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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

FOG - 8915

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

FOG - 8915

1. APPLICANT

Kodak Australasia Pty Ltd of 173 Elizabeth Street Coburg Victoria 3058 has submitted a limited notification statement with their application for an assessment certificate for FOG-8915.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, FOG-8915, is considered to be non-hazardous. Therefore, the chemical name, molecular and structural formula, methods of detection and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Other name: FOG-8915

Molecular weight: 320.3

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical is manufactured as a 0.5% solution in water. All properties listed below are those for the chemical unless otherwise specified.

Appearance at 20°C and 101.3 kPa: colourless liquid (0.5% solution in water)

Melting Point: Not determined

Density: not determined

Water solubility: > 4 g\L

Hydrolysis as a function of pH: not determined

Vapour pressure: not determined

Partition coefficient: not determined

Adsorption/desorption: not determined

Decomposition Temperature: not determined

Dissociation constant: not determined

Flash point: not applicable

Autoignition temperature: not applicable

Explosive limits: not determined

Flammability limits:	flammable (based on a structurally similar chemical)
Pyrolysis products:	not determined
Combustion products:	not determined
Particle size:	not applicable
Reactivity/Stability:	reactive (based on a structurally similar chemical)

. Comments on Physico-Chemical Properties

The notifier has provided data for the parent compound giving an estimated log P_{OW} as 1.9 and water solubility of 50.7 mg/L. With the derived salt expected to be much more water soluble, it is agreed that the log P_{OW} will be much lower than 1.9 for the salt, and it is unlikely to strongly adsorb to organic matter. Also, the chemical contains no functionalities that are likely to be subject to hydrolysis under environmental conditions. Under acidic to neutral conditions, the chemical is expected to revert to the parent form.

4. PURITY OF THE CHEMICAL

Degree of purity:	>99.9%
Toxic impurities (> 0.1% by weight):	none
Non-hazardous impurities (> 1% by weight):	none

5. INDUSTRIAL USE

FOG-8915 will be manufactured at a Kodak Australasia site, for use in photographic film/paper. The parent compound is currently imported into Australia under a Low Volume Chemical Permit. It is estimated that 400 batches will be made per year giving up to 200 kg of FOG-8915 as a 0.5% aqueous solution.

6. OCCUPATIONAL EXPOSURE

The new chemical is manufactured when the parent compound is added to a vessel with sodium hydroxide. The resulting slurry will be added to water to form an aqueous solution which is added to a mix vessel. Exposure to the notified chemical during this process will be for approximately 10 minutes/batch at the rate of 400 batches per year, and will involve up to 16 operators. Other addenda will be added to the mix vessel and the resulting gelatin dispersion is pumped to closely controlled automated processing equipment where the dispersion is incorporated into photographic film and paper. During this process 27 operators are likely to be exposed to the notified chemical. Once the notified chemical forms part of the under overcoat layers of the article no employee exposure is anticipated. This process will be carried out only at one site in Australia.

7. PUBLIC EXPOSURE

The notified compound is to be used in the manufacture of photographic film/paper only within the notifier's plant. In the final products, the notified compound is covered by overcoat layers and public exposure is not anticipated.

8. ENVIRONMENTAL EXPOSURE

. Release

The company states there are no anticipated releases to the environment of the pure chemical. Approximately 0.1 % of the aqueous solution (0.5% FOG-8915) from the dissolving and dispensing tanks could be released to the municipal sewer. Any of the chemical released from the automated processing equipment is trapped as "filter cake" on recovering silver. Any chemical trapped in the filter cake would be expected to be destroyed when the filter cake is smelted to regenerate silver; smelting is performed in the USA.

The likely dilution factor for the new chemical released as an aqueous solution to the municipal sewer is approximately 1:10,000 resulting from the sewer flow from the Kodak plant. The flow from Kodak is approximately 400,000 L per day and mixes with the average daily inflow to the Werribee treatment plant of 500 megalitres.

. Fate

Waste from the production of a batch of the aqueous solution is expected to be released to sewer, with treatment by the Werribee treatment works.

The company expects that the compound will co-ordinate with some (transition) metals and is likely then to partition to sediments.

Solid wastes may be sent to a secured landfill.

Biodegradation

According to *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), no biodegradation data needs to be provided when the notified chemical has an annual import volume of <1000 kg per year. However, the company provided data for the parent compound which indicated that it was not readily biodegradable (35% and 24% degradation, OECD 301B test guideline); the degree to which it is inherently biodegradable is unknown.

Bioaccumulation

According to the Act, no bioaccumulation data needs to be provided when the notified chemical has an annual import volume of <1000 kg per year. However, with its low log P_{OW} and high water solubility, it is not expected to bioaccumulate (1).

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data are not required for annual manufacture volume of < 1 tonne per year under the Act. However, the following studies on acute oral and dermal toxicity, skin irritation, eye irritation, skin sensitisation and mutagenicity were submitted for the parent compound (test material).

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of the parent compound

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 2000 mg/kg	(2)
Acute dermal toxicity	Rat	LD_{50} > 2000 mg/kg	(4)
Skin Irritation	Rabbit	non-irritant	(5)
Eye irritation	Rabbit	irritant	(9)
Skin sensitisation	Guinea-pig	non-sensitiser	(10)

9.1.1 Oral Toxicity (2)

Species/strain: rats, CD®(SD)BR VAF/Plus®

Number and sex of animals: 5/sex

Method of administration (vehicle) orally by gavage (2000 mg/kg) in 0.5% aqueous suspension of guar gum

Clinical observations: No signs of systemic toxicity were noted during the study. The animals did not show any signs of abnormal behaviour or abnormal appearance that could be ascribed to treatment with the test substance.

Mortality: no deaths

Morphological findings: no abnormalities were noted at necroscopy

Test Method: OECD 401, 84/449/EEC (3) Test B1

Result: LD_{50}: > 2000 mg/kg

9.1.2 Dermal Toxicity (4)

Species/strain: rats, CD®(SD)BR VAF/Plus®

Number and sex of animals: 5/sex

Method of administration (vehicle): Dermally administered (2000 mg/kg) as a solid thoroughly moistened with water.

Clinical observations: No treatment related changes were noted at necropsy. The animals did not show any signs of abnormal behaviour or abnormal appearance that could be ascribed to treatment with the test substance.

Mortality: no deaths

Morphological findings: no abnormalities were noted at necroscopy

Test Method: OECD 401, 84/449/EEC (3) Test B1

Result: LD_{50}***:*** > 2000 mg/kg

9.1.3 Skin Irritation (5)

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

Method of administration: 500 mg test substance semi-occlusive dressing. Solid moistened thoroughly with water

Test Method: directive OECD 404; 42/449/EEC (3) Test B4

Result: Non-irritant to rabbit skin

Draize (6) Scores:

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

9.1.4 The Eytex Assay (7)

Basis: The EYETEX reagent is a highly organised protein matrix which undergoes conformation and hydration changes when challenged with a test material which is an eye irritant. These changes are considered relevant to *in vivo* irritation since disturbance of protein conformation and hydration have been identified as components of corneal injury and ocular irritation. Changes in turbidity of the EYETEX reagent are correlated with expected Draize scores.

Aim: To assess the potential eye irritancy

Test System: The EYTEX Upright Membrane Assay was used for the assay.

Doses: 20. 30, 40, 50 and 70 mg (10% suspension of the test material)

Test Method: SOP No. CB 199 (EYETEX^{TM} Test Procedure) (8)

Result: Test material may have the potential to produce severe to extreme eye irritation

9.1.5 Eye Irritation (9)

Comments: Based on the results of in vitro test (EytexTM Assay), only a single animal in each treatment group (unwashed eye and washed eye) was initially dosed. Based on the significant irritation observed in the single unwashed eye, further testing in additional animals was not performed.

Species/strain: Male New Zealand White rabbits *Number of animals:* 2

Method of administration: A single 100 mg dose of the test substance. After administration of the test substance one eye was immediately washed with running distilled water; the other eye was not irrigated.

Test Method: OECD 405; 84/449/EEC (3) Test B5

Result: irritant to the rabbit eye

Draize (8) Scores

	Time after instillation			
	1 Hour	**1 day**	**2 days**	**3 days**
CORNEAL OPACITY				
1 (washed)	0	0	0	0
2 (unwashed)	0	0	0	0
IRIDIAL INFLAMMATION				
1 (washed)	0	0	0	0
2 (unwashed)	0	1	1	0
CONJUNCTIVAL REDNESS				
1 (washed)	1	0	0	0
2 (unwashed)	2	3	3	2
CONJUNCTIVAL CHEMOSIS				
1 (washed)	0	0	0	0
2 (unwashed)	3	2	1	0
OCULAR DISCHARGE				
1 (washed)	-	-	-	-
2 (unwashed)	-	-	-	-

9.1.6 Skin Sensitisation (10)

Species/strain: Albino guinea pig *Number of animals:* 10/sex in test group, Crl:(HA)BR
5/sex in control group

Concentration for the induction and challenge phases:

Intradermal induction: 5% in corn oil
5% in FCA + water emulsion (1:1)

Topical induction: 25% in petroleum

Topical challenge: 25% in petroleum

Skin reactions after topical induction: no signs of skin irritation were observed in any of 10 controls.
The 25% test dilution did not induced signs of skin irritation in the 20 test animals.

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.

Comments: One of the 20 animals assigned to the test group developed an abnormality unrelated to the sensitisation study (prolapsed rectum) and was removed from the study.

Test Method: directive 84/449/EEC (5) Test B6

Result: non-sensitiser to guinea pig skin

9.2 Genotoxicity

9.2.1 Induction of Point Mutations (11)

Strains: *Salmonella typhimurium* TA 1535, TA 1537, TA 98, TA 100 and *Escherichia coli* strain *WP2uvrA(pKM101)*

Concentration range: 100 - 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 (5) Test B13, B14

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 controls, 2-Aminoanthracene with metabolic activation and 2-nitrofluorene, sodium azide, ICR-191 and 4-nitroquinoline without metabolic activation produced marked increases in the number of revertant colonies.

9.3 Overall Assessment of Toxicological Data

FOG-8915 parent compound has been shown in animal studies to have low acute oral toxicity (LD50: > 2000mg/kg). It is not a skin irritant or sensitiser to guinea pig

skin. However, it is an eye irritant to the rabbit eye. It 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 could be classified as hazardous in accordance with *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)] in relation to irritant effects (eye).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

According to the Act, no ecotoxicological data needs to be provided when the notified chemical has an annual import volume of <1000 kg per year.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Production of a 100 kg batch of the aqueous solution containing 500 g of new chemical, with an expected waste of 0.1%, would result in release of 0.5 g of the notified chemical to sewer. This quantity will be diluted by 500 ML at Werribee, giving a concentration of approximately 0.001 ppb.

Additionally, less than 1% of gelatin dispersion wastes may be sent to a secured landfill. This would equate to less than 2 kg of FOG-8915 per annum.

FOG-8915 will mainly enter the environment when the aqueous solution containing the notified substance is discharged to the sewer. FOG-8915 could undergo some microbial degradation in the sewerage system, although the degree to which this occurs would depend on the pH of the system and whether it occurs as the sodium salt or parent compound. Some of the chemical, as the salt, may also partition to sediment (sludge) on binding to metals. Any remaining chemical existing as the salt would enter receiving water and be further diluted giving a final concentration in receiving water well below 0.001 ppb.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

No toxicology data was submitted for FOG-8915. However, studies carried out with the parent compound demonstrated low oral and dermal toxicity. It was not a skin irritant nor a skin sensitiser and was not mutagenic. But the parent compound was found to be an eye irritant. Based on these observations FOG-8915 could potentially be an eye irritant.

FOG-8915 is classified hazardous in accordance with *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)] in relation to irritant effects (eye). However, since, it is manufactured as a 0.5% solution in water that formulation will not be hazardous.

Occupational exposure to the notified chemical is expected to be minimal due to short durations (10 minutes/batch) of batch operations and use of closely-controlled automated processing equipment.

As the notified chemical is considered a potential eye irritant, eye protection should be worn if necessary during the manufacturing process.

In the final products, the notified compound is covered by overcoat layers and public exposure is not expected to occur. In view of the low potential for exposure and the anticipated low toxicity (based on the studies conducted with the parent compound), FOG-8915 is unlikely to pose a risk to public health.

In the case of accidental spillage during transport, the public may be exposed to FOG-8915. This is minimised by the recommended practices for storage and transportation as stipulated under section 7.3 (Transport and Storage) of the notification package. Emergency procedures for the containment and clean up of accidental spills are available and should be followed as described in section 13.1 (occupational Emergency Procedures) of the notification package.

13. RECOMMENDATIONS

To minimise occupational exposure to FOG-8915 the following guidelines and precautions should be observed:

. If engineering controls and work practices are insufficient to reduce exposure to a safe level, then personal protective devices which conform to and are used in accordance with Australian Standard/ New Zealand Standard (AS/NZS) for eye protection, AS 1336, AS/NZS 1337, (12,13) should be worn.

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

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

14. MATERIAL SAFETY DATA SHEET

The attached MSDS for FOG-8915 was provided in a suitable format.

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 Australiasia Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of FOG-8915 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

16. REFERENCES

1. Connel DW 1989. General Characteristics of organic compounds which exhibit bioaccumulation, Chapter 3, in Connel DW (ed) "Bioaccumulation of xenobiotic compounds". CRC Press, Boca Raton, USA. pg 56.

2. Acute Oral Toxicity of FOG-8915 parent. Data on File, Eastman Kodak Company, Rochester, NY, 14652-6272, USA.

3. 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).

4. Acute Dermal Oral Toxicity of FOG-8915 parent. Data on File, Eastman Kodak Company, Rochester, NY, 14652-6272, USA.

5. Acute Dermal Irritation of FOG-8915 parent. Data on File, Eastman Kodak Company, Rochester, NY, 14652-6272, USA.

6. 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**.

7. Eytex Bioassay of FOG-8915 parent. Data on File, Eastman Kodak Company, Rochester, NY, 14652-6272, USA.

8. SPO No. CB 199 (EYETEX ™ Test Procedures), and in "The EYETEX™ System Manual", Revision D, obtained from In Vitro International.

9. Acute Eye Irritation of FOG-8915 parent. Data on File, Eastman Kodak Company, Rochester, NY, 14652-6272, USA.

10. Skin Sensitisation of FOG-8915 parent. Data on File, Eastman Kodak Company, Rochester, NY, 14652-6272, USA.

11. Salmonella - Escherichia Coli/Mammalian-Microsome Reverse Mutation Assay of FOG-8915 parent. Data on File, Hazleton Washington Inc, Vienna, Virginia 22182.

12. Standards Australia, 1994, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, Australia.

13. Standards Australia, 1992, *Australian Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Australia.