOWWIN a water solubility of 0.2

μg/L at 25°C was obtained.

TEST FACILITY SafePharm Laboratories (2001a)

Hydrolysis as a Function of pH Test not performed

Remarks A hydrolysis test could not be performed owing to the low water solubility of the

test item. In addition, no substance specific methods of analysis were available that would be capable of monitoring the test material and any degradation products.

TEST FACILITY SafePharm Laboratories (2001a)

Partition Coefficient (n-octanol/water) Test not performed

Remarks The log Pow could not be determined as the test item is insoluble in water and n-

octanol. An HPLC test was carried out, but the test item failed to elute from the column, even with 100% organic solvent. Computer predictions using KOWWIN estimated a log Pow of 6.2, however, this figure is based on smaller substructures

of the test material.

TEST FACILITY SafePharm Laboratories (2001a)

Adsorption/Desorption

Test not performed

Remarks The OECD test method is not applicable to the test substance as it contains organic

acid groups and has no suitable reference standard to calibrate it to. Furthermore, the test material is a high molecular weight reaction mixture/polymer and is unsuitable for HPLC estimation. QSAR estimations predict a log Koc of >5.12. The notified polymer is insoluble in water and thus is not likely to be mobile in

soil.

Dissociation Constant

Test not performed

Remarks The notifier indicates that the test was not performed because the test material is a

complex polymeric material. Based on the structural formula of the test substance, there is one functional group that can dissociate, carboxylic acid, which has an

approximate dissociate constant of 4.

Particle Size $41.6\% < 10 \mu m$

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (µm)	Cumulative Mass (%)	
> 10	41.6	
> 5	8.83	
> 2.5	1.37	
> 1.25	0.51	

Remarks The mass median aerodynamic diameter (MMAD) was 14.7 µm (mean of 3

determinations). All measurements were by a cascade impactor. Misleading

results were obtained by sieving.

TEST FACILITY SafePharm (2001a)

Flash Point Not applicable for a solid

Flammability Limits Not highly flammable

METHOD 92/69/EEC A.10 Flammability (solids).

Remarks The notified polymer is combustible and will burn in a fire, evolving noxious

fumes (oxides of carbon).

TEST FACILITY SafePharm (2001c)

Autoignition Temperature > 400°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

Remarks

TEST FACILITY SafePharm (2001c)

Explosive Properties Variation to data requirement

Reactivity

Remarks The notified polymer:

is not expected to have oxidising properties based on its structure and

experience in use.

• will react with strong oxidising agents.

• is stable under normal conditions

• will not undergo hazardous polymerisation

7. TOXICOLOGICAL INVESTIGATIONS

Only one toxicological study was provided.

7.8. Genotoxicity - bacteria

TEST SUBSTANCE CMCAB

METHOD OECD TG 471 Bacterial Reverse Mutation Test.

EC Directive 2000/32/EC B.13/14 Mutagenicity - Reverse Mutation Test

using Bacteria.

Plate incorporation procedure

Species/Strain S. typhimurium:

TA1535, TA1537, TA98, TA100

E. coli: WP2 uvrA

Metabolic Activation System

Concentration Range in a) With metabolic activation:

50-5000 μg/plate.

Main Test b) Without metabolic activation: 50-5000 μg/plate.

Vehicle acetone

Remarks - Method

RESULTS No significant increases in the frequency of revertant colonies were

recorded for any of the strains of bacteria, at any dose level either with or

without metabolic activation.

Remarks - Results The notified polymer was non-toxic to the strains of bacteria used in the

preliminary test (TA100 and WP2uvrA). In the main study, a white, fibrous precipitate was observed at and above 500 µg/plate but this did

not prevent the scoring of revertant colonies.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions

of the test.

TEST FACILITY SafePharm (2001d)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

No toxicological data were provided.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release

Based on the use pattern and environmental releases, it is expected that exposure to the notified polymer in the environment will be low. The notified polymer is imported in powder form. No release to sewer is anticipated during formulation or application of the spray paint. The notifier expects wastes generated during formulation will be less than 1% (300 kg at market maturity) as the powder can be reused, and wastes generated during spray application to manufactured articles will be less than 0.5% (150 kg at market maturity) of the notified polymer. However, losses through overspray during application can be as high as 30%.

Assuming as a worst case that 30% of the entire import volume at market maturity is collected as overspray in spray booths, approximately nine tonnes of the notified polymer may require disposal each year. The polymer wastes are expected to be disposed of in an inert, hardened form either in landfill or by incineration.

Fate

The notified polymer is a high molecular weight polymer, which is very slightly volatile, and is insoluble in water. Once the paint is dried, the polymer will become inert by the hardening process. Therefore, leaching in landfill is unlikely to occur. Abiotic or slow biotic processes are expected to be largely responsible for the degradation of the notified chemical disposed of to landfill. Incineration would result in the production of water and oxides of carbon.

Should the polymer enter the aquatic environment via the sewer, it is expected to partition to sludge, from where it may enter landfill during land disposal of the sludge. In view of the high molecular weight and low water solubility, the bioaccumulation potential is considered to be low (Connell 1990).

9.1.2. Environment – effects assessment

No ecotoxicological data were submitted.

9.1.3. Environment – risk characterisation

The majority of the notified polymer will be incorporated in coatings on manufactured articles and should become inert by the hardening process. Up to 9 tonnes of waste could require disposal each year as a result of overspray. This material is expected to be landfilled in an inert and hardened form, or may be incinerated. The environmental risk to the aquatic environment is considered to be low under the reported use pattern.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Workers involved in the weighing and introduction of the notified polymer to the formulation tank may be dermally and inhalationally exposed to the notified polymer. Due to the small particle size of the notified chemical (41.6% < 10 μ m), intermittent dust generation during the weighing and addition of the notified polymer to the tank is expected. Weighing and introduction of the notified polymer to the tank is carried out under local exhaust ventilation and workers wear protective clothing and gloves during these processes.

The coating containing the notified polymer is applied via brush, roller, or spray and dermal exposure is possible through these application routes. Generation of aerosols during spraying may also lead to inhalation and ocular exposure, however this exposure will be reduced under local exhaust ventilation. Personal protective equipment, including respiratory protection may be worn during paint application.

9.2.2. Public health – exposure assessment

The extent of public exposure to the notified polymer via coated articles has not been determined, however, in this form the notified polymer exists in the form of a solid coating and as such is not bioavailable.

Indirect public exposure is unlikely during formulation and application of the coating, nor during transport of the notified polymer.

9.2.3. Human health - effects assessment

The notified polymer was not mutagenic in a Bacterial Reverse Mutation Test. No other toxicity data were submitted. The polymer is a high molecular weight polymer (Mn > 10~000) making absorption unlikely. It is not expected to be irritating to skin or eyes, or to be a skin or respiratory sensitiser.

The notified polymer is imported as a powder with a Mass Median Aerodynamic Diameter of $14.7 \, \mu m$. Approximately 41.6% of the powder consists of particles with a diameter of less than $10 \, \mu m$ which may reach the lower bronchioles and alveolar regions of the lung following inhalation (NOHSC, 1995).

9.2.4. Occupational health and safety – risk characterisation

Opportunity for exposure to the notified polymer exists during the reformulation of the polymer into the final coating product and during the application of the product. The notified polymer has no reactive functional groups of a high or moderate concern, and is of high molecular weight, so it is expected to be of low toxicity. The powder form of the notified polymer, however, contains a proportion of respirable particles that may, if inhaled, result in alveolar deposition.

Therefore, the risk of systemic toxicity is low and the risk of adverse effects resulting from inhalation of fine particles is reduced through use of local exhaust ventilation during weighing and addition operations. The NOHSC exposure standard for nuisance dust is 10 mg/m3 TWA (NOHSC, 1995) Australia does not have a national exposure standard for respirable dust, however, the ACGIH TLV is 3 mg/m³ TWA (ACGIH, 2001).

Additionally, spray application of the formulation of the notified polymer may also pose an inhalation risk through generation of aerosols containing the notified polymer during spraying. Engineering controls are expected to obviate inhalation exposure and workers wear protective clothing and gloves to minimise dermal contact. Therefore, the risk associated with the notified polymer during application, is considered low given the reliance on local exhaust ventilation for respiratory protection against dust and aerosols.

9.2.5. Public health – risk characterisation

The notified polymer is of low hazard and presented in articles in a form that is not likely to lead

to significant public exposure. The risk to public health is considered negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a).

10.2. Environmental risk assessment

The notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is low concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is negligible concern to public health when used solely in industrial applications.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDSs for the notified polymer and products containing the notified polymer provided by the notifier and by the extension applicant were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicants.

11.2. Label

The labels for the notified polymer and products containing the notified polymer provided by the notifier and by the extension applicant were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the labels remains the responsibility of the applicants.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Spray application of the paint containing the notified polymer should be conducted in accordance with the NOHSC Spray Painting National Guidance Material (NOHSC, 1999).
- Avoid generation of dust clouds when handling the notified polymer.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - Dust mask with appropriate filter
 - Goggles
 - Gloves
 - Overalls

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

 Atmospheric monitoring should be conducted to measure workplace concentrations of total and respirable dust during handling of the notified polymer and ensure that these concentrations do not exceed the NOHSC (1995) exposure standard of 10 mg/m³ TWA, or the ACGIH value of 3 mg/m³ TWA for respirable dust (ACGIH, 2001).

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

• Do not allow material to enter drains, sewers or watercourses.

Disposal

• The notified chemical should be disposed of in landfill or be destroyed through incineration.

Emergency procedures

• Spills/release of the notified chemical should be handled by shovelling up and placing in a container for salvage or disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under sub-section 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

ACGIH (2001) The American Conference of Governmental Industrial Hygienists (ACGIH): Threshold Limit Values for Chemical Substances and Physical Agents and Biological Indices 2001; ACGIH Cincinnati, Ohio.

Connell DW (1989) General characteristics of organic compounds which exhibit bioaccumulation. In: Connell DW ed. Bioaccumulation of xenobiotic compounds. Boca Raton, USA, CRC Press, pp 47-57.

Mensink BJWG. Montforts M, Wijkhuizen-Maslankiewicz L, Tibosch H. and Linders JBHJ (1995) Manual for summarising and evaluating the environmental aspects of pesticides. National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands. Report No. 679101022.

NOHSC (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1994b) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1995) Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:3008(1995)] & [NOHSC:1003(1995)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1999a) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (1999b) National Guidance Material for Spray Painting. National Occupational Health and Safety Commission, Canberra, AusInfo.

SafePharm Laboratories (2001a) CMCAB: Determination of General Physico-chemical Properties Project Number: 1328/018. SafePharm Laboratories Limited, Derby, UK. Unpublished report provided by notifier.

SafePharm Laboratories (2001b) CMCAB: Determination of Vapour Pressure Project Number: 1328/020. SafePharm Laboratories Limited, Derby, UK. Unpublished report provided by notifier.

SafePharm Laboratories (2001c) CMCAB: Determination of Hazardous Physico-chemical Properties Project Number: 1328/019. SafePharm Laboratories Limited, Derby, UK. Unpublished report provided by notifier.

SafePharm Laboratories (2001d) CMCAB: Reverse Mutation Assay "Ames Test" using Salmonella Typhimurium and Escherichia Coli Project Number: 1328/013. SafePharm Laboratories Limited, Derby, UK. Unpublished report provided by notifier.