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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

C-1742

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

C-1742

1. APPLICANT

Kodak Australasia Pty Ltd. of 173 Elizabeth St., Coburg, Victoria, 3058 has submitted a standard notification with an application for an assessment certificate for a standard notification of C-1742.

2. IDENTITY OF THE CHEMICAL

According to Worksafe Approved Criteria for the Classifying of Hazardous Substances (1), C-1742 is not considered hazardous. There are no requirements for the disclosure of the chemical name. In the interests of commercial confidentiality the chemical name, molecular formula, structural formula and methods of determination have been exempted from publication in the Full Public Report and the Summary Report.

Chemical Abstracts Service (CAS) Registry No.:	not available
Molecular weight:	649.27

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white solid
Odour:	none
Melting Point:	83-88°C
Density:	1,138.5 kg/m^3
Vapour Pressure:	<4.1 x 10^{-4} Pa at 25°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	>7.8 at 23-26ºC
Fat solubility:	2.55 g/100g of corn oil at 37ºC
Water Solubility	<220 ng/L at 25ºC
Hydrolysis as a function of pH:	not conducted due to the low solubility of the test substance in the pH buffers.

Adsorption/desorption:	not conducted due to the low solubility of the test substance in the 0.01M $CaCl_2$ matrix.
Dissociation constant:	the test substance was not soluble enough in water or in organic solvent/water mixture for determination of pKa by potentiometric titration.
Particle size:	456.170 µm
Flammability Limits:	not highly flammable
Combustion Products:	carbon dioxide, carbon monoxide, hydrogen chloride gas and oxides of nitrogen.
Autoignition Temperature:	not auto-ignitable below 400°C
Explosive Properties:	not explosive
Reactivity/Stability:	not oxidising

Comments on Physico-Chemical Properties

All physico-chemical data were determined in accordance with the appropriate OECD Test Guidelines.

The solubility in water was calculated from the octanol/water coefficient using the equation log 1/S = 3.339(log K_{ow}) - 0.978 (units of S mol/L). The solubility has been calculated to be < 220 ng/L using the equation log S = -1.37 log K_{ow} + 7.30 - 0.015t_m (units of S µmol/L; t_m is the melting point of substance) (1). The solubility equation used was derived from compounds having a mixture of functional groups.

The notified substance does not contain any readily ionisable groups.

As a result of the high P_{ow}, strong adsorption to soil is expected.

The substance contains both ester and amide functionalities which could hydrolyse in the environment; however, this is not expected to occur due to its very low solubility in water.

4. PURITY OF THE CHEMICAL

Degree of purity: 98%

Toxic or hazardous impurities: none

Non-hazardous impurities (> 1% by weight): none

Additives/Adjuvants: none

5. INDUSTRIAL USE

The notified chemical will be used in the manufacture of photographic film/paper at relatively low concentrations.

The notified chemical will be imported into Australia in preweighed units in sealed shipping containers, and distributed by either road or rail, to a single manufacturer of photographic film/paper. It has been estimated that 3500 kg will be imported in the first year (1995), increasing to 40000 kg by 1998.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported into Australia as a 98% pure dry solid in preweighed units. These will not routinely require reweighing within Australia.

The notified chemical is added manually to a mix tank by up to 15 operators, 280 times per year. There is an estimated 15 minutes exposure during this stage. Employees will be wearing overalls, industrial safety glasses (conforming to Australian Standard AS1337), disposable vinyl gloves and a disposable dust and particle mask (conforming to Australian Standard AS 1716) to minimise potential exposure to the chemical. To reduce airborne concentrations during addition to the mix tank air extractors with mechanical ventilation will be utilised.

Other addenda are added to the mix tank resulting in a gelatin dispersion. This gelatin dispersion will be chilled and stored in covered cans for up to several weeks. The dispersion will then be taken from storage and manually added to melt tanks, where other addenda will be added. Up to 24 workers will be exposed to the notified chemical at relatively low concentrations when handling the gelatin dispersion. Employees will wear overalls, safety glasses (conforming to AS 1337) and disposable vinyl gloves to minimise exposure to the notified chemical in the gelatin dispersion.

The gelatin dispersion will be automatically pumped to controlled automated processing equipment where the notified chemical will be incorporated into photographic film/paper under overcoat layers.

7. PUBLIC EXPOSURE

No significant public exposure to the notified chemical is expected to occur during the manufacture of photographic paper/film. Public contact with treated products is also not expected to result in any significant exposure as the chemical will be under overcoat layers.

Disposal of waste chemical will be either to sewer (approx. 5%) or to secured landfill (< 1.0 %). Any chemical in the manufacturing plant effluent is expected to be at a low concentration and will be subject to dilution on entering community sewerage systems. Disposal of the notified chemical is not expected to result in significant public exposure.

8. ENVIRONMENTAL EXPOSURE

Release

Releases to the environment should be limited. As the notified chemical is imported pre-weighed, there should be no waste generated during the preparation of the gelatin dispersion. The gelatin dispersion is then stored in cans before the gelatin is added to the melt tanks, where other addenda are added. Then the melt is used in the automated processing equipment where the notified chemical is incorporated into the articles (photographic films and papers). As the notified chemical is subsequently overcoated with other layers, there shouldn't be any further releases of the chemical. The melt tanks are part of the automatic processing equipment and any waste from this equipment is sent to Kodak's silver recovery unit (New York, USA). The only waste generated (chemical lost) is from residues of the gelatin dispersion in the storage cans (estimated at 5% of the gelatin dispersion), which is disposed of to the sewer.

After the articles (photographic films/papers) containing small amounts of the notified chemical are developed, they could be disposed of with the normal household waste. As the chemical is incorporated into a gelatin matrix, any releases that do occur from the articles will be slow, gradual and widely dispersed.

Fate

The fate of most of the notified chemical is identical to that of the articles to which it is bound. The notifier expects most of these articles to be disposed of with the normal domestic waste, ie by incineration or landfill.

The waste released during processing will be discharged to the sewer and is expected to be trapped with the solids in the sludge, which is normally landfilled or incinerated.

The notified chemical was classified as not readily biodegradable [(OECD TG 301B, modified Sturm test, results -10% and -3% (replicates)]. However, as the notified chemical has a large number of functional groups that are expected to undergo biodegradation, the results of the test may reflect its low solubility in water. The

notified chemical could possibly biodegrade in the environment, however, this process is likely to be very slow.

9. EVALUATION OF TOXICOLOGICAL DATA

All tests were performed according to OECD guidelines (2)

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of C-1742

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} >2000 mg/kg	(3)
Acute dermal toxicity	Rat	LD_{50} >2000 mg/kg	(4)
Skin Irritation	Rabbit	non-irritant	(5)
Eye irritation	Rabbit	slight irritant	(6)
Skin sensitisation	Guinea-pig	non-sensitiser	(8)

9.1.1 Oral Toxicity (3)

LD_{50}: >2000 mg/kg *Species/strain: Sprague-Dawley rats*

Number/sex of animals: 5/sex *Observation period:* 14 days

Method of administration (vehicle): gavage, (20% suspension in 5% guar oil)

Clinical observations: none

Mortality: none *Morphological findings:* none

9.1.2 Dermal Toxicity (4)

LD_{50}: >2000 mg/kg *Species/strain:* Sprague-Dawley rats

Number/sex of animals: 5/sex *Observation period:* 14 days

Method of administration (vehicle): applied as a solid moistened with water under occlusive dressing for 24 hours.

Clinical observations: none *Mortality:* none *Morphological findings:* none

9.1.4 Skin Irritation (5)

Result: non-irritant **Species/strain:** New Zealand White rabbits

Number of animals: 3

Method of administration: 0.5 g under occlusive dressing for 4 hours

9.1.5 Eye Irritation (6)

Result: slight irritant

Species/strain: New Zealand White rabbits **Number of animals:** 6

Method of administration: 0.1 g of test material in conjunctival sac

Draize (7) Scores[i]

Animal	Time after instillation											
	1 hours			1 day			2 days			3 days		
CORNEA:	opacity area			opacity area			opacity area			opacity area		
1	0			0			0			0		
2	0			0			0			0		
3	0			0			0			0		
4	0			0			0			0		
5	0			0			0			0		
6	0			0			0			0		
IRIS												
1	0			0			0			0		
2	0			0			0			0		
3	0			0			0			0		
4	0			0			0			0		
5	0			0			0			0		
6	0			0			0			0		
CONJUNCTIVA	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]
1	2	1	0	1	0	0	0	0	0	0	0	0
2	2	1	y	1	0	0	0	0	0	0	0	0
3	2	1	y	1	0	0	0	0	0	0	0	0
4	1	0	0	0	0	0	0	0	0	0	0	0
5	1	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0

1-3 unwashed, 4-6 washed
[a] redness [b] chemosis [c] discharge

9.1.6 Skin Sensitisation (8)

Result: not a skin sensitiser

Species/strain: Crl:(HA) BR VAF/Plus ® Guinea Pigs

Number of animals: 30 males

Induction: Day 0 three pairs of intradermal injections 1) intradermal injection of 0.1mL of test material (5%) in corn oil; 2) 0.1 mL of Freunds Complete Adjuvant (FCA); 3) 0.1 mL of test material (5%) in FCA emulsion. Day 7 25% concentration of test material in petrolatum applied with a patch to application site.

Challenge: Day 21 A fully loaded patch with 25% of the test material in petrolatum applied to left flank of the animal.

Results: no adverse reactions

9.2 Repeated Dose Toxicity (9)

Species/strain: Sprague-Dawley rats **Number/sex:** 5/sex/group

Method of administration (vehicle): oral gavage, test article in corn oil

Dose/ Duration of administration: 0, 100, 300, or 1000 mg/kg/day for 29 days

Toxicologically Significant Observations: no mortality, no signs of toxicity and no pathological changes as a result treatment were observed. No statistically significant differences in hematology parameters were observed among male groups although mean corpuscular hemoglobin concentration levels were significantly higher for females at all dose levels compared to control groups, and mean prothrombin values were statistically higher for the 300 and 1000 mg/kg female groups when compared to control groups.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (10)

Result: no signs of bacterial toxicity, no increase in number of revertants above background, not mutagenic

Strains: *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537 and *Escherichia coli* strains WP2 and WP2uvrA

Concentration range: 100-5000 μg/ plate with and without metabolic activation using rat liver S9.

9.3.2 Cytogenetic test in Chinese Hamster Ovary Cells (11)

Result: did not cause chromosomal aberrations

Species/strain: Chinese hamster ovary cells

Doses: 2.35-299 µg/mL (in absence of metabolic activation
99.7-998 µg/mL (in the presence of metabolic activation)

Exposure time: 20 hours

9.4 Overall Assessment of Toxicological Data

C-1742 was of low acute oral and dermal toxicity in rats (LD_{50}>2000 mg/kg), was non-irritating to the skin of rabbits, was slightly irritating to the eyes of rabbits, and was not a skin sensitiser in guinea-pigs. In rats, repeated administration of C-1742 at up to 1000 mg/kg/day for 29 days produced no signs of toxicity attributable to treatment. C-1742 was not mutagenic in *S. typhimurium* or *E. coli* using *in vitro* bacterial reverse mutation assays and did not cause chromosomal damage in Chinese hamster ovary cells *in vitro.*

According to Worksafe Australia Approved Criteria for the Classifying of Hazardous Substances (12), C-1742 is classed as non hazardous.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been provided by the notifier. These studies were conducted according to international standards (EEC directives and OECD Guidelines) for static tests. A dispersing agent (DMF) was used in the fish, daphnia and algal tests. White particulates or masses were observed on the surface of the all test solutions after 24 hours. The concentrations used in the reported results were based on the HPLC analysis of DMF stock solutions. Only one of the aqueous solutions tested at time 0 and 48 hours had detectable amounts of the test compound replicate B, 20.0 mg/L (nominal); <1.0 mg/L, HPLC.

Test	Species	Result (nominal)
Acute toxicity	Fathead Minnow	96h LD_{50} and NOEC =20.3 mg/L
Acute toxicity	Daphnia	48h EC_{50} and NOEC >20.4 mg/L
Growth inhibition	Green Algae	72h EC_{50} > aqueous solubility, 72 hr NOEC not determined (21% enhancement)
OECD TG 209	Activated Sludge	EC_{50}> 1000 mg/L, NOEC =100 mg/L

The ecotoxicity studies show that the notified chemical's toxicity to aquatic organisms is much higher than the expected solubility. Significant effects on aquatic organisms are not expected when the chemical is released to waterways.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notifier has calculated the concentration of the chemical released to be 70 ppb. This is based on the estimate of 5% lost per batch of the gelatin dispersion (batch size of 685 kg) which is released to the sewer and treated at Werribee (flow of 500 ML).

The calculation of the notifier does not take into account the concentration of the chemical in the gelatin dispersion nor the number of batches prepared per day. The notifier has stated that when in full production 8 batches of the gelatin dispersion will be prepared per day. Thus:

Amount of chemical released per day :	685 X 0.05 X 0.06 X 8 = 16.44 kg per day
Concentration in effluent discharged from Werribee	33 ppb

The estimated concentration is at least 2 orders of magnitude below the NOEC for the species tested. This calculation assumes that there was no removal of the notified chemical by the sewage treatment process and that all of the chemical is released via the waste water. As the P_{OW} is very high and solubility in water very low, the chemical should adsorb to the sludge and therefore significantly reduce the actual concentration that is discharged to the environment. Also there is further dilution upon discharge into Port Phillip Bay.

Articles coated with the gelatin gels containing the notified chemical are expected to be eventually disposed of in the domestic garbage, which is incinerated or landfilled. The notified chemical is not expected to be removed during the processing/ development of the articles (photographic films/papers) coated with the gelatin gel.

Incineration of the notified chemical will generate oxides of carbon and nitrogen as well as water. As the chemical has a high P_{OW}, it will not leach when consigned to landfill. The environmental hazard from the disposal of articles and sludges containing the notified chemical by landfill is rated as negligible.

The only other sources of environmental contamination during normal usage is from accidental spills etc. The MSDS is adequate to limit the environmental exposure from spills etc. and together with the low solubility and high K_{OW} the environmental effects from possible accidents should be negligible.

The overall environmental hazard can be rated as negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

According to Worksafe Australia Approved Criteria for the Classifying of Hazardous Substances (12), C-1742 is classed as non hazardous based on the toxicological data given.

There is expected to be exposure to the notified chemical during the initial addition to the mix tanks as a dust, allowing the potential for dermal and respiratory exposure. However, engineering controls such as mechanical ventilation should result in minimising exposure to workers.

There is the potential for high levels of dermal exposure to the notified chemical in the gelatin dispersion during the transference of the chilled mixture in covered cans and manual addition to melt tanks.

As the coating process is automated, occupational exposure is expected to be minimal.

No significant public exposure to C-1742 is expected to occur as a result of using treated products as the notified chemical will be under overcoat layers in the finished product. Based on the toxicological data submitted, if exposure were to occur such exposure is not expected to pose a health risk to the public.

13. RECOMMENDATIONS

The use of the notified chemical in the manufacture of photographic films/papers has been rated as posing a negligible health and environmental risk.

To minimise occupational exposure to C-1742 the following guidelines and precautions should be observed:

. if engineering controls and work practices are insufficient to reduce exposure to C-1742 to a safe level, then the following personal protective equipment which conforms to Australian Standard (AS) or Australian/New Zealand Standard (AS/NZS) should be worn:

the appropriate respiratory device should be selected and used in accordance to AS/NZS 1715 (13) and should comply to AS/NZS 1716 (14).

eye protection should be selected and fitted in accordance to AS 1336 (15) to comply with AS/NZS 1337 (16).

industrial clothing must conform to the specifications detailed in AS 2919 (17).

industrial gloves or mittens should conform to AS 2161 (18).

all occupational footwear should conform to AS/NZS 2210 (19).

spillage of the notified chemical should be avoided.

good personal hygiene should be practised to minimise the potential for ingestion.

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

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for C-1742 was provided in Worksafe Australia format (20).

This MSDS was provided by Kodak Australasia Pty Ltd as part of their notification statement. The accuracy of this information remains the responsibility of Kodak Australasia Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of C-1742 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

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18. Standards Australia, 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves*), Standards Association of Australia Publ., Sydney, Australia.

19. Standards Australia, Standards New Zealand 1994, *Australian/ New Zealand Standard 2210 - 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications,* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

20. National Occupational Health and Safety Commission, 1990, G*uidance Note for the Completion of a Material Safety Data Sheet,* 2nd. edition, AGPS, Canberra.

[i] The 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	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Disharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

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