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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

LE 3580

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

LE 3580

1. APPLICANT

International Sales and Marketing Pty Ltd of 55 Halstead Street SOUTH HURTSVILLE NSW 2221 (ABN 36-467-259-314) has submitted a notification statement in support of their application for an assessment certificate for the synthetic polymer of low concern (PLC) LE 3580.

2. IDENTITY OF THE CHEMICAL

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

Other names: modified polymer; alkyl modified polyacrylate

Marketing name: LE 3580

3. POLYMER COMPOSITION AND PURITY

Details of the polymer composition have been exempted from publication in the Full Public Report.

Purity (%): 98%

Hazardous impurities (other than residual monomers and reactants): None

Non-hazardous impurities at 1% by weight or more: None

Additives/adjuvants: None

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

Property	Result	Comments
Appearance	Brown liquid	
Boiling point		Not determined
Density	Approximately 1020 kg/m3 at 25^{o}C	
Water solubility	10.6 mg/L	
Particle size	Not applicable	
Flash point	> 100 ^{o}C	
Flammability		Not determined
Autoignition temperature		Not determined
Explosive properties	Not expected to be explosive.	
Stability/reactivity	There is no specific reactivity.	
Hydrolysis as function of pH		No hydrolysis is expected in the normal pH range 4-9.
Partition coefficient		Not determined
Adsorption/desorption		Not determined
Dissociation constant		The polymer contains no functional groups which could undergo dissociation

5.1 Comments on physical and chemical properties

Only a summary report on water solubility was provided by the notifier stating that the water solubility of the polymer was determined using the Flask Method. Two replicate samples were prepared by adding 200 mg each of the test substance to 200 mL of water held at 40^{o}C. The samples were stirred for 30 minutes. The solution was then cooled to 25^{o}C, and stirred continuously for a further 24 hours, while maintaining a constant temperature of 25^{o}C. The solution was allowed to stand for 24 hours before the water soluble fraction was removed using a syringe. The water soluble fraction was analysed for the carbon content to determine the average concentration of the chemical dissolved in water. The substance is only slightly soluble in water.

The partition and adsorption coefficients of the notified polymer were not determined. A poorly water soluble polyacrylate would be expected to partition into the octanol phase and to be lipophilic. Similarly, in soils the polymer would be expected to adsorb to organic matter, and in sewage treatment systems, it would be retained in the sludge.

6. USE, VOLUME AND FORMULATION

Use:

LE 3580 is currently in use in many countries as a deaerator (for elimination of micro and macrofoam) for radiation curable (both UV and electron beam) coatings, specifically those based on acrylic oligomers for use in printing inks.

It is a non-silicone based additive which yields superior recoatability characteristics and is used at an addition rate of 0.3 to 1.0% of the final coating formula.

Import volume:

The import volume of the notified chemical is expected to be 3 – 5 tonnes per year for the first five years.

Formulation details:

The notified polymer will be imported unformulated in 20 L plastic drums or 200 L steel or plastic drums.

7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier
Ink Manufacture		
Ink blending, QC testing and unloading		
dermal, ocular	Ink blending typically involves small scale (50 – 100 g) colour matching followed by full scale blending and sampling for quality control during which the inks are tested for colour in the same way as is done for the small scale colour matching. Workers (1 – 2 in both blending and quality control) will spend 5 – 6 hours per day, 50 days per year in these processes which involve pumping the inks and additives to a closed blending vessel and dispensing the final formulation via gravity feed into the 10 kg ink containers. Maximum losses are estimated at less than 1%. Dermal and	Reaction vessel enclosed, local exhaust ventilation, personal protective equipment including coveralls, nitrile gloves and eye goggles.

	secondary ocular exposure is possible. Similarly exposure is possible during washing of blending vessels and lines with solvent and/or detergent. Initially the blending is carried out manually to establish the recipe after which blending is automated. The notified chemical is present at a maximum concentration of 1% in the ink formulation.	
End use		
Printing		
dermal, ocular	Printers (50 – 100) working up to 24 hours per day, 300 days per year add ink to the printing machines via pump feed. The printing machines are enclosed and the ink is typically dosed automatically. Cleaning of the machines with solvent and/or detergent is infrequent as the ink residues can be left in the machines between print runs. The washings are captured in drums for disposal to an approved liquid waste disposal facility.	It is industry practice to wear coveralls, eye goggles and gloves during cleaning. Printing machines are typically enclosed and ink is dosed automatically.
Transport and storage		
dermal, ocular	Shipping containers transferred to ink manufacturers warehouse where the drums containing the notified chemical are unloaded and stored by 1 – 2 workers.	None.
Disposal		
Removal of empty drums, removal of tank washings, removal of printing machine washings		
dermal, ocular	Ink manufacturing workers and printing workers are responsible for cleaning of tanks or printing machines with solvents and	PPE described above.

collecting the washings for disposal by licensed contractors.

8. PUBLIC EXPOSURE

Neither the imported pure polymer nor the inks will be sold to the public. The inks, which contain low concentrations of the notified polymer, will only be used in industrial printing presses. The public will come into contact with the notified polymer after it is bound into the UV cured polymer matrix on the surfaces of articles where it is not bioavailable.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

The notifier anticipates < 1% of the notified polymer will remain as residues in the import containers. Hence a total of 50 kg out of a maximum import volume of 5 tonnes is expected to remain as residues in the import containers.

No estimates of the residues expected to remain in the used container of the blended products were provided. However, only 0.05% of these blended products will be notified polymer. If it is assumed that 1% of residues will remain in the blended product containers after use, then about 25 grams of notified polymer will remain as residues in containers.

During the ink blending process at customer facilities, it is estimated that < 1% of the notified polymer will be lost. Release of the polymer will occur mainly through washing of mixing vessels. It is expected that these wastes will be drummed and given to a licensed waste contractor.

Cleaning of the printing presses is expected to result in minimal release of the polymer given the low frequency of cleaning and the small percentage of the polymer in the final formulated ink product. The ink can be left on the printing presses for extended periods before cleaning is required because it needs to be cured by UV radiation in order to dry. During cleaning, the ink is removed using organic solvents or detergents. The residual ink is washed from the printing machines and collected in drums for disposal to an approved waste disposal facility.

In summary, it is expected that approximately 100 kg of notified polymer will be released into the environment as residues or from vessel cleaning. Most of this polymer will be either incinerated or disposed of in landfill. No release of the notified polymer into the aquatic environment is expected.

9.2. Fate

Only about 100 kg of the notified polymer will enter the environment directly as a result of residues or operational spills and cleaning. It is expected that these wastes will be drummed and given to a licensed waste contractor who will dispose of the wastes by incineration or in landfill.

Most of the imported polymer will be used in the manufacture of ink. The ink formulation will be bound up in the polymer matrix of the cured ink and deposited on packaging. As such, the fate of the polymer will follow the fate of the products onto which the inks are deposited. At the end of their useful life, most packaging products will most likely be sent to landfill, recycled, or incinerated.

No degradation data were provided in the notification dossier. Acrylic coatings are resistant to thermal and photooxidation and to hydrolysis. Hence, the polymer is not expected to readily degrade in the environment. At landfill sites, the polymer will undergo slow degradation by abiotic and microbial degradation processes along with the packaging materials or substrates containing the polymer blend.

The main factors influencing the movement of chemicals across biological membrane are lipid and water solubility, molecular weight, chemical structure and chemical stability. Given the high molecular weight (NAMW 4839) of the new polymer it is not expected to cross biological membranes or to bioaccumulate (Connell, 1990).

10. EVALUATION OF HEALTH EFFECTS DATA

A skin sensitisation study (Biochem, 1994) was submitted for the notified polymer and is evaluated below.

Species/strain: Albino guinea pig/Pirbright

Number of animals: 10 test and 5 control

Induction procedure:

test group:

day 1 Three pairs of intradermal injections (0.1mL/site) were made in the shoulder region:

- Freund's Complete Adjuvant (FCA), diluted 50:50 with water
- The notified chemical at a 25% concentration in sesame oil
- 25% notified chemical, emulsified in FCA

day 7 The shoulder area was rubbed with 10% sodium-dodecyl-sulfate (SDS) in vaseline to provoke a mild inflammatory reaction.

day 8 1 mL of undiluted notified polymer was topically applied to the clipped shoulder area using a occlusive patch for 48 hours.

control group: Control animals were treated similarly to the test animals except without the notified chemical.

Challenge procedure:

day 22 Undiluted notified polymer was applied topically to flanks for 24 hours under occlusive dressing for 24 hours.

Test method: EC Directive 92/69/EEC Method B.6

Challenge outcome:

Challenge concentration	*Test animals*		*Control animals*	
	*24 hours**	*48 hours**	*24 hours*	*48 hours*
undiluted	0/10	0/10	0/5	0/5

*time after patch removal
** number of animals exhibiting positive response

Result: The notified chemical was non-sensitising to the skin of guinea pigs.

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were provided.

12. ENVIRONMENTAL RISK ASSSESSMENT

Release of the notified polymer to the environment during blending, cleaning or application of ink or is not expected. Cleaning of the printing presses is expected to result in minimal release of the chemical given the low frequency of cleaning and the small percentage of the chemical in the final formulated ink product. All spills and any residual ink washed from the printing machines are collected in drums for disposal through an approved waste disposal facility.

Most polymer will be bound up in the polymer matrix of the coatings and will be inert. The fate of the polymer will follow the fate of the products onto which the inks are deposited. At the end of their useful life, it is expected that these products will be either recycled, sent to landfill, or incinerated.

Under normal usage, the new polymer is not expected to enter the aquatic environment. The high molecular weight of the notified polymer will prevent any movement across biological membranes, hence the polymer is not expected to bioaccumulate (Connell, 1990).

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

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

The notified polymer fulfils the criteria for a synthetic polymer of low concern and can be considered not to be a health hazard. This was confirmed for skin sensitisation using guinea pigs where no sensitisation was detected. The notified polymer is imported in a 98% pure form.

13.2. Occupational health and safety

Transport and storage of the containers of notified polymer should result in minimal worker exposure and consequent health effects except in the event of accidental container rupture.

Workers may be involved in some blending of colours with the notified polymer in which small volumes are tested for colour matching prior to pumping inks and the notified polymer to enclosed blending vessels. Small samples are taken for colour determination and adjustment if necessary. Typically inks are blended by hand until recipes are established. The final batch is then pumped into vessels of 10 kg capacity. The blend tanks, pumps and lines and flushed with short chain alcohols or detergents and the washings collected in drums for disposal. The notifier suggests that losses during these processes are small. This, together with the low concentration of notified polymer in the blended inks suggests that the risk to workers of adverse health effects from exposure to the notified polymer should be minimal. There may be some risk of skin, eye or respiratory irritation from exposure of workers to other components of typical inks but this is controlled by the use of coveralls, gloves and eye goggles. Employers are responsible for maintaining the atmospheric concentration of ink components below the NOHSC exposure standards.

After transport to printers the ink is pumped to an enclosed printing press. The ink is cleaned from the press infrequently with short chain alcohols or detergent and the washings placed in drums for disposal. Printers wear eye goggles, coveralls and gloves which, together with the low concentration of the notified polymer in the inks should result in minimal exposure. Therefore, the risk to printers of adverse health effects from exposure to the notified polymer is low. Again, there may be some risk of skin, eye or respiratory irritation from exposure of workers to other components of the inks but this is controlled by the use of coveralls, gloves and eye goggles.

Conclusion

The notified polymer is of low concern to human health and safety and no specific risk reduction measures are necessary.

13.3. Public health

In view of its high molecular weight, low toxicity, low concentrations in the inks and the use pattern, the notified polymer is unlikely to pose a significant hazard to public health.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

14.2. Label

The label for the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

15. RECOMMENDATIONS

Control Measures

No specific precautions are required to control exposure to the notified polymer. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed:

Occupational Health and Safety

- Spillage of the notified polymer should be avoided. Spillages should be cleaned up promptly with absorbents which should then 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 products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

15.1 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 Section 64(1) of the Act; if
- the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

(2) Under 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.

16. REFERENCES

Biochem (1994) Skin Senstisation Study According to Magnusson and Kligman. Tegomer AC 100. Report No. 93 10 42 533, Biochem GmbH, Karlsruhe, Germany (unpublished report submitted by International Sales and Marketing Pty Ltd).

Connell D. W. (1990) General characteristics of organic compounds which exhibit bioaccumulation. In Connell D. W., (Ed) Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

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