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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

SR3470K

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989,* 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 Human Services and Health.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

SR3470K

1. APPLICANT

Inchcape Office Products Pty Ltd of 12 Barcoo Street East Roseville NSW 2069 has submitted a limited notification statement in support of their application for an assessment cerificate for SR3470K.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, SR3470K, is considered to be non-hazardous. Therfore, the chemical identity, spectral data, and composition have been exempted from publication in the Full Public Report and the Summary Report.

Trade name: SR3470K
EPOMIK SR3470K

3. PHYSICAL AND CHEMICAL PROPERTIES

The following data refer to the notified polymer and not to the product containing it.

Appearance at 20°C and 101.3 kPa: Pale yellow powder

Odour: Not provided

Melting Point: Does not melt, but decomposes or reacts at about 250°C

Glass-transition Temperature: Not determined

Specific Gravity: 1170 kg/m^3 at 21.5°C

Vapour Pressure: Not determined as it is a solid substance with high melting point and molecular weight. The vapour pressure estimated to be 0.64 Pa at 25°C, using the modified Watson correlation

Water Solubility: < 4.1 mg/L at 20°C (Column elution method)

Partition Co-efficient (n-octanol/water) log P_{OW}: ≥ 6; estimated by calculation due to the low solubilities in water and n-octanol

Hydrolysis as a function of pH:	Not determined. The notified polymer's low water solubility "prevented a hydrolysis study according to the guidelines in force." Polymers contains no functionalities likely to hydrolyse under environmental conditions.
Adsorption/Desorption:	Not determined. The low water solubility of the notified polymer prevented the determination of adsorptive/desorptive characteristics. The level of entry into soil is expected to be very low.
Dissociation Constant pKa**:**	> 13. The result indicates that the reaction centres will not be completely dissociated and dissociation has no relevant effect on the environment
Flash Point:	Not determined
Flammability Limits:	The notified polymer is not highly flammable
Combustion Products:	Not provided
Pyrolysis Products:	Not provided
Decomposition Temperature:	Temperatures above 50°C
Decomposition Products:	Based on other epoxy compounds, the following thermal decomposition products are expected: oxides of carbon, benzene, methane, acetylene, ethylene and acetone.
Autoignition Temperature:	> 400°C
Explosive Properties:	Not considered to present any risk of explosion.
Reactivity/Stability:	This polymer contains hydroxyl functional groups. At elevated temperatures, it may undergo further polymerisation or cross-linking reactions with amino resins or with isocyanates. The polymer is also unstable Conditions contributing to instability of polymer are sunlight and temperatures above 50°C.

Particle size distribution:

<63µm	0.43% (w/w)
63 - < 100µm	0.75% (w/w)
100 - < 200µm	3.63% (w/w)
200 - < 500µm	12.28% (w/w)
500 - < 1000µm	25.16% (w/w)
1000 - < 2000µm	44.31% (w/w)
≥ 2000µm	

Comments on physico-chemical properties

The above comments provided by the notifier are supported by test reports and are adequate. Based on the notified polymer's low water solubility and high Log Pow it is likely to adsorb to soil/sediment and organic matter or be immobile in soils.

4. PURITY OF THE CHEMICAL

Degree of purity : 99.5%

5. INDUSTRIAL USE

The notified polymer will not be manufactured in Australia, but imported as a component of photocopier toners and developers in prepackaged cartridges packed in cardboard boxes and distributed by road to various establishments throughout Australia

The estimated import volume for the notified polymer will be less than ten tonnes per annum for the first five years.

6. OCCUPATIONAL EXPOSURE

EPOMIK SR3470K will not be manufactured in Australia. The notified polymer will be imported as a component of photocopier toners and developers. The concentration of the notified chemical in the formulated toners is reported as approximately 93%, and in developers as 4.7-4.8%.

The main category of workers potentially exposed to the formulated products containing SR3470K are, photocopier service engineers, who will be involved in the installation and maintenance of dry photocopiers. There are approximately 150-160 service engineers involved in these tasks in Australia. Office workers and workers in office photocopy rooms may be exposed to the notified chemical during handling toner cartridges.

The total number of employees likely to be exposed to formulated products containing the notified chemical cannot be specified with any great certainity, as this will depend on the number of machines used (which is dependent on market share) and the amount of photocopying carried out on each individual machine will vary, which will mean that the toner cartridge will need replacing more often or less often.

7. PUBLIC EXPOSURE

The potential for public exposure to EPOMIK SR3470K is low. The chemical is contained in prepacked cartridges which allow for minimal exposure to the formulated product. The public may be exposed through contact with residues on photocopied paper, but such residues are likely to be low.

8. ENVIRONMENTAL EXPOSURE

Release

The notified polymer is a component of a toner that is contained within a cartridge. When the photocopier indicates that it requires more toner, the operator removes a toner cartridge and replaces it with another. Therefore, release of the notified polymer under normal conditions of use is expected to be negligible, as practically no waste is generated.

Releases to the environment as a result of accidents (during transport or in the workplace) are expected to be negligible.

The toner cartridge and any spills of toner can be disposed of as domestic waste, in accordance with government regulations (eg landfill, incineration).

Releases to the environment may occur through processing of waste paper. This possibility is explored further below.

Fate

Disposal of the notified polymer to landfill is unlikely to result in contamination of surface and ground. Its low water solubility and high Log P_{ow} indicate it is unlikely to leach.

Combustion of the notified polymer in the presence of excess air will result in products of oxides of carbon and water.

Unless incinerated, the polymer is likely to arrive in a dispersed manner in landfill bound to waste paper. As such, it will be immobile, and no leaching from landfill would be expected despite the polymer's expected persistence.

Paper recycling is a growing industry in Australia. Wastepaper is repulped using a variety of alkalis, dispersing agents, wetting agents, water emulsifiable organic solvents and bleaching agents. These chemicals enhance fibre separation, ink detachment from the fibres, pulp brightness and whiteness of the paper. After pulping, the contaminants and the ink are separated from the fibres by pumping the stock through various heat washing, screening, cleaning, flotation and dispersion stages. The notifier has provided no data on the likely behaviour of the polymer during the recycling process. The polymer is likely to survive the above conditions, either remaining bound to the pulp or becoming associated with the sludge. In the latter case, the polymer will either arrive in landfill where it can be expected to remain intact, or be destroyed through incineration.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data are not required for polymers of number-average molecular weight (NAMW) >1000 according to the *Industrial Chemicals (Notification and Assessment) Act, 1989*. However, the following studies on acute oral toxicity, skin irritation, eye irritation and skin sensitisation were submitted for the notified polymer.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of SR3470K

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 5000 mg/kg	(1)
Skin Irritation	Rabbit	non-irritant	(3)
Eye irritation	Rabbit	slight irritant	(5)
Skin sensitisation	Guinea-pig	non-sensitiser	(6)

9.1.1 Oral Toxicity (1)

LD_{50}: > 5000 mg/kg *Species/strain*: rats, Sprague-Dawley

Number and sex of animals: 5/sex

Method of administration (vehicle): orally by gavage (5000 mg/kg) in arachis oil

Clinical observations: No signs of systemic toxicity were noted during the study.

Mortality: no deaths *Morphological findings:* no abnormalities were noted at necroscopy

Test Method: OECD 401, 84/449/EEC (2) Test B1

9.1.2 Skin Irritation (3)

Result: The notified chemical has no skin irritation potential in rabbits

Species/strain: Male New Zealand White rabbits *Number of animals:* 3

Method of administration: 500 mg test substance semi-occlusive dressing. Vehicle: distilled water.

Test Method: directive OECD 404; 42/449/EEC (2) Test B4

Draize (4) Scoresi:

Animal	Time after decontamination			
	60 min	1 day	2 days	3 days
ERYTHEMA/ ESCHAR FORMATION				
1	1	0	0	0
2	0	0	0	0
3	0	0	0	0
OEDEMA FORMATION				
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0

9.1.3 Eye Irritation (5)

Result: The notified chemical is a slight irritant to the rabbit eye

Species/strain: Male New Zealand White rabbits *Number of animals:* 3

Method of administration: 82mg = 0.1 ml powdered test substance

Observations: Diffuse corneal opacity was noted in one treated eye at the 24 and 48 hour observations. No other adverse corneal effects were noted.
Iridial inflammation was noted in all treated eyes one hour after treatment and persisted in one treated animal at the 24-hour observation. No other adverse iridial effects were noted.
Minimal to moderate conjunctival irritation was noted in all treated eyes one hour after treatment and persisted in one treated eye at the 24-hour observation with minimal conjunctival irritation at the 48-hour observation.
Treated eyes appeared normal 24 to 72 hours after treatment.

Test Method: OECD 405; 84/449/EEC (2) Test B5

Draize (8) Scoresii

Animal Number	Time after instillation 1 Day	2 Days	3 Days
CORNEAL OPACITY			
1	1	1	0
2	0	0	0
3	0	0	0
IRIDIAL INFLAMMATION			
1	1	0	0
2	0	0	0
3	0	0	0
CONJUNCTIVAL REDNESS			
1	2	1	0
2	0	0	0
3	0	0	0
CONJUNCTIVAL CHEMOSIS			
1	2	0	0
2	1	0	0
3	1	0	0

9.1.4 Skin Sensitisation (6)

Result: non-sensitiser to guinea pig skin

Species/strain: Albino guinea pig Dunkin-Hartley

Number of animals: 20 females in test group
10 females in control group

Maximum concentration not giving rise to irritating effects in the preliminary study:

Intradermal induction: 5%
Topical induction: 50%

Concentration for the induction and challenge phases:

Intradermal induction:	5% (w/v)	in arachis oil B.P.
	5% (w/v)	in FCA + arachis oil B.P. (1:1)
Topical induction:	50% (w/v)	in arachis oil B.P.
Topical challenge:	50% (w/v)	in arachis oil B.P.

Skin reactions after topical induction: Scattered mild redness and moderate and diffuse redness were elicited by the test material. Incidents of small superficial scattered scabs and an isolated incident of

fissuring were also noted at the 24-hour observation.

Skin reactions after topical challenge: No adverse reactions were noted at the test material and vehicle control sites of the test or control animals at the 24-hour and 48-hour observations.

Test Method: directive 84/449/EEC (2) Test B6

9.2 Genotoxicity

9.2.1 Induction of Point Mutations (7)

Result: No toxicity was exhibited to any of the strains of bacteria used. No significant increases in the number of revertant colonies of bacteria were recorded for any of the strains of bacteria used, at any dose level, either with or without metabolic activation.
The positive control substances all produced marked increases in the number of revertant colonies and the activity of the S9 fraction was found to be satisfactory.

Strains: *Salmonella typhimurium:* TA 1535, TA 1537, TA 98, TA 100
Escherichia coli: WP2 uvrA

Concentration range: 312.5 - 5000 µg/plate

Toxicity to bacteria: >5000 µg/plate

Metabolic activation: Aroclor 1254-induced rat liver S9-mix *Solvent:* DMSO

Test Method: directive 92/69/EEC (2) Test B13, B14

9.4 Overall Assessment of Toxicological Data

The notified polymer has been shown in animal studies to have low acute oral toxicity (LD50: > 5000mg/kg). It is not a skin irritant and is a non-sensitiser to guinea pig skin. However, it is a slight eye irritant to the rabbit eye. EPOMIK SR3470K was not mutagenic in an Ames *Salmonella* reverse mutation assay in the presence or absence of metabolic activation.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)] in relation to irritant effects (skin and eye), acute lethal effects (oral) and sensitising effects (skin).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of NAMW > 1000 according to the *Act*.

The notified polymer is not likely to exhibit toxic characteristics in the environment because large polymers of this nature are not readily absorbed by biota.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The low environmental exposure of the polymer as a result of normal use indicates that the overall environmental hazard should be negligible.

Environmental exposure to the notified substance could occur when paper containing the polymer is recycled or disposed of. In each case, the final destination is likely to be landfill where the polymer can be expected to persist but remain immobile, being either bound to paper or to the sludge from the recycling process.

Accidental spillage of the polymer should result in negligible hazard as it will be marketed in cartridges for direct insertion into photocopier machines.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer is not expected to be a health hazard as the high number-average molecular weight (>1000) should preclude absorption of the molecules across biological membrances. The purity is reported as 99.5% polyol resin, with a maximum weight percentage of low molecular weight polymers (≤1000 molecular weight) of 5.2%. Residual monomers and other reactants are estimated to be present at ≤ 0.2%.. The notified polymer is a slight eye irritant to the rabbit eye. Therefore, eye contact with the products containing SR3470K should be avoided.

As the notified chemical will be imported in cartridges which are inserted directly into the photocopier, occupational exposure is expected to be low. Potential for exposure occurs during loading of cartridges, but is controlled by safe work practices to minimise dust generation.

Formulated products which contain SR3470K, may contain additional components which require the following exposure standards to be observed (carbon black - TWA 3 mg/m^3 and iron oxide TWA 5 mg/m^3) in the event of an accident.

Given the low intrinsic health hazard of the notified chemical together with expected low exposure, occupational health risk arising from use is expected to be low.

The potential for public exposure to EPOMIK SR3470K is low. The notified chemical is contained in prepacked cartridges which allow for minimal exposure to the formulated product. The public may be exposed through contact with residues on photocopied paper, but such residues are likely to be low.

In the case of accidental spillage during transport, the public may be exposed to EPOMIK SR3470K. This is minimised by the recommended practices for storage and transportation. Emergency procedures for the containment and clean up of accidental spills are available and should be followed.

13. RECOMMENDATIONS

To minimise occupational exposure to SR3470K the following guidelines and precautions should be observed:

. when changing toner cartridges containing the notified polymer, care should be taken to avoid exposure to the toner adhering to the plastic tape which seals the cartridge. Should exposure occur, the toner should be removed immediately by washing.

. in the event of an accidental spill, effective decontamination, vacuuming dust and cleaning of contaminated walls and surfaces must be carried out.

. avoid generation of dust and good personal hygiene should be observed

. a copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The attached Material Safety Data Sheets (MSDS) for Rioch Color Toner Type D Black and Ricoh Color Developer Type E Black containing the notified chemical were provided in acceptable formats (8).

These MSDS were provided by Inchcape Office Products Pty Ltd as part of their notiification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Inchcape Office Products Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of SR3470K 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 Limited.1992, *Acute Oral Toxicity (Limit Test) in the Rat* , Project No. 114/391, Mitsui Petrochemical Industries Ltd (data on file).

2. EEC Council Directive 84/449 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations, *Official Journal of the European Communities,* No. L251 (19 September 1984).

3. Safepharm Laboratories Limited.1992, *Acute Dermal Irritation Test in the Rabbit*, Project No. 114/392, Mitsui Petrochemical Industries Ltd (data on file).

4. Draize J H, 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* 49.

5. Safepharm Laboratories Limited.1992, *Acute Eye Irritation Test in the Rabbit*, Project No. 114/393, Mitsui Petrochemical Industries Ltd (data on file).

6. Safepharm Laboratories Limited.1992, *Magnusson & Kligman Maximisation Study in the Guinea Pig*, Project No. 114/394, Mitsui Petrochemical Industries Ltd (data on file).

7. Safepharm Laboratories Limited.1992, *Reverse Mutation Assay "Ames Test" Using Salmonella Typhimurium and Escherichia Coli*, Project No. 114/395, Mitsui Petrochemical Industries Ltd (data on file).

8. Worksafe Australia, February 1990, Guidance Note for a Completion of a Material Safety Data Sheet, Australian Publishing Service, Canberra.

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iThe Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	rating	Oedema Formation	rating
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by by definite raising)	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

iiThe Draize scale for evaluation of eye reactions is as follows:

CORNEA			
Opacity	**rating**	**Area of Cornea involved**	**rating**
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translu cent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE					
Redness	**rating**	**Chemosis**	**rating**	**Discharge**	**rating**
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal from normal	1 slight	Any swelling above normal	1 slight	Any amount different	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 moderate	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red severe	3 severe	Swelling with lids half-closed	3 mod.	Disharge with moistening of lids and hairs and considerable area around eye	3
		Swelling with lids half-closed to comp-letely closed	4 severe		

IRIS	
Values	**rating**
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe