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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

AQUALEN TOP D2012

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989, as amended* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health, Housing, Local Government and Community Services.

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**AQUALEN TOP D2012****1. APPLICANT(S)**

Sandoz Australia Pty Ltd, 675 Warrigal Road, Chadstone, Victoria 3148.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, Aqualen Top D2012 is not considered to be hazardous. Therefore, the details of chemical name and monomer composition have been exempted from publication in the Full Public Report.

Trade name: Aqualen Top D2012
(product, containing 13% of the notified polymer)

Molecular weight:

Number-average molecular weight: 177000 (average)
The number-average molecular weight of the lowest weight composition is approximately 10,000

Maximum percentage of low molecular weight species (molecular weight < 1000): < 1% (estimate)

Method of detection and determination: Gel permeation chromatography; infra-red spectroscopy.

Spectral data: An infra-red spectrum was provided with major peaks at 1100, 1160, 1230, 1300, 1360, 1390, 1460, 1540 1730 cm⁻¹.

3. PHYSICAL AND CHEMICAL PROPERTIES

All properties listed below refer to the product containing the notified polymer unless otherwise specified.

Appearance at 20°C and 101.3 kPa:	White, milky liquid
Odour:	Not identified
Boiling Point:	Approximately 100°C
Glass-transition Temperature:	Not applicable
Density:	1030 kg/m ³
Vapour Pressure:	2.3 kPa at 25°C
Water Solubility:	A dispersion in water, low solubility is expected
Fat Solubility:	Not determined
Partition Co-efficient (n-octanol/water) log P_{O/W}:	Not determined
Hydrolysis as a function of pH:	
Adsorption/Desorption:	Not determined
Dissociation Constant pK_a:	Not applicable
Flash Point:	Not applicable (chemical is a non-flammable aqueous dispersion)
Flammability Limits:	Not flammable
Combustion Products:	Not determined
Pyrolysis Products:	Not determined

Decomposition Temperature:	Not applicable
Decomposition Products:	Not applicable
Autoignition Temperature:	Not determined
Explosive Properties:	Not explosive
Reactivity/Stability:	Stable and will not decompose under normal storage and handling conditions
Particle size distribution:	Not applicable

. **Comments on physico-chemical properties**

The notifier states that there is no data on water solubility for the notified polymer. It is prepared as an aqueous dispersion and as such it is infinitely miscible with water. The solubility should be clarified if the import volume rises above 1 tonne.

The polymer contains a number of carbamate and amide linkages and as the polymer is infinitely miscible with water, it may be susceptible to hydrolysis, though this would be expected to be minimal under environmental conditions.

4. PURITY OF THE CHEMICAL

Degree of purity (of the notified chemical alone): 99% polymeric material

Maximum content of residual monomer(s): None

Additive(s)/Adjuvant(s): None

5. INDUSTRIAL USE

The notified polymer will be imported as a component of Aqualen Top D2012 which will be used as a surface coating in leather finishing. The estimated quantity of Aqualen Top D2012 imported will be 5 tonnes per year for the next five years. As the

notified polymer will constitute 13% of the product, this equates to approximately 0.65 tonnes of polymer being imported per annum.

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported in sixty litre plastic carboys and delivered directly to the warehouse, and from there to three tanneries (Melbourne, and Queensland) in the same containers. The product will not undergo any reformulation or packaging in Australia. At each tannery 10 workers will be exposed to the notified polymer during the leather finishing process. The finish coat for leather is prepared by diluting the product with water. The finish coat is applied manually or with an automatic spray gun in an enclosed booth or by a roller coater under positive ventilation.

It is envisaged that the workers will be exposed for approximately one hour a day during the preparation of the finish coat and quality control checks. During warehousing and transportation exposure is expected to be limited to accidental spills.

7. PUBLIC EXPOSURE

The public may not be exposed to the notified polymer during application to leather. However, the public may come into contact with the polymer as a component (13%) of surface coatings in finished leather products.

8. ENVIRONMENTAL EXPOSURE

. Release

The notifier states that environmental release to the atmosphere is unlikely with this product as it is applied, as a spray, in a closed system equipped with water scrubbing. Losses during the spraying process are estimated to be between 10-15%. The scrubbing water is collected and treated in the tanneries' effluent treatment system. Solids are precipitated and removed from the effluent stream and the waste water is subject to water supply authorities' regulations.

The notifier estimates that the amount of chemical released to the environment when the product is applied by roller is nil. Given the large molecular weight of the polymer it is unlikely to be volatile and should not be released to the environment during this process.

During transport risk of environmental release is limited to incidents involving accident or a leaking drum.

Fate

The polymer may be discharged to sewer or be removed with tannery wastes during treatment. Due to the low solubility of the polymer, the majority of the polymer is expected to be absorbed to the waste and be disposed of by landfill or incineration. Any of the notified substance that is not absorbed will be discharged to the wider aquatic environment where it will be adsorbed to sediment and suspended particulates and not likely to persist due to its biodegradability.

A similar polymer, Promul 68, which differs only in the chain extender from the polymer in Aqualen Top D2012, was tested for biodegradability (OECD Guideline for Testing of Chemicals 301 Part E). This test showed 59% degradation, which is below the 70% limit for ready biodegradation defined by the test protocol, but does indicate that the polymer degraded to a significant extent. Persistence of the notified polymer should therefore be low to moderate.

Similar considerations lead to the expectation that residues consigned to landfill will slowly degrade. Significant leaching appears unlikely, although the notified substance, as a colloidal suspension, may move with bulk water flow.

No data was presented on the bioaccumulation of the polymer in Aqualen Top D2012 which is acceptable considering the molecular weight (NAMW>1000).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

In the study described below, Melio Promul 68 is used. This product contains a similar polymer to that notified. It differs from the notified polymer only in the chain extender.

Toxicological data are not required under the *Industrial Chemicals (Notification and Assessment) Act, 1989*, for polymers with a NAMW >1000. However, for the polymer containing Aqualen Top D2012 data on acute oral toxicity from a similar polymer (Melio Promul 68) was included in the submission.

Table 1 Summary of the acute toxicity of Melio Promul 68

Test	Species	Outcome	Reference
Oral	rats	LD ₅₀ >5000 mg/kg	(1)

9.1.1 Oral Toxicity (1)

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 401 (2)

A single dose of 5000 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 >5000 mg/kg for Melio Promul 68 in male and female rats.

9.2 Overall Assessment of Toxicological Data

Melio Promul 68 has low acute oral toxicity in rats.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Tests showed that a very similar polymer, Promul 68, was found to be practically non-toxic to daphnia (OECD Guideline for Testing of Chemicals 202 Part I; $EC_{50}=128.5\text{mg}\cdot\text{L}^{-1}$) and non-toxic to waste water bacteria ($IC_{50}>100\text{mg}\cdot\text{L}^{-1}$).

The notified polymer has a number average molecular weight >1000 and therefore unlikely to cross biological membranes.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notifier estimates the amount of waste spray to be between 10% and 15% of that applied. A typical formulation involves a dilution of Aqualen Top D2012 of 1 in 3.

Assuming a maximum of waste spray of 15%, the amount of chemical lost during spray operations is 0.65%. This is based on the percentage of polymer in Aqualen Top D2012 (13%) multiplied by the dilution of Aqualen Top D2012 (1:3) multiplied by the maximum percentage waste spray (15%). Therefore 19.5 kg of polymer will be lost for each 1000 kg of Aqualen Top D2012 used. The estimated release to the environment of the notified chemical is 97.5 Kg/year. Assuming that half of this is released at one tannery and that there is 240 000 L of liquid waste per day (typical values), the effluent will contain 0.92 ppm of the polymer. This assumes that all of the polymer sprayed onto the leather will be bound to the leather and not removed in subsequently operations.

The tanneries effluent is treated to remove solids by precipitation and the waste water is then subject to the local water supply authorities regulations. The tanneries solid waste (amount?) is disposed of in landfill. Assuming that all the polymer is in the waste, water, worst case scenario, i.e. 0.92 ppm, then there will be further dilution in the municipal sewerage and for a rural town there will be an estimated further dilution of 20 fold (population 20 000, 5 ML waste water per day)

to give an environment release of 46 ppb. This is more than three orders of magnitude below the EC50 for daphnia. It is likely that most of the polymer will be in the solid waste, at the tannery or the sewage treatment works, with little in the waste water. The actual release is expected to be significantly less than 46 ppb as a result of incorporation in the solid wastes.

Due to the large molecular weight of the polymer it is not expected to bioaccumulate and will biologically degrade, thus it will not build up in the environment. The Environmental hazard of Aqualen Top D2012 and the polymer is expected to be low due and with the small quantities to be imported it will not present an environment hazard.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

There is no information on the effect of Aqualen Top D2012 on human exposure. Based on the results of animals studies on a similar polymer (Melio Promul 68), the notified polymer may have low acute oral toxicity.

Aqualen Top D2012 has low vapour pressure is not explosive is not flammable and is non-reactive under normal use conditions.

The maximum exposure of each worker to the notified polymer is one hour a day during preparation of the finish coat and quality control checks. The application of the finish coat is carried out in an enclosed booth or under positive ventilation. Under normal use conditions, given the physico-chemical profile of the notified chemical together with the engineering controls, this exposure is unlikely to result in any adverse health effects.

The public is unlikely to be exposed to the notified polymer during importation and transport to tanneries. However, the public may have contact with the polymer, when it is used as a component in leather surface coatings.

13. RECOMMENDATIONS

To minimise occupational exposure to the polymer containing Aqualen Top D2012 the following guidelines and precautions should be observed:

- . the work place should be well ventilated and spray booths or positive ventilation should be used during application of the finish coat;
- . good work practices to avoid spillages;
- . if engineering controls and work practices are insufficient to reduce exposure to a safe level, the following personal protective equipment which complies with Australian Standards should be worn such as respiratory protective devices (AS 1715-1991 (3), AS 1716-1992 (4)), safety spectacles, goggles or faceshields (AS 1336-1982 (5), (AS 1337-1982 (6)) and gloves (AS 2161-1978 (7)); and
- . a copy of the Material Safety Data Sheet (MSDS) should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for polymer containing Aqualen Top D2012 was provided in Worksafe Australia format (8). This MSDS was provided by Sandoz 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 Sandoz Australia Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of polymer containing Aqualen Top D2012 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**

1. Safepharm Laboratories Ltd., "Melio Promul 68 Acute Oral Toxicity to the Rat". Data on file, Project No: 47/166, 1987.
2. OECD Guidelines for Testing of Chemicals, "Acute Oral Toxicity" No: 401, 1981.
3. Australian Standard 1715-1991, "Selection, Use and Maintenance of Respiratory Protective Devices", Standards Association of Australia Publ., Sydney, 1991.
4. Australian Standard 1716-1991, "Respiratory Protective Devices", Standards Association of Australia Publ., Sydney, 1991.
5. Australian Standard 1336-1982, "Recommended Practices for Eye Protection in the Industrial Environment", Standards Association of Australia Publ., Sydney, 1982.
6. Australian Standard 1337-1984, "Eye Protectors for Industrial Applications", Standards Association of Australia Publ., Sydney, 1984.
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, *Guidance Note for the Completion of a Material Safety Data Sheet*, 2nd. edition, AGPS, Canberra, 1990.