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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

UVT 1876

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Fujifilm Australia Pty Ltd (ABN 80 000 064 433) of 114 Old Pittwater Road Brookvale NSW 2100.

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Purity, Hazardous and Non-hazardous Impurities, Additives/Adjuvants, Import Volume, Use Details, Identity of Manufacturer/Recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Dissociation Constant, Flash Point, Acute Inhalation Toxicity, and Bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Japan (June 2002), Belgium (December 2002), and USA (January 2004).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
UVT 1876

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None are present at above the relevant cut off level for classification of the notified chemical as a hazardous substance.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported as fully formulated products.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1	<1	<1	<1	<1

USE

As an ingredient (<3%) in liquid photographic developers used in the photofinishing industry.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Fujifilm Australia Pty Ltd.

TRANSPORTATION AND PACKAGING
The notified chemical will be transported by road and distributed throughout Australia as a component of an end-use product in sealed high-density polyethylene (HDPE) bottles, which are packed in corrugated carton boxes (cartridges). No repackaging will occur in Australia. Storage will be in a cool dry environment out of direct sunlight.

5.2. Operation description

No manufacturing, reformulation, filling or refilling of bottles will be carried out in Australia. For replacement of the photographic developer, operators or end users in photofinishing laboratories will load the cartridge into a processor machine, a fully automated and enclosed system, with no contact between the chemicals and the operator. When the machine's door is closed, the valves of the cartridge open automatically and the processing agents in the bottles will flow into the replenisher tank. Bottle cleaning will also occur automatically within the machine.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and warehouse workers	22	30 min/day	5 days/week
Photoprocessing operators	600	6 hr/day	5 days/week
Chemical disposal operators	50	1 hr/day	1 day/week
Service engineers	small	short	

Exposure Details
The notified chemical will be handled only within sealed bottles and cartridges. Transport and photoprocessing workers therefore are unlikely to be exposed to the notified chemical except when packaging is accidentally breached. Should a spill occur, it is expected to be contained and collected using absorbent materials, and placed into suitable containers for recovery or disposal in accord with the MSDS and official regulations.

Chemical disposal workers may be potentially exposed to the notified chemical when collecting liquid waste from Waste Collection tanks at photographic laboratories. However, exposure would be of short duration and with low concentrations of the notified chemical.

Service engineers may be intermittently exposed to the notified chemical contained in the cartridge via skin contact during cleaning and maintenance tasks. The service engineers will wear gloves and receive appropriate training in servicing techniques.

Contact with photographic media developed and finished with the developers containing the notified chemical is unlikely to result in dermal exposure as the chemical will be washed out in subsequent processing steps such as bleach-fixing and rinsing processes.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Since the notified chemical will not be manufactured or reformulated locally, there will be no environmental exposure associated with these processes in Australia.

RELEASE OF CHEMICAL FROM USE

No release to the environment is anticipated for the notified chemical, however some of the preparation may be lost to the waste water of the minilab as a result of cleaning the production equipment. This however will involve very small quantities.

5.5. Disposal

The waste of the photo-minilabs is collected and disposed of as chemical waste. Since the notified chemical is not consumed or converted in the process, approximately 0.8% ends up in waste water and 99.2% is collected and disposed off as chemical waste after usage in the mini-labs.

5.6. Public exposure

The notified chemical is intended for use in the photofinishing industry only. There may be potential for dermal exposure of the public to photographic media containing residues of the notified chemical. However, such exposure would be negligible. Public exposure to the notified chemical in the event of a transport accident or spillage is unlikely.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Pale yellow powder

Melting Point Decomposes before melting

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.

Remarks The test was performed using a differential scanning calorimeter. Melting of the notified chemical was not observed between 25ºC and 380ºC. Up to 210-215ºC, part of the test substance (probably some volatile components or impurities) evaporated (endothermic effect). Above these temperatures, reaction or decomposition of the test substance was observed (exothermic effect). Because the endothermic effect changed gradually into the exothermic effect, it is possible that both processes interfered and that reaction or decomposition of the test started even below 210ºC.

TEST FACILITY Notox (2002b)

Boiling Point Decomposes before boiling at 101.3 kPa

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.

Remarks As above

TEST FACILITY Notox (2002b)

Density 1610 kg/m^3 at 20ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.

Remarks The test was performed using a gas comparison pycnometer.

TEST FACILITY Notox (2002c)

Vapour Pressure 1.5×10^{-3} kPa at 20ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.

Remarks The vapour pressure at 20ºC was extrapolated from the vapour pressure curve using static vapour pressure measurements made with a capacitance manometer. They are 15.32 Pa at 37.54ºC, 8.51 Pa at 32.87ºC, and 3.13 Pa at 25.35ºC.

TEST FACILITY Notox (2002d)

Water Solubility >1000 g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.

Remarks The flask method was used. During a preliminary test, the notified chemical was determined to be miscible with water in at least a 1:1 (w/v) ratio by visual observation. Therefore, no main study was performed. The pH of the aqueous solution was 9.5. The temperature was 20.0 ± 0.5ºC.

TEST FACILITY Notox (2002e)

Hydrolysis as a Function of pH Hydrolytically stable

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$*
4	25	>1 year
7	25	>1 year
9	25	>1 year

Remarks Less than 10% hydrolysis was observed at 50ºC after 5 days in all buffer solutions. Hence, the notified chemical is hydrolytically stable.

TEST FACILITY Notox (2002f)

Partition Coefficient (n-octanol/water) log $P_{ow} \leq$ -5.8 at 20ºC

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks The Estimation method was used.
The solubility of the notified chemical at 20ºC was $\leq 1.5 \times 10^{-3}$ g/L in n-octanol and >1000 g/L in water. The partition coefficient (n-octanol/water), P_{ow}, calculated as a quotient of the n-octanol solubility and water solubility of the notified chemical, is $\leq 1.5 \times 10^{-6}$ (log $P_{ow} \leq$ -5.8).

TEST FACILITY Notox (2002g)

Adsorption/Desorption log $K_{oc} \leq$ -2.00 (worst case value)

METHOD Expert Statement – calculated using the QSAR method described in the Technical Guidance Document on Risk Assessment (European Commission, 1996).

Remarks For calculation of adsorption/desorption of the notified chemical, several chemical classes such as non hydrophobics (I), alcohols (II) and triazines (III) having different QSARs and a log $P_{ow} \leq$ -5.8 for the notified chemical were used:
(I) log $K_{oc} = 0.52 \log P_{ow} + 1.02 \leq$ -2.00
(II) log $K_{oc} = 0.39 \log P_{ow} + 0.50 \leq$ -1.76
(III) log $K_{oc} = 0.30 \log P_{ow} + 1.50 \leq$ -0.24
log $K_{oc} \leq$ -2.00 (worst case value ie lowest adsorption to soil, based on the log P_{ow} of the notified chemical). In conclusion, the different QSARs give different outcomes of the log K_{oc}. For risk assessment purposes, the worst case calculated value should be used, in view of all uncertainties using QSAR.

TEST FACILITY Notox (2002h)

Dissociation Constant Not determined

Remarks The notified chemical contains a number of strong acid functionalities which are expected to remain deprotonated throughout the environmental pH range (4-9).

Particle Size

METHOD Laser Diffraction Particle Size Analysis – recognised by the OECD guidelines.

Range (μm)	*Mass (%)*
<7.22	<10
<22.72	<25
<46.05	<50
<73.42	<75
<107.20	<90

Remarks The proportion by mass of particles which, if inhaled, can be expected to achieve deposition throughout the respiratory tract is approximately 10%.
TEST FACILITY Chilworth Technology (2002)

Surface Tension 56.3 mN/m at 20ºC

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Concentration: 1.006 g/L. Based on the criteria as outlined in the guideline, with a surface tension <60 mN/m, the notified chemical is regarded as a surface active material.
TEST FACILITY Notox (2002i)

Flash Point Not determined

Remarks Test was not performed as the notified chemical is a solid at room temperature.

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
EC Directive 92/69/EEC A.12 Flammability (Contact with Water).
Remarks The notified chemical could not be ignited, although it emitted yellow sparks and turned black in contact with the flame of a gas burner. After removal of the ignition source, no more sparks were observed but the notified chemical glowed for another 6 seconds. No propagation throughout the notified chemical pile was observed.

The notified chemical did not react with water that might lead to evolution of highly flammable gases in dangerous quantities. It is known to be water soluble.
TEST FACILITY Notox (2002j & k)

Autoignition Temperature >400ºC

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks No self-ignition of the notified chemical was observed, it changed into a black powder.
TEST FACILITY Notox (2002l)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Test was not performed as the notified chemical does not contain any chemically unstable or highly energetic groups that might lead to an explosion.
TEST FACILITY Notox (2002m)

Oxidizing Properties Not oxidising

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks Test was not performed as the notified chemical contains no chemical groups that would imply oxidising properties.
TEST FACILITY Notox (2002n)

Reactivity Stable under normal environmental conditions

Remarks	There are no known hazardous decomposition products or incompatibility with other substances. However, the notified chemical is combustible and will burn in a fire, evolving noxious fumes such as oxides of carbon, sulphur, and nitrogen.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rat, acute inhalation	test not conducted
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOAEL = 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	non genotoxic
Toxicokinetic assessment	low absorption/bioavailability

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar Crl:(WI) BR
Vehicle	Milli-U water
Remarks - Method	Correction was made for the specific gravity of the test substance inadvertently. Therefore, the animals received approx 1800 mg/kg bw. This deviation from the test guidelines was approx 10% less than the intended 2000 mg/kg bw. Also, based on the results of this study and of the 28-day oral gavage study (see below), the study integrity and the conclusion were considered not to have been adversely influenced.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 females	1800	0/3
II	3 males	1800	0/3

LD50	>2000 mg/kg bw (actual dose approximately 1800 mg/kg bw)
Signs of Toxicity	Lethargy was noted among all females and in one male on day 1. A decreased body weight gain was noted for females between days 8 and 15. The mean body weight gain shown by the males over the study period was considered to be normal.
Effects in Organs	No abnormalities were found at macroscopic post mortem examination of the animals.
Remarks - Results	The actual dose was approximately 1800 mg/kg bw. It was anticipated that a single exposure to the intended dose of 2000 mg/kg bw would not have considerably altered the study results. Therefore, the oral LD50 value of the notified chemical in Wistar rats was established to exceed 2000 mg/kg bw.
CONCLUSION	The notified chemical is of low toxicity via the oral route.

TEST FACILITY Notox (2002o)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD OECD TG 402 Acute Dermal Toxicity.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).

Species/Strain	Rat/Wistar Crl:(WI) BR
Vehicle	Milli-U water
Type of dressing	Occlusive
Remarks - Method	As above

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 females	1800	0/3
II	5 males	1800	0/3

LD50	>2000 mg/kg bw (actual dose approximately 1800 mg/kg bw)
Signs of Toxicity - Local	Scales and/or erythema were seen on the treated skin area of the two females out of five between days 3 and 8. Yellow staining of the back shown by most animals between days 1 and 5 was considered to be related to staining properties of the test substance. Brown staining of the snout was shown by one female on day 1.
Signs of Toxicity - Systemic	Lethargy was shown by all males on days 1 and 2. The changes noted in body weight gain in males and females were within the range expected for rats used in this type of study and were therefore considered not indicative of toxicity.
Effects in Organs	A reduced size of the testes and epididymis were found in one male. Macroscopic post mortem examination of the other animals did not reveal any abnormalities.
Remarks - Results	The actual dose was approximately 1800 mg/kg bw. It was anticipated that a single exposure to the intended dose of 2000 mg/kg bw would not have considerably altered the study results. Therefore, the dermal LD50 value of the notified chemical in Wistar rats was established to exceed 2000 mg/kg bw.

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY Notox (2002p)

7.3. Acute toxicity – inhalation

Remarks	Test was not conducted. Due to the expected low vapour pressure and the imported liquid form of the notified chemical, inhalation exposure would be unlikely.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males

Vehicle	Milli-U water (moistened)
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks – Method	No significant protocol deviations

RESULTS

Remarks - Results	There was no evidence of dermal corrosion or irritation caused by 4 h exposure to the notified chemical. No staining of the treated skin was observed. No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY Notox (2002q)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Observation Period	7 days
Remarks - Method	No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.7	1	2.7	3	72 h	0
Conjunctiva: chemosis	0.3	0	0.3	1	24 h	0
Conjunctiva: discharge	0.3	0.3	0	1	24 h	0
Corneal opacity	0	0	0	0	0 h	0
Iridial inflammation	0	0	0	0	0 h	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	Instillation of approx 60 mg of the notified chemical into one eye of each of three rabbits resulted in irritation of the conjunctivae, which had resolved within 72 h in two animals and within 7 days in the other animal. No iridial irritation or corneal opacity was observed, and treatment of the eyes with 2% fluorescein 24 h after instillation of the notified chemical revealed no corneal epithelial damage in any of the animals. One animal showed bleeding at the lower site of the sclera at 24 and 48 h after instillation. This finding had resolved within 72 hours. There was no evidence of ocular corrosion. No staining of (peri) ocular tissues by the notified chemical was observed. No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Notox (2002r)

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD	OECD TG 406 Skin Sensitisation – Maximisation Test. EC Directive 96/54/EC B.6 Skin Sensitisation – Maximisation Test.
Species/Strain	Guinea pig/Himalayan
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: <1% in Milli-U water topical: 50% in Milli-U water
MAIN STUDY	
Number of Animals	Test Group: 10 females Control Group: 5 females
INDUCTION PHASE	Induction Concentration: intradermal: 20% in Milli-U water or 40% in 1:1 mixture of Freund's Complete Adjuvant and water topical: 50% in Milli-U water
Signs of Irritation	During induction, erythema was noted in all test animals (scores of 1 to 2 for intradermal and scores of 1 to 3 for epidermal), compared to 3/5 and 2/5 control animals (scores of 1 only) for intradermal and epidermal, respectively. The reactions noted after the epidermal induction were considered to be enhanced by the SDS treatment.
CHALLENGE PHASE	
1st challenge	topical: 50% in Milli-U water
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	No skin reactions were evident after the challenge exposure in the experimental and control animals. Yellow staining was observed at the treated skin sites 24 h after challenge. This staining did not hamper the scoring of the skin reactions. No mortality occurred and no symptoms of systemic toxicity were observed. A separate positive control study with alpha-hexylcinnamic aldehyde confirmed the sensitivity of the test system.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Notox (2002s)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Wistar Crl:(WI) BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 0 day
Vehicle	Milli-U water
Remarks - Method	The following protocol deviations were noted: 1) Samples of formulations were analysed in week 4 instead of after the in-life phase. 2) On days 6, 17, 19, 23 and 24, the maximum time between the earliest and latest dosing of 4 hours was exceeded with a maximum of approximately 30 minutes. 3) The arena observation scheduled for days 22 and 28 were performed on days 23 and 27 respectively. 4) On days 1, 4, 7 and 8, the maximum time between dosing and formulation of 4 hours was exceeded with a maximum of approximately 1 hour.

5) No terminal body weight was recorded for animal number 35
6) The following tissues/organs were not examined macroscopically from animal number 25:

- sciatic nerve (not found in pot during trimming)
- parathyroid (not found on slide at final check)

Evaluations:
1) Analyses have been performed within a reasonable time limit
2) Deviations were slight and incidental in nature
3) Observations were performed within a reasonable time limit.
4) Deviations were slight an incidental in nature also considering the stability of the test substance in vehicle over at least 96 hours
5) & 6) Sufficient information was available for evaluation
Based on the above evaluations, these deviations were considered not to have affected study integrity.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 per sex	0	0/10
II (low dose)	5 per sex	50	0/10
III (mid dose)	5 per sex	150	0/10
IV (high dose)	5 per sex	1000	0/10

Mortality and Time to Death
No mortality occurred during the study period.

Clinical Observations
There were no clinical signs of toxicity or behavioural changes over the 28-day observation period that were considered to be related to treatment.

Incidental findings that were noted included alopecia or scabs among some control males and males dosed at 150 mg/kg/day. These findings are commonly noted in rats of this age and strain which are housed and treated under the conditions in this study. At the incidence observed, these were considered to be of no toxicological significance. No clinical signs were noted among the other animals.

No changes were observed in hearing ability, pupillary reflex, static righting reflex and grip strength in the animals treated with the notified chemical, when compared to control animals. The variation in motor activity did not indicate a relationship with treatment.

Body weight and body weight gain of treated animals remained in the same range as controls over the 4-week study period.

There were no differences in food consumption before or after allowance for body weight that were considered to be related to treatment. Relative food intake of control animals was slightly high (mainly in week 1) based on the range of values to be expected for this type of study. However, body weight and absolute food consumption values of these control males were considered to be normal as were relative food intake values of other groups/animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Haematological parameters of treated rats were considered not to have been affected by treatment. The apparent increase of monocyte counts of males dosed at 150 mg/kg/day was considered to have been caused by a slightly high value of one male (no. 13). There was no dose-related incidence. The reduced platelet counts of high dose males were considered to have occurred by chance since supportive findings were absent and values were within the normal range. No explanation could be given for the notably high individual value of the partial thromboplastin time of one control male (no. 2). These changes were considered to be of no toxicological significance.

The mean urea value of high dose males was increased, with two males (no. 19 and 20) showing increased values.

The slightly high aspartate aminotransferase activity and sodium value of one high dose female (no. 39) was not supported by other findings and was not reflective of a group response. These changes were considered to be of no toxicological relevance.

Effects in Organs
Organ weights and organ:body weight ratios of treated animals were considered not to have been affected by treatment. Statistically significant changes of epididymides and (relative) adrenal weights between treated and control animals were considered not to be a sign of toxicity in the absence of a dose-related response.

Macroscopic observations at necropsy did not reveal any alterations that were considered to have arisen as a result of treatment. Findings among control and/or treated animals included pelvic dilation, enlargement and/or pale discolouration of the kidneys, red discolouration of the mandibular lymph nodes and/or thymus, sores and alopecia, enlargement of the thymus and red foci on the thymus. These findings are occasionally seen among rats used in these types of studies. In the absence of a treatment-related incidence they were considered to be of no toxicological significance. No macroscopic findings were noted among high dose males.

There were no microscopic findings recorded which could be attributed to treatment with the test substance. All microscopic findings were within the range of background pathology encountered in Wistar rats of this age and strain and occurred at similar incidences and severity in both control and treated rats.

Remarks – Results
The increased mean urea value of high dose males was evident in two individuals only. Also, since this effect was not accompanied by functional or morphological disturbances it was considered to be non-adverse.

There were no changes at determination of clinical appearance, performance of functional observations, body weight and food consumption measurements, or alterations during haematological investigations, macroscopic examination, organ weight determination and microscopic examination that were considered to be an effect of treatment.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day, which is the highest dose tested in this study.

TEST FACILITY Notox (2002t)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2*uvrA*

Metabolic Activation System S9 fraction from Aroclor 1254 induced rat liver

Concentration Range in Main Test a) With metabolic activation: 3, 10, 33, 100, 333, 1000, 3330, 5000 µg/plate
b) Without metabolic activation: 3, 10, 33, 100, 333, 1000, 3330, 5000 µg/plate

Vehicle Milli-U water

Remarks – Method Two independent tests were conducted, each in triplicate.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*

Absent				
Test 1	>5000 (TA100 & WP*2uvrA*)	>5000 (other strains)	>5000	Negative
Test 2	--	>5000 (all strains)	>5000	Negative
Present				
Test 1	>5000 (TA100 & WP*2uvrA*)	>5000 (other strains)	>5000	Negative
Test 2	--	>5000 (all strains)	>5000	Negative

Remarks - Results

In strain TA100, 2-fold increases relative to controls in the number of revertant colonies were observed at the dose levels of 10 and 33 µg/plate in the absence of S9. However, these increases were only observed in the first experiment and related to a low mean solvent control value. Furthermore, the increases were observed at two intermediate dose levels and no dose relationship was observed. Therefore, these increases are considered to be not biologically relevant and the notified chemical is considered to be not mutagenic.

All other bacterial strains showed negative responses over the entire dose range, ie no dose-related, two-fold increase in the number of revertants in two independently repeated experiments. The vehicle and positive controls responded appropriately.

CONCLUSION

The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Notox (2002u)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity – In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line: Peripheral human lymphocytes
Metabolic Activation System: S9 fraction from Aroclor 1254 induced rat liver
Vehicle: Milli-U water
Remarks - Method: Two independent tests were conducted in duplicate.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1000*, 3330*, 5000*	3 h	24 h
Test 2	1000*, 3330*, 5000*	24 h or 48 h	24 h or 48 h
Present			
Test 1	1000*, 3330*, 5000*	3 h	24 h
Test 2	1000*, 3330*, 5000*	3 h	48 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*

Absent				
Test 1	>5000	>5000	>5000	Negative
Test 2	--	>5000	>5000	Negative
Present				
Test 1	>5000	>5000	>5000	Negative
Test 2	--	>5000	>5000	Negative

Remarks - Results: The number of cells with chromosomal aberrations found in the vehicle control cultures were within the laboratory historical control data range. Both in the presence and absence of S9-mix, the notified chemical did not induce a statistically significant or biologically relevant increase in the number of cells with chromosomal aberrations in two independent experiments. The vehicle and positive controls responded appropriately.

CONCLUSION: The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY: Notox (2002v)

7.10. Toxicokinetic assessment

TEST SUBSTANCE: Notified chemical

ASSESSMENT

The acute oral and dermal toxicity of the notified chemical is low (LD50>2000 mg/kg bw). The 28-day toxicity study also revealed that the chemical has a relatively low toxicity, with a NOAEL of 1000 mg/kg/day. Therefore, an extensive toxicokinetic assessment is considered of limited value.

The water solubility of the notified chemical is high (>1000 g/L), caused by the presence of the strongly polar sulfonic acid groups. The strong polarity of these groups makes it very unlikely that this compound easily passes the gastrointestinal wall. Therefore, it is to be expected that the oral bioavailability, and thus the systemic exposure, of the notified chemical will be low.

In the case absorption of the chemical occurs, extensive hydroxylation of the aromatic rings is anticipated, followed by a rapid sulphation or glucuronidation. Another possibility is that dealkylation at the secondary amines occurs. The resulting metabolites, as well as the parent compound will be extensively excreted via urine or bile.

The notified chemical will show a low volume of distribution equalling extracellular body water (approximately 0.7 L per kg bw). Accumulation in fatty tissues is not anticipated. The plasma protein binding is expected to be low.

Uptake via inhalation is not anticipated, because of the particle size distribution (<10% < 7.2 μm).

Since the bioavailability of dermally applied compounds can be assumed to be zero for substances with a log P_{ow} below -1 and over 5 or a relative molecular mass over 700, it is not to be expected that the notified chemical will be absorbed through the skin.

Based on the expected kinetic behaviour in the body, as described above, the notified chemical will hardly be absorbed after oral administration, because of the presence of strongly polar groups in the molecule. If absorption occurs, the notified chemical will be extensively metabolised in the liver. Therefore, accumulation in the body during prolonged exposure will be very low.

This is supported by the low systemic toxicity observed in both the acute and subacute toxicity studies.

TEST FACILITY: Notox (2002x)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. Directive 92/69/EEC, C.4/C.4C
Inoculum	Activated sludge freshly obtained from a municipal sewage treatment plant "Waterschap de Maaskant" 's Hertogenbosch, The Netherlands. The sludge was kept under continuous aeration until further treatment. Before use, the sludge was allowed to settle for 30-90 minutes and the liquid decanted for use as inoculum at the rate of 10mL/L of mineral medium.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Carbon dioxide produced during the test was reacted with barium hydroxide in a gas scrubbing bottle and precipitated as barium carbonate. The amount of carbon dioxide was determined by titrating the remaining barium hydroxide with 0.05M standardised hydrochloric acid solution.
Remarks - Method	None

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	0	2	20.2
5	0	5	42.6
7	0	7	53.5
9	0.4	9	60.3
14	1.2	14	69.7
23	1.8	23	81.2
26	1.9	26	82.4
27	1.9	27	82.4
29	1.9	29	86.6

Remarks – Results	In the toxicity control 24.2% degradation occurred in 14 days. This was just below the 25%-level (based on $ThCO_2$), the criterion at which a test substance may be assumed to be inhibitory to micro organisms. However, it should be noted that a recovery of the CO_2 production in the toxicity control was observed during the test period. Therefore, it may be possible that the test substance had a delayed effect on microbial activity In spite of a recovery of microbial activity, no significant degradation of the test substance occurred in the test vessels. Degradation of the reference substance confirmed the suitability of the inoculum and validity of test conditions.
CONCLUSION	The test substance cannot be considered to be readily biodegradable according to the OECD criteria
TEST FACILITY	Notox (2002aa)

8.1.2. Bioaccumulation

No bioaccumulation data were provided. However, the bioaccumulation potential of the notified chemical is low due to its high water solubility and the low lipid solubility and log P_{ow}.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static.
Species	Carp (*Cyprinus carpio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	A pre-test was performed to test stability of the test substance in light and dark. Also stability during storage in a freezer at - 20 °C was tested. During this pretest extra peaks appeared in the chromatograms of samples taken from the test solution exposed to light whereas these peaks were not observed in the chromatograms of the samples tested in the dark. Further the results showed no significant difference between the concentrations measured in fresh and frozen samples. Analysis of the samples taken during the pre-test showed that the measured concentration of all samples taken at the start of the test were between 98 and 102 mg/L. During the exposure period the measured concentration of the samples taken from the vessels which were kept in the dark remained constant. Therefore the study was continued with a range-finding test and a limit test, which were both performed in the dark. All test solutions were clear and colourless. Oxygen content (5.6-8.9 mg O_2/L), pH (7.4-8.0) and temperature (20.9-21.5°C) were satisfactorily maintained.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*4 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	7	0	0	0	0	0
100	100	7	0	0	0	0	0

LC50	>100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	Under the conditions of the study, the notified chemical did not induce lethal effects in carp at 100 mg/L after 96 hours of exposure. Thus, the LC50 96 h for Carp exposed to the notified chemical is >100 mg/L.
CONCLUSION	The notified chemical is very slightly toxic to *Cyprinus carpio* (carp) according to Mensink *et al.* (1995).
TEST FACILITY	Notox (2002bb)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	
Remarks – Method	Analysis of the samples taken during the pre-test showed that the measured concentrations of all samples taken at the start of the test were between 98 and 102mg/L. During the exposure period the measured

concentrations of the samples taken from the vessels which were kept in the dark remained constant. Therefore the study was continued with a range-finding test and a limit test, which were both performed in the dark. All test solutions were clear and colourless. Oxygen content (8.7-9.2 mg O_2/L), pH (7.9-8.2) and temperature (19.8-20.7°C) were satisfactorily maintained.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h**	*48 h*
0		20	0 (1)	0
10		20	0 (1)	0
18		20	0	0
32		20	0	0
56		20	0	1
100		20	0	0

* Between brackets: number of daphnids observed trapped at the surface of the test solutions. These daphnids were reimmersed in the respective solutions before scoring of mobility.

EC50	>100 mg/L at 48 hours
NOEC (or LOEC)	100 mg/L at 48 hours
Remarks – Results	The data show no immobility in the blank-control and no immobility in the test concentrations after 48 hours of exposure, except for one daphnid in the 56 mg/l concentration, which was not considered to be significant.

CONCLUSION — The notified chemical is very slightly toxic to *Daphnia magna* according to Mensink *et al.* (1995).

TEST FACILITY — Notox (2002cc)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE — Notified chemical

METHOD — OEC TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.
ISO Standard 8692, 1st Edition, 15 November 1989

Species	Fresh water Algae *Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	
Nominal	0-100 mg/L
Actual	0-100 mg/L
Auxiliary Solvent	Not applicable
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	
Remarks – Method	Analysis of the samples taken from 100 mg/l showed that both in the combined limit/range-finding test and in the limit test measured concentrations were stable and in agreement with nominal during the first 24 hours in the dark, but rapidly decreased during the 72-hour test period with illumination. In the controls, cell density increased by an average factor of >16 within 3 days after the lag phase of 24 hours in the dark. Further, test conditions (pH and temperature) remained within the ranges prescribed by the protocol. The decrease of measured concentrations could be related to the photosensitivity of the test substance. During the acute toxicity study to fish, a pre-test was performed to test stability of the test substance in light and dark. Also stability during storage in a freezer at - 20 °C was tested. During this pretest extra peaks appeared in the chromatograms of

samples taken from the test solution exposed to light whereas these peaks were not observed in the chromatograms of the samples tested in the dark. Further the results showed no significant difference between the concentrations measured in fresh and frozen samples.

As expected the chromatograms of the 100-mg/L samples taken at 0 hours and after the first 24 hours in the dark did not differ significantly and no extra peaks were observed. However, new peaks appeared in the chromatograms of the 96-hour samples after the 72-hour period in continuous light.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOEC mg/L*	*E_rC50 mg/L at 72 h*	*NOEC mg/L*
>100	100	>100	100

Remarks – Results: The EC50 values could not be estimated for both growth inhibition (E_bC50 (0-72h)) and growth rate reduction (E_rC50 (0-72h)) Both the EC50 for cell growth inhibition (E_bC50: 0-72h) and the EC50 for growth rate reduction (E_rC50: 0-72h) were above a loading of 100 mg/L.

CONCLUSION: Under the conditions of the study with *Selenastrum capricornutum,* no inhibition of cell growth or reduction of growth rate was recorded at 100 mg/L of the notified chemical.

TEST FACILITY: Notox (2002dd)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 67/548 amended 1987 (87/302) Part C, Publication No L133, adopted May 30, 1988.

Inoculum: Municipal sewage treatment plant "Waterschap de Maaskant" 's Hertogenbosch, The Netherlands.

Exposure Period: 0.5 hours

Concentration Range

Nominal: 100 mg/L

Remarks – Method: None

RESULTS

IC50: >100 mg/L

NOEC: 100 mg/L

Remarks – Results: No significant inhibition of respiration rate of the sludge was recorded at 100 mg/L of the notified chemical. A duplicate measurement confirmed the result.

CONCLUSION: Under the conditions of the test, the notified chemical was not toxic to waste water (activated sludge) bacteria at a concentration of 100 mg/L

TEST FACILITY: Notox (2002ee)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported into Australia as a component in prepackaged photographic developer solutions to be used at photo-minilabs. Since the notified chemical is not consumed or converted in the developing process, approximately 0.8% ends up in waste water and 99.2% is collected as chemical waste after usage in the mini-labs. The waste from the photo-minilabs is collected and disposed of as chemical waste. At the waste contractor's site the waste will enter the liquid waste stream and be sent to the onsite treatment works before being discharged to sewer.

A worst-case scenario is considered assuming that all of the liquid waste containing the notified chemical will be discharged to the sewer. A maximum of 1000 kg per annum was estimated (as a worst-case) to be discharged into the Australian sewage system and subsequently enter the sewage treatment plants. The daily release on a nationwide basis to receiving waters is estimated to be 2.86 kg/day (based on discharge occurring 350 days per year). The worst-case predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 0.71 µg/L (Environment Australia, 2003). Assuming a national population of 20.1 million and that each person contributes an average 200 L/day to overall sewage flows, with no removal of the chemical during sewage treatment. Based on the respective dilution factors of 0 and 10 for inland and ocean discharges of effluents, the PECs of the notified chemical in freshwater and marine water may approximate 0.71 µg/L and 0.071 µg/L, respectively.

Import containers will automatically be rinsed in situ before disposal to landfill. Hence the import containers will contain little of the notified chemical.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below.

Organism	*Duration*	*End Point*	*mg/L (Measured)*
Fish	96 h	LC50	>100
Daphnia	48 h	EC50	>100
Algae	72 h	E_bC50	>100
		E_rC50	>100
Microorganisms	0.5 h	IC50	>100

A predicted no effect concentration (PNEC - aquatic ecosystems) of >1 mg/L has been derived by dividing the end point of >100 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels).

9.1.3. Environment – risk characterisation

The risk quotient (RQ) values (PEC/PNEC) for the aquatic environment were determined as follows assuming the chemical is released to the sewer nationwide and that the chemical is not removed in STP.

Location	PEC µg/L	PNEC µg/L	RQ
Worst Case			
Ocean outfall	0.071	1000	<<1
Inland River	0.71	1000	<<1

The resulting RQ values for the discharge to the aquatic environment are well below 1 for both fresh and marine water, indicating no immediate concern to the aquatic compartment. Further, the notified chemical is expected to photodegrade (as noted in the aquatic toxicity tests) further reducing the PEC and the risk quotients.

Based on the proposed use pattern the notified chemical is not expected to pose an unacceptable risk to the health of aquatic life.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Photographic developer bottles and cartridges are sealed and worker exposure to the developer solution is minimised by following the manufacturer's instructions on handling, replacing and disposing of photographic cartridges. Exposure by inhalation is expected to be negligible due to the physicochemical properties of the notified chemical, ie high molecular weight, low vapour pressure and high water solubility.

Up to hundred maintenance workers will be potentially exposed to the developers containing the notified chemical. However, they are adequately trained and wear disposable gloves to minimise the skin exposure. In addition, spillage is unlikely because of the fully enclosed cartridges. Personnel involved in cleaning-up of spills should protect themselves against respiratory, skin and eye exposure.

9.2.2. Public health – exposure assessment

The photodevelopers containing the notified chemical are not available for sale to the public. The potential for public exposure to the notified chemical via dermal contact with printed photographic media is assessed as negligible.

9.2.3. Human health – effects assessment

The notified chemical has a low acute oral and dermal toxicity in rats (LD50>2000 mg/kg/bw). It is not irritating to the skin but slightly irritating to the eyes of the rabbit. It shows no sensitising activity at up to 50% solution in an adjuvant study in guinea pigs. The NOAEL was established to be 1000 mg/kg bw/day, which is the highest dose tested in a 28-day repeat dose oral study in rats. The notified chemical was not mutagenic in a bacterial reverse mutation assay, and did not reveal any genotoxic potential in an in vitro test.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low, given the low hazard of the chemical, the packaging design of photographic cartridges, the good work practices and safety measures including use of appropriate personal protective equipment by workers. Although inhalation exposure to the developer solution is unlikely, photographic processors should be positioned in well-ventilated areas.

For routine handling of photographic cartridges, the following precautions are recommended: (1) Avoid contact of the developer solution with the eyes, skin and clothing; (2) Wash hands after use with soap and cold water. The photo-processor should be positioned in well-ventilated areas to avoid accumulation of any dusts, gases or fumes.

9.2.5. Public health – risk characterisation

Given the notified chemical will only be used in the photographic industry, the risk to public health is considered negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

The notified chemical is not classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) for both health and environmental hazards.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the notified chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the product (CP-49E PC) containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified chemical itself, however, these should be selected on the basis of all ingredients in the formulation.
  - Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- In the interest of occupational health and safety, the following guidelines and precautions should be observed for use of the notified chemical as introduced in developer bottles and cartridges:
  - Wearing cotton or disposable gloves during replacement of photographic bottles and cartridges, machine maintenance and repair services;
  - Adequate induction and training programs for service personnel.
  - Photographic machines should be positioned in well-ventilated areas.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of by incineration or to landfill in accordance

with State/Territory waste disposal regulation.

Emergency procedures

- Spills of the notified chemical should be contained with an absorbent, inert material (soil, sand, sawdust, vermiculite) and collected in sealable, labelled containers for disposal.

12.1. 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(2) of the Act:
  – if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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