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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Melio Tex SP 3948

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**Melio Tex SP 3948****1. APPLICANT**

Assessment of Melio Tex SP 3948 (formerly identified as Aqualen Top D2012) was carried out under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) as NA/131, with the Summary Report published in the *Chemical Gazette* of March 1994.

In the initial notification the import volume was estimated to be 0.65 tonnes per annum for the first five years. Clariant (Australia) Pty Ltd (formerly Sandoz Australia Pty Ltd) notified the Director that the quantity of Melio Tex SP 3948 will now exceed 100 tonnes per annum in the near future.

Under Section 65 of the Act the Director published a notice in the *Chemical Gazette* of 4 May 1999, requiring the secondary notification of Melio Tex SP 3948 by Clariant (Australia) Pty Ltd. This notice stipulated that the following additional data were required to undertake further assessment of the notified polymer:

Part A Summary of Notification

Part B Identity, Properties and Use:

B.1 Identity of Chemical

B.1.d CAS Number

B.1.e Molecular/Structural Formula

B.2 Composition

B.3 Use

B.5 Manufacture/Import Volume

B.6 Occupational Health and Safety

B.7 Environmental Impact

B.9 Physical and Chemical Data

B.9.d Water Solubility

B.11 Label

B.12 MSDS

Part D Polymer Information - Identity and Composition

This report represents the revised assessment for Melio Tex SP 3948 when introduced in quantities of 100 to 150 tonnes per annum. In addition, in the period since the original notification, the methods of preparation and use of the leather finishing formulations have become more automated. Therefore, occupational health and safety has been re-assessed.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition and details of exact formulation concentration have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name: Melio Tex SP 3948;

Formulation Names: Melio Foam R05 – aqueous dispersion containing the notified polymer in the range 30 to 60%;
Melio Promul 66 – aqueous dispersion containing the notified polymer in the range 30 to 60%;
The product Aqualen Top D2012, containing the notified polymer, identified in Assessment Report NA/131 has been superseded and is no longer used.

Method of Detection and Determination: Infrared (IR) Analysis

Spectral Data: An IR spectra was submitted for the identification of the notified polymer.
A Gel Permeation Chromatography trace was supplied to determine the NAMW.

3. PHYSICAL AND CHEMICAL PROPERTIES

Properties listed below refer to the aqueous dispersion, Melio Promul 66 containing the notified polymer at 30 to 60% w/v.

Appearance at 20°C and 101.3 kPa: Opaque, white liquid

Boiling Point: 100°C

Specific Gravity: 1.0

Vapour Pressure: 2.3 kPa at 25°C

Water Solubility: miscible

Particle Size: Aqueous dispersion

Partition Co-efficient (n-octanol/water):	Not determined
Hydrolysis as a Function of pH:	Not determined
Adsorption/Desorption:	Not determined
Dissociation Constant:	Not determined
Flash Point:	None up to boiling point
Flammability Limits:	Non flammable
Autoignition Temperature:	Not self igniting
Explosive Properties:	Not explosive
Reactivity/Stability:	Stable and will not decompose under normal storage and handling conditions

Comments on Physico-Chemical Properties

The polymer was never isolated as a defined entity but manufactured as an aqueous dispersion/emulsion. The notifier did not determine either the boiling point or vapour pressure of the notified polymer. The vapour pressure of the polymer solution would be expected to be that of water.

The notifier did not determine the water solubility of the notified polymer. At a particular concentration, the polymer may dissolve in water to form a totally clear dispersive solution through micelle formation since it is positively charged. However, because of its hydrophobicity, once past this solubility concentration the polymer will form either a cloudy emulsion or a water-white milky liquid.

The polymer contains amide and ester linkages and could be expected to undergo hydrolysis under extreme pH. However, this is unlikely in the environmental pH range of 4 to 9.

Because the polymer is surface active no meaningful results can be obtained from measurements of octanol-water partitioning, adsorption/desorption and dissociation. The notified polymer is expected to be insoluble in water and will largely partition into non polar media. Therefore, the polymer is expected to become associated with the organic component of soils and sediments.

No dissociation constant was provided for the notified polymer. The polymer has no units likely to dissociate but contains a small percentage of fully dissociated carboxylic acid ammonium salt groups with the pKa expected to be in the range 3 to 5.

4. PURITY OF THE CHEMICAL

Degree of Purity:	100%
Hazardous Impurities:	None
Non-hazardous Impurities (> 1% by weight):	None
Additives/Adjuvants:	Not applicable

5. USE, VOLUME AND FORMULATION

Use

The notified polymer is used as an ingredient in leather finishing in tanneries.

Import Volume

The notified polymer will not be manufactured in Australia. It will be imported at 100 to 150 tonnes per year, either in 1 000 L Schultz containers or 120 L plastic drums in products identified as Melio Promul 66 or Melio Foam R05, each containing the notified polymer in the range of 30 to 60%.

Formulation and Leather Treatment Process

The products will be delivered either directly to customers or held by the notifier before distribution to customers. No repackaging or reformulation will take place prior to delivery to customers.

Melio Promul 66 or Melio Foam R05 will be used at major tanneries, as well as a number of smaller ones.

At the customer site, the leather treatment agent is prepared by computer controlled pumping of ingredients (Melio Promul 66 or Melio Foam R05, water, pigments, fillers and waxes) directly from packaging into a 1 000 L mixing vessel. The leather treatment liquor containing less than 30% of polymer is applied to the leather in a conveyor system that comprises roller application, spray application, drying and stacking of finished hides. After passage through drying chambers, the polymer becomes crosslinked and fixed to the leather.

6. OCCUPATIONAL EXPOSURE

Leather Treatment Process

<i>Category of Worker</i>	<i>Number of Workers</i>	<i>Maximum Exposure</i>	<i>Personal Protective Equipment</i>
Storeworker	12	30 minutes/day, 12 days/year;	safety glasses, protective gloves;
Mixing operators	10	2 hours/day, 50 days/year;	protective aprons, safety glasses, PVC gloves;
Technicians	5	1 hour/day, 50 days/year;	safety glasses, protective gloves;
Leather treatment operators	18	4 hours/day, 75 days/year.	safety glasses, PVC gloves.

Nature of Work Done

Transport workers deliver the imported solution directly to the notifier or customers. Exposure is expected to be limited to spills.

Storeworkers move palletised product drums or Schutz containers by forklift. Worker exposure is not expected except in the event of a spill.

The leather treatment liquor is prepared by computer-controlled pumping of the ingredients from raw material containers into a mixing vessel. Mixing operators may be exposed to the notified polymer by skin contact during manual connection/disconnection of pump lines from the original import container. After blending of the liquor, the vessel is moved by forklift to the conveyor system.

Quality control technicians may be exposed to small amounts of the notified polymer during sampling of vessel contents and during spray application of the liquor onto leather samples in a spray cabinet.

Leather treatment operators supervise the treatment of leather in automated spray or roller coating booths. Worker exposure may occur as pumping equipment is connected to containers in which the leather liquor treatment is held. After hides have been treated by roller coating with a treatment base coat, worker exposure can also occur as hides are manually assisted from the engraved rollers to a spray coating chamber or to a drying chamber. The treated leather moves automatically through drying tunnels where the polymer becomes crosslinked and fixed to the leather substrate and is not bioavailable. The conveyor system is semi enclosed during spray application and drying and a negative pressure exists in the spray chamber to prevent vapours being released into the work area.

End users of the treated leather would have negligible exposure to the treated leather as the polymer would be cross linked to the leather protein and not separately available for exposure or absorption.

7. PUBLIC EXPOSURE

The public is unlikely to be exposed to the notified polymer during importation and transport to tanneries.

Public exposure will occur when it is used as a component in leather surface coatings. However, the notified polymer is not available for use by members of the general public and, after application of the leather treatment to hides, the notified polymer is bound to the leather and does not create a risk for the public when exposed to upholstery covered with treated leather.

8. ENVIRONMENTAL EXPOSURE

Release

After importation by sea the polymer will be transported by road without repackaging in 1 000 L Schultz containers and 120 L plastic drums; potential release would only be through accidental spills. The Material Safety Data Sheet (MSDS) details procedures to protect the environment in these cases. Once received by customers, the containers are emptied and the polymer formulated. Drums are rinsed with water and the rinsate added to the leather treatment formulation. The notifier indicates that 400 g of product may remain in each drum. For 1 000 Shultz containers, up to 10 L of product may remain after emptying.

The polymer formulation is applied to leather by either roller coating by the gravure process or by spraying. The notifier indicates that roller coating results in very little or no loss. Generally, the only losses generated are through the cleaning of the application equipment. Based on experience from previous assessments, this would amount to about a 2% loss of polymer formulation. The notifier indicates that one third of the introduced polymer will be applied to leather by roller coating. This will result in approximately 1 tonne of polymer waste.

When sprayed onto leather in a semi-enclosed area, 20% of the polymer formulation will be lost by overspray. If two thirds of the introduced polymer are applied by spraying, approximately 20 tonnes of polymer waste will be produced.

Fate

The fate of the bulk of the polymer will be tied to the fate of the finished leather. Most of the treated leather will be disposed of to landfill, either as trimmings during the making of leather articles or when the goods are finally discarded.

The waste polymer formulation from the cleaning of roller coating equipment and overspray capture from the spray chamber water bath is diverted to the tannery wastewater treatment

plant. Here either acid or alkali is added to break down emulsions. Solid materials are collected by flotation, filter pressed and partially dried. Licensed waste disposal companies collect the solids. Liquid waste is discharged to sewer.

Empty containers and drums are sent to licensed container recycling companies.

Polymer released to soil in either a spill or leak from a storage container, is expected to bind strongly to soil due to its negligible water solubility. If released to an aquatic environment, the polymer would tend to partition out of water and into sediment. Once adsorbed to soil/sediment, the fate of the polymer is unknown. A ready biodegradability of a 59% was obtained with a similar polymer, Promul 68, which differs only in the chain extender from the polymer in Melio Tex SP 3948. This is below the 70% limit for ready biodegradation defined by the test protocol, indicating that the polymer is significantly degraded. Similar consideration suggests that residues of the notified polymer consigned to landfill will slowly degrade. Significant leaching appears unlikely, although the notified polymer, as an emulsion, may move with bulk water flow.

The polymer is not expected to cross biological membranes, due to the low solubility and high molecular weight, and as such should not bioaccumulate (Connell, 1989).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

An acute oral toxicity study on Melio Promul 68 was submitted. The polymer in Melio Promul 68 differs from the notified polymer only in the chain extender.

Table 1 Summary of the acute toxicity of Melio Promul 68

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD ₅₀ >5 000 mg/kg	Safepharm, 1987

9.1.1 Oral Toxicity

This study was carried out according to OECD TG 401.

A single dose of 5 000 mg/kg of Melio Promul 68 at a dose volume of 4.85 mL/kg was administered by gavage to Sprague-Dawley rats (5/sex). The animals were observed at 1 and 4 hours after dosing and subsequently once daily for 14 days. No deaths were noted during the study. All animals showed the expected gain in body weight over the study period. No abnormalities were noted at necropsy.

The results of this study indicate an oral LD₅₀ of >5 000 mg/kg for Melio Promul 68 in male and female rats. Melio Promul 68 has very low acute oral toxicity in rats and does not meet the criteria for classification as hazardous for this toxicological end point (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Two ecotoxicity studies on Melio Promul 68 were submitted. The polymer in Melio Promul 68 differs from the notified polymer only in the chain extender.

<i>Test</i>	<i>Species</i>	<i>Outcome</i>
acute toxicity	<i>Daphnia sp</i>	EC ₅₀ for 128.5 mg/L
	waste water microorganisms:	IC ₅₀ > 100 mg/L

The notifier did not supply full test reports to substantiate these results for Promul 68. However, these results indicate that the notified polymer, Melio Tex SP 3948 would be expected to be practically non-toxic to daphnia and microorganisms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Most of the notified polymer will be disposed of to landfill with the leather to which it is cured. There should be no environmental hazard from such disposal.

Approximately 21 tonnes in total of polymer waste will be generated at all tanneries. If we assume that the notified polymer will be used at only the five major tanneries, typical water use per day is 240 000 L each treatment takes place 365 days per year, the concentration of notified polymer in the effluent discharged per day to the on-site wastewater treatment plant at a single tannery would be approximately 48 mg/L. Due to insolubility in water, approximately 95% of polymer waste is expected to be trapped during treatment processes and disposed of to landfill. The concentration of notified polymer in the effluent discharged to sewer would, therefore, be approximately 2.4 mg/L. If we assume a water discharge of 5 ML for a rural sewer treatment plant then the concentration of notified polymer in the effluent discharged from the plant would be approximately 4.8×10^{-7} mg/L. This represents an environmental safety margin of several orders of magnitude for exposure to the most sensitive aquatic organism, *Daphnia magna*, as judged from results on a related polymer.

Once in the aquatic environment, the chemical is also expected to dilute even further to undetectable concentrations, dissipate to sediment and undergo slow biotic and abiotic degradation.

Given the above, environmental exposure and the overall environmental hazard is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer has been in use in Australia since granting of the Assessment Certificate in 1994. The notifier states that during that time there have been no known injuries or disease resulting from worker exposure to the polymer.

The notified polymer is a polyurethane, of very high molecular weight, low residual monomer content and lacks functional groups of high concern. Therefore, it generally expected to have low reactivity and, consequently low toxicity.

Based on the toxicology of Melio Promul 68, a product containing a polymer similar to the notified polymer, the notified polymer is expected to have very low acute oral toxicity and would not be considered a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) for this toxicological end point.

Occupational Health and Safety

During import and transport of the notified polymer, there is unlikely to be worker exposure, except in the event of a spill. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier. No risk to health is expected for transport and storage workers given the predicted low hazard of the notified polymer.

The leather treatment process is described as a mostly enclosed, automated system, with negative pressure ventilation. Worker exposure is expected to be limited to dermal contact to drips and spills as pumps and hoses are connected to mixing vessels and spray coating chambers, during quality control testing and handling of treated hides. Worker tasks are expected to occupy less than two or four hours a day, during these activities and exposure will be minimised by the use of PVC protective gloves, safety glasses and coveralls. Under normal use conditions, exposure would be controlled by the engineering controls and personal protective equipment as proposed by the notifier. Therefore, no significant risk to health is expected from its use under the described conditions. Moreover, no significant risk is expected for end users of the treated leather as the polymer would be cross linked to the leather protein and not available for separate exposure or absorption.

Public Health

The public is unlikely to be exposed to the notified polymer during importation and transport to tanneries.

Public exposure will occur when it is used as a component in leather surface coatings. However, the notified polymer is not available for use by members of the general public and, after application of the leather treatment to hides, the notified polymer is bound to the leather and does not create a risk for the public when exposed to upholstery covered with treated leather.

Based on the above information, it is considered that the notified polymer will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Melio Tex SP 3948 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand. (1992).); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1994) and AS 3765.1 (Standards Australia, 1994); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

If the conditions of use are varied from the notified use, greater exposure of the public to the product may occur. In such circumstances, further information may be required to assess the hazards to public health.

14. MATERIAL SAFETY DATA SHEET

The MSDS for Melio Promul 66 was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under section 64 of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

Connell DW. (1989) General Characteristics of Organic Compounds which Exhibit Bioaccumulation. In Connell DW (Ed) Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton.

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

NOHSC. (1999). Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Australian Government Publishing Service, Canberra.

Safepharm (1987). Melio Promul 68 Acute Oral Toxicity to the Rat. Project No. 47/166, Safepharm Laboratories Limited.

Standards Australia. (1987). AS 2919-1987, Australian Standard Industrial Clothing. Standards Australia: Sydney.

Standards Australia. (1994). AS 1336-1994, Australian Standard Eye protection in the Industrial Environment. Standards Australia: Sydney.

Standards Australia. (1998). AS/NZS 2161.2:1998, Australian/New Zealand Standard Occupational Protective Gloves Part 2: General Requirements. Standards Australia and Standards New Zealand: Sydney/Wellington.

Standards Australia/Standards New Zealand. (1992). AS/NZS 1337-1992, Australian/New Zealand Standard Eye Protectors for Industrial Applications. Standards Australia and Standards New Zealand: Sydney/Wellington.

Standards Australia/Standards New Zealand. (1994). AS/NZS 2210-1994, Australian/New Zealand Standard Occupational Protective Footwear. Standards Australia and Standards New Zealand: Sydney/Wellington.