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File No: SN/2

Date: July 1993

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

SECONDARY NOTIFICATION OF
NONANOIC ACID, POTASSIUM SALT

{Use Trade Name if Chemical Name is exempt information}

Text must begin on line 30

This Assessment has been compiled in accordance with the provisions of the Industrial Chemicals (Notification and Assessment) Act 1989, as amended 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 Health, Housing, Local Government and Community Services.

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

SECONDARY NOTIFICATION OF
NONANOIC ACID, POTASSIUM SALT

INTRODUCTION

This report represents the revised assessment for nonanoic acid, potassium salt when introduced in quantities >1 tonne/year.

Assessment of nonanoic acid, potassium salt was carried out under the Industrial Chemicals (Notification and Assessment) Act, 1989 (the Act) and the Summary Report of that assessment was published in the Chemical Gazette No. C 9 dated 7 September 1993.

In the initial notification the import volume was estimated to be less than one tonne/year for the first five years. Under the Act, data on toxicology and ecotoxicology testing were not required. However, some literature data in these areas were included in the 27 July, 1993 report.

Kodak Australasia Pty Ltd notified the Director that the quantity of nonanoic acid, potassium salt imported into Australia will exceed 1000 kg per year by 1 October, 1993.

As a result the Director published a notice in the Chemical Gazette No. C910 dated 5 October, 1993, requiring the secondary notification of nonanoic acid, potassium salt from Kodak Australasia Pty Ltd. This notice stipulated that the following additional toxicity data were required to undertake further assessment of the notified chemical:

- . Acute toxicity
 - . Oral route LD50 or Limit Test
 - . Dermal route LD50 or Limit Test
 - . Skin irritation
 - . Eye irritation
 - . Skin sensitization
 - . Repeated dose toxicity (14 or 28 days)
 - . Genetic toxicity
 - . Gene mutation assay
 - . Chromosomal damage in mammalian cells
1. APPLICANT

Kodak Australasia Pty Ltd, 173 Elizabeth Street, Coburg, Victoria, 3058

2. IDENTITY OF THE CHEMICAL

Chemical name: Nonanoic acid, potassium salt

Chemical Abstracts Service
(CAS) Registry No.: 23282-34-0

Other names: Potassium nonanoate
Pelargonic acid, potassium salt

Trade names: None

Molecular formula: C₉H₁₈O₂.K

Structural formula: CH₃-(CH₂)₇-COOK

Molecular weight: 197.34

Method of detection and determination: Infra-red spectroscopy

Spectral data: (nonanoic acid. sodium salt) major IR peaks at 1430, 1450, 1560 and 2940 cm⁻¹

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: Clear liquid when dissolved in solution

Melting Point: 250°C (nonanoic acid sodium salt) (1)

Density: 1170 kg/m³ at 25°C (octanoic acid, potassium salt) (2)

Vapour Pressure: Not available. Fatty acid salts would not be expected to be volatile.

Water Solubility: Saturation point not determined. An aqueous solution of 18 g/100 mL at 90°C has been reported for the sodium salt (3). The sodium salt forms complex solutions that may contain free ionic and neutral molecules as well as ionic and neutral micelles. Similarly, nonanoic acid, potassium salt would be expected to be essentially miscible with water.

Hydrolytic Stability: Data not available. Neutralisation to the stable free acid would be expected at low pH.

Partition Co-efficient (n-octanol/water) log P_{o/w}: Not available. This is not relevant for compounds which dissociate in solution. Salts of aliphatic carboxylic acids are not expected to be lipophilic. The n-butanol coefficient remains below 1 for a 0.1 M solution of octanoic acid, potassium salt (4).

Adsorption/Desorption: Not available

Dissociation Constant: Not available. Solutions expected to be alkaline. The pH of a 0.1 M aqueous solution of sodium acetate at 25°C is 8.9.

Flash Point: Not available
Flammability Limits: Not available
Decomposition Temperature: Not available
Autoignition Temperature: Not available
Explosive Properties: Not available
Reactivity/Stability: Not available
Particle size distribution: Not available
(The chemical will be imported as an aqueous solution.)

4. PURITY OF THE CHEMICAL

Degree of purity: Approximately 94%

Toxic or hazardous impurity/impurities: None

Non-hazardous impurity/impurities: (> 1% by weight)

. Chemical name: Octanoic acid, potassium salt
CAS No.: 764-71-6
Weight percentage: 4%

. Chemical name: Decanoic acid, potassium salt
CAS No.: 13040-18-1
Weight percentage: 2%

Additives/Adjuvants: None

5. INDUSTRIAL USE

Nonanoic acid, potassium salt will be imported as a component of the aqueous developer solution, MX-1587-1, which will be used in aqueous lithographic plate processing in the printing industry.

It is estimated that approximately 2.5 tonnes of nonanoic acid potassium salt will be imported in 1994 and this will increase to 3.5 tonnes in 1996.

6. OCCUPATIONAL EXPOSURE

The aqueous developer solution, MX-1587-1, containing nonanoic acid, potassium salt will be transported and stored in polyethylene drums (5 US Gallons).

The notified chemical in the developer solution will be distributed by Kodak to about 150 commercial printing establishments in Australia. At each establishment 1-2 people will be involved in manual handling of the developer solution. The developer solution will be either poured or pumped directly into the Automatic Plate Processor holding tanks.

Almost all of the lithographic plate processing in Australia is conducted in a closed system using a 3-bath automated plate processor consisting of the following three phases:

1. development (closed loop recirculation)
2. water wash (either closed loop or flush-to-sewer); and
3. "gumming" (closed loop recirculation).

7. PUBLIC EXPOSURE

Nonanoic acid, potassium salt contained in the lithographic plate developer, MX-1587-1 will only be supplied to commercial printing establishments and will not be available to the public. Although no information on the binding of the notified chemical to the final printed product has been provided, transfer of the notified chemical to the printed product, and therefore public exposure, is expected to be negligible. The potential for public exposure as a result of disposal to sewer is expected to be low.

8. ENVIRONMENTAL EXPOSURE

. Release

The principal route of environmental exposure will be through disposal of diluted and spent solutions to sewer. Each m² of plate processed requires the addition of 50 mL of MX-1587-1 (3.5 g notified substance) to the development tank. Automatic processors operate at up to 2 m per minute (plates are approx 1 m wide) with cycle times around 3.5 minutes and water consumption 7.8 L per minute. At the maximum processing speed of 2 m per minute, the concentration of notified substance leaving the processor would be 7 g in 7 L, or 1000 ppm. The material safety data sheet indicates that spills will also be flushed to sewer with large amounts of water. Neutralisation will convert the notified substance to the free acid, which is listed on AICS.

. Fate

Biodegradability testing is not required for small volume notifications. However, fatty acids and their salts are recognised as being easily biodegradable (5). Biodegradation occurs enzymatically, with beta-oxidation by lipases leading to cleavage of the hydrocarbon chain. In standard dilute sewage, nonanoic acid has a 5-day BOD of 0.59, approximately 20% of theoretical (6). This indicates that partial degradation should occur during sewage treatment, and that residues should not persist in the environment.

Removal of soaps from sewage treatment works and aquatic environments also occurs through precipitation as the insoluble calcium and magnesium salts.

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicity data on nonanoic acid, potassium salt were submitted. However, some toxicity data was available for the parent acid, nonanoic acid. Further data were on the toxicity of other longchain aliphatic carboxylic acids and their salts.

9.1 Acute Toxicity

Table 1: Summary of the acute toxicity of nonanoic acid.

Test	Route	Species	Outcome	Ref.
Acute toxicity (undiluted material)	Oral	Rat	LD50 > 3200 mg/kg	(7)

Acute toxicity (undiluted material)	Oral	Rat	LD50 > 9,040 mg/kg	(8)
Acute toxicity (undiluted material)	IP*	Rat	LDLo = 3200 mg/kg	(7)
Acute toxicity (undiluted material)	IV+	Mouse	LD50 = 224 mg/kg	(9)
Acute toxicity (10% in corn oil)	Oral	Mouse	LD50 >3200 mg/kg	(7)
Acute toxicity (10% in corn oil)	IP*	Mouse	LDLo = 1600 mg/kg	(7)
Acute toxicity	Dermal	Rabbit	LD50 >5000 mg/kg	(9)
Acute toxicity	Dermal	Rabbit	LD50 >9,040 mg/kg	(8)
Acute toxicity	Inhalation	Rat	460 mg/m ³ < LC50 < 3800 mg/m ³	(10)
Skin irritation	Dermal	Rabbit	Severe irritant	(11)
Skin irritation	Dermal	Guinea pig	Severe irritant	(9)
Skin corrosion	Dermal	Rabbit	Corrosive	(12)

* IP = Intraperitoneal

+ IV = Intravenous

9.1 Acute Toxicity

There were no deaths when nonanoic acid was administered orally to rats at a dose of 3,200 mg/kg (7) or 9,040 mg/kg (8). However 4/5 deaths occurred with oral dosing of male rats at 19,400 mg/kg and gross examination of these rats during necropsy showed indications of gastrointestinal irritation (8).

Deaths in rats also occurred when dosed intraperitoneally with nonanoic acid at 3,200 mg/kg (7).

Nonanoic acid administered to mice by the intravenous route had an LD50 of 224 mg/kg (9). A 10% solution of nonanoic acid in corn oil failed to kill mice at dose of 3,200 mg/kg when given orally, but caused death at a dose of 1,600 mg/kg by the intraperitoneal route. Symptoms in mice included laboured respiration and roughing of the coat, death was observed as long as 4 days after dosing (7).

The dermal LD50 for nonanoic acid in rabbits has been reported to be >5,000 mg/kg (9) and >9,040 mg/kg with 24-hour exposure (8). Rabbit skin when treated with nonanoic acid at 9,040 mg/kg for 24 hours showed mild to moderate erythema and oedema which diminished in severity during the second week following treatment and marked desquamation was observed during the second week (8). In the same study, majority of the rabbits treated at 4,190 or 9,040 mg/kg showed coriaceousness and fissuring of the skin.

In an acute inhalation study (10) no lethal effects were noted in rats exposed for 4 hours to an aerosol of 460 mg/m³ of nonanoic acid. However, at concentrations of 3,800 mg/m³, 8/10 deaths were observed and gross examination at necropsy showed indications of pulmonary irritation.

These data show that nonanoic acid has low acute toxicity by the intravenous, intraperitoneal, oral or dermal routes. Therefore, the potassium salt would also be expected to have low acute toxicity.

9.2 Skin Irritation

Solutions of 0.5 M or 1.0 M nonanoic acid in propanol caused skin irritation in 25 human volunteers when applied under occlusive patches (9). Similarly, 20% nonanoic acid solution in propanol produced skin reactions in 94% of the 116 healthy male volunteers who were patch tested. The lesions consisted of mainly erythema at 48 hours and pigmentation at 96 hours (13).

Nonanoic acid, left in contact with the skin for 24 hours, was found to be a moderate skin irritant in rabbits treated at 500 mg/kg (9). In another study, undiluted nonanoic acid (500 mg/kg) was applied to intact and abraded rabbit skin for 24 hours (11) and found to cause severe erythema and moderate to severe oedema of both intact and abraded skin which was evident at 72 hours after removal of the dressing. The same chemical in an undiluted form produced severe skin irritation in guinea pigs when applied to the skin (9).

A skin corrosion test was performed in rabbits with nonanoic acid applied to the skin for 4 hours (12). Microscopic examination of the treated skin 35 days after application revealed irreversible damage to the basal layer of the skin in all rabbits tested and the chemical was classified as a corrosive substance.

Based on these data it could be concluded that nonanoic acid is a severe skin irritant and causes skin corrosion. However, these effects are likely to be due to the acidity of nonanoic acid and may not apply to its potassium salt which would have slightly alkaline properties.

9.3 Eye Irritation

Severe irritation was produced by the application of 91 mg of nonanoic acid to the rabbit eye (9). Undiluted nonanoic acid (0.1 mL) was instilled into one eye of each of three albino rabbits and the eyes were examined at 1, 24, 48, and 72 hours, and again at 7 days after treatment (8). Moderate erythema, oedema and discharge were observed in addition to corneal opacity were observed in all animals up to 7 days after treatment, although the severity had subsided slightly by the seventh day. Iritis was also observed in two of these rabbits. In another study, nonanoic acid (0.1 mL) caused severe erythema, slight to moderate oedema and slight to severe discharge and slight to moderate corneal opacity in 3/3 albino rabbits at 24 hours after treatment. Only slight corneal opacity in 1/3 rabbits was observed 14 days after treatment. The effect of rinsing was also studied and found to be slightly palliative.

These data show that nonanoic acid is a severe eye irritant.

9.4 Respiratory Irritation

Rats exposed to atmospheric concentrations of 840 mg/m³ (125 ppm) for a period of 6 hours showed no symptoms of toxicity. However, in another study, test animals (species not specified) were subjected to an atmospheric concentration of 3.75 mg/L (1150 ppm) for a period of 6 hours. Clinical signs were nasal discharge, blinking, and laboured breathing (7).

Inhalation exposure indicated nonanoic acid to be a respiratory irritant.

9.5 Skin Sensitisation

No sensitisation reactions were observed in 25 human volunteers after patch testing with 12% nonanoic acid solution in petroleum ether (9).

9.6 Mutagenicity

The potential of octanoic (C8), decanoic (C10), lauric (C12) and tetradecanoic (C14) acids, which differ from octanoic acid only in chain length, to cause gene mutations was investigated in the *Salmonella typhimurium* reverse mutation assay using strains TA97, TA98, TA100, TA1535, and TA1537 and a preincubation protocol (14). These compounds were negative both in the presence or absence of metabolic activation.

9.7 Mechanistic Studies

9.7.1 Skin Irritation

The effects of a series of sodium salts of aliphatic carboxylic acids (C8, C10, C12, C14 and C16) on DNA synthesis in guinea-pig kidney fibroblasts, the release of histamine from isolated rat peritoneal mast cells and the release of cytoplasmic proteins from guinea-pig kidney fibroblasts have been studied as a model for the irritant effects of such compounds (15). The C12 compound was the most potent in the series in inhibiting DNA synthesis (0.1 mM) and inducing histamine (0.4 mM) and protein (7.1 mM) release. The order of potency was C12 > C14 > C16 > C10 > C8.

9.7.2 Inhibition of Transport Across Membranes

Octanoic acid, sodium salt at 5 mmol/kg administered intravenously to rhesus monkeys induced a 20-minute coma with myoclonia followed by complete muscular atony and disappearance of ocular movements (16). At the same dose, a clinical and electroencephalographic syndrome resembling hepatic encephalopathy was observed in 5 rhesus monkeys (17).

Octanoic acid, sodium salt at a concentration of 0.2 M was administered to rabbits by slow intravenous infusion over 4 hours. Significant inhibition of regional Na/K-ATPase activity was detected in the cortex, thalamus, hypothalamus, pons and medulla (18).

Octanoic acid, sodium salt at a concentration of 4.4 mmol modified the intracellular action potential in isolated rabbit atrium and papillary muscle. The rate of depolarisation and time of repolarisation were markedly decreased, while there was no change in the resting membrane potential. The amplitude of the action potential and reverse potential showed moderate decreases (19).

In another study, a series of sodium salts of aliphatic carboxylic acids (C3, C4, C5, C6 and C8) were tested for their effects on sodium transport by the toad bladder. Low concentrations (0.1 - 1.0 mmol) stimulated sodium transport, while higher concentrations (5 - 20 mmol) reversely inhibited sodium transport (20).

Octanoic acid, sodium salt at a concentration of 0.37 μ mol decreased the incorporation of L-leucine into normal rat liver slices and hepatoma cells by approximately 75% (21).

Overall, these data indicate that octanoic acid sodium salt may be interfering with transport across the cell membrane.

9.7.3 Platelet Aggregation

Intravenous administration of octanoic acid, sodium salt to rabbits (dose not specified) resulted in a pronounced, although transient, inhibition of platelet adhesiveness. A single oral dose had no effect on platelet adhesiveness, while

repeated oral dosing (up to 3 weeks) resulted in progressive and significant decrease in platelet adhesiveness (22).

9.8 Overall Assessment of Toxicological Data

No toxicity data on nonanoic acid potassium salt were submitted. The toxicity profile of the notified chemical would be expected to be similar to that of closely related compounds. Some toxicity data on nonanoic acid, the parent compound, were submitted and additional data on octanoic acid, sodium salt were available in the literature. The secondary notification contained further toxicity data on nonanoic acid.

Nonanoic acid has low acute toxicity via the oral and dermal routes. The LD50 values for nonanoic acid, administered by the intravenous or intraperitoneal route also indicate that this substance has a relatively low acute toxicity. An inhalation toxicity study showed nonanoic acid to have low to moderate acute inhalation toxicity in the rat.

Nonanoic acid was shown to be a primary skin irritant in both humans and animals. It was found to cause severe skin irritation in rabbits and guinea pigs, and be corrosive to rabbit skin. Severe eye irritation in rabbits was also observed with nonanoic acid. In addition, this substance was found to cause respiratory irritation. There was no evidence of skin sensitisation with nonanoic acid in human patch testing.

Several aliphatic carboxylic acids (C8, C10, C12 and C14) were found to be negative in the Salmonella typhimurium reverse mutation assay.

A homologous series of sodium salts of aliphatic carboxylic acids (C8, C10, C12, C14 and C16) were found to inhibit DNA synthesis and cause the release of protein from fibroblasts. These compounds also induced histamine release from mast cells.

Several studies on octanoic acid, sodium salt indicated that it had the potential to interfere with transport across the cell membrane.

Octanoic acid, sodium salt was shown to inhibit platelet adhesiveness in vivo.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The aquatic toxicity of nonanoic acid potassium salt may be estimated by comparison with the free acid and its sodium salt, for which quantitative structure activity relationships have been developed (23).

Fatty acid sodium salts were found to be less toxic than the parent acids, and toxicities of both increased with chain length (between 6 and 12 carbons). This behaviour is typical of a non-specific aquatic toxicant, with toxicity dependent on the partitioning between water and fish. Good correlation was obtained between the log LC50 to red killifish and the estimated log CMC (critical micelle concentration) for sodium caprylate, caprate and laurate (8, 10 and 12 carbons).

Critical concentrations of surfactants depend almost entirely on their hydrophobic portion. For homologous fatty acid salts, the critical micelle concentration (CMC) may be readily estimated from the equation:

$$\log \text{ CMC} = A - 0.3n$$

where n is the number of carbon atoms and A is equal to 1.85 for sodium (23) and 1.70 for potassium (24). This equation can be used to predict that the LC50 of

nonanoic acid, potassium salt to red killifish should be approximately 100µg.L-1.

Toxicity to algae may be estimated by comparison with data for soaps in general. For example, a range of 180-320µg.L-1 has been reported for *Chlorella vulgaris* (4). Nonanoic acid, potassium salt would therefore not be expected to be significantly toxic to algae.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

For 150 customers, the estimated import volume corresponds to around 5kg per customer per year, or a daily use per establishment of 20g, assuming each processor operates for 250d per year. In a hypothetical worst case situation of 10 such customers discharging to a rural sewage treatment works with a daily flow of 5ML, the concentration of notified substance in the effluent would be reduced to 40ppb simply by dilution, and further by any degradation or sorption that occurs.

The above clearly represents the average situation, as the estimated daily use would be consumed in about 10minutes by the typical automatic processor operating at 2µm per minute. It is likely that use at individual establishments will fluctuate and be significantly higher on particular days. As noted above, processor effluent will contain up to 1000ppm of the notified substance. However, the photographic industry's code of practice (25) requires that effluent be directed to balancing tanks with a minimum detention time of 1hour, in order to dilute processor effluent before it enters sewers.

In view of the low aquatic toxicity predicted for nonanoic acid potassium salt and lack of bioaccumulation potential, the environmental hazard associated with the proposed lithographic use would appear negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

No toxicity data were provided for nonanoic acid potassium salt. However, the notified chemical would be expected to have a similar toxicity profile to nonanoic acid and salts of aliphatic carboxylic acids of similar chain length. Nonanoic acid, potassium salt would be expected to have low oral and dermal acute toxicity, be a primary skin and eye irritant, able to interfere with transport across the cell membrane, and reduce platelet adhesiveness. Thus, oral exposure and eye and skin contact with the notified chemical should be avoided.

The use pattern indicates that occupational and public exposure to nonanoic acid, potassium salt will be minimal under normal use conditions. Therefore, the notified chemical would be expected to be of low hazard to human health.

13. RECOMMENDATIONS

To minimise occupational exposure (and public/environmental if recommendations have been made by these agencies) to nonanoic acid, potassium salt the following guidelines and precautions should be observed:

. If engineering controls are insufficient to reduce exposure to a safe level, the following personal protection equipment should be worn, as the notified chemical is a severe eye and moderate skin irritant:

- . face shield (AS 1336 and AS 1337) (26,27);
- . impervious gloves (AS 2161) (28);
- . protective clothing (AS 3765.1, AS 3765.2) (29,30);

. good work practices should be implemented to avoid spillages or splashings and in the case of handling nonanoic acid, potassium salt and the formation of a mist;

. Any spillages should be promptly cleaned up and disposed according to local or state regulations;

. good personal hygiene should be observed; and

. a copy of the Material Safety Data sheet for nonanoic acid, potassium salt and products containing it should be easily accessible to workers.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for nonanoic acid, potassium salt (Attachment 1) was provided in Worksafe Australia format (31). This MSDS was provided by Kodak Australasia Pty Ltd as part of their notification statement. It is reproduced here as a matter of public record. 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 (the Act), secondary notification of nonanoic acid potassium salt shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

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