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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Ammonium thiolactate

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Ammonium thiolactate

1. APPLICANT

Asia Pacific Specialty Chemicals Limited of 15 Park Road SEVEN HILLS NSW 2147 has submitted a limited notification statement in support of their application for an assessment certificate for Ammonium thiolactate.

The applicant has not claimed for any exempt information.

2. IDENTITY OF THE CHEMICAL

Chemical Name: propanoic acid, 2 mercapto-, monoammonium salt

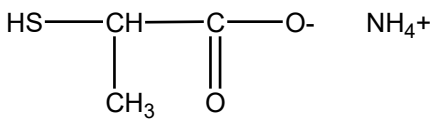
Chemical Abstracts Service (CAS) Registry No.: 13419-67-5

Other Names: lactic acid, thio-monoammonium salt
ammonium 2-mercaptopropionate

Marketing Name: Ammonium thiolactate

Molecular Formula: $C_3H_6O_2S\text{-}H_3N$

Structural Formula



Molecular Weight: 123.17

Method of Detection and Determination: Qualitatively detected by formation of a violet complex with iron ions and quantitatively estimated by titration with iodine solution with starch indicator

Spectral Data: not provided

Comments on Chemical Identity

No spectral data have been supplied by the notifier for the chemical. However, this is acceptable because the chemical has a very simple structure that is easily researched in the literature sources and the parent thiolactic acid is present on AICS.

3. PHYSICAL AND CHEMICAL PROPERTIES

The following data correspond to 58% ammonium thiolactate in water, unless otherwise specified.

Appearance at 20°C and 101.3 kPa:	waterwhite to faint pink liquid
Boiling Point:	100-105°C (water)
Density:	1 150 kg/m^3
Vapour Pressure:	1.5 kPa at 25°C
Water Solubility:	highly soluble (see comment below)
Partition Co-efficient (n-octanol/water):	Log K_{ow} = 1.18 (calculated; see comments below)
Hydrolysis as a Function of pH:	not determined (see comment below)
Adsorption/Desorption:	no provided (see comments below)
Dissociation Constant:	pKa (COOH) = 3.63 (20°C) pKa (SH) = 10.24 (20°C)
Flash Point:	not applicable
Flammability Limits:	not flammable
Autoignition Temperature:	not applicable
Explosive Properties:	not explosive
Reactivity/Stability:	solutions of ammonium thiolactate are reactive with strong oxidising agents; the reaction product ammonium dithiodilactate is not considered hazardous however, under the influence of heat (> 150°C) hydrogen sulphide can be evolved

Comments on Physico-Chemical Properties

The notifier claims that the chemical is miscible with water at any ratio. However, no test results were supplied. Based on its ionic nature it is considered to be very soluble with water.

No value for hydrolysis was provided by the notifier on the grounds that the chemical contains no groups that will hydrolyse. Environment Australia agrees with this statement.

The value for Partition Coefficient has been calculated for thiolactic acid and from the structural formula by the method of Hansch and Leo (1979). The value for the ammonium salt may be expected to be lower.

No data were provided for the adsorption/desorption behaviour of the notified chemical. Based on the high water solubility, low molecular weight and expected low partition coefficient the chemical is expected to be mobile in soils and sediments.

The dissociation constants supplied are for thiolactic acid.

4. PURITY OF THE CHEMICAL

Degree of Purity:	58 – 70% ammonium thiolactate solution in aqueous solution
Non-hazardous Impurities (> 1% by weight):	none

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as an ingredient in a permanent waving solution for human hair. It will not be manufactured in Australia but will be imported as a 58 – 70% aqueous solution in 200 L steel drums and stored at the notifiers warehouse.

The notified chemical will be transported to the customer and blended and repackaged in 30 mL containers to final cosmetic concentrate products containing 35% notified chemical; these will be transported to sales outlets.

At hairdressing salons, the concentrate product will be mixed with lotion (28 mL concentrate plus 62 mL lotion), to give a final concentration of < 11% notified chemical, that is applied to hair.

Less than one tonne per annum of the notified chemical will be imported in the first five years. This corresponds to an expected 45,000 units of concentrate.

6. OCCUPATIONAL EXPOSURE

The notified chemical has a low-moderate vapour pressure. Thus, inhalation and dermal (including eye) exposure may occur for workers handling cosmetic concentrate products containing 35% of the notified chemical.

Transport and storage
The aqueous solution of chemical will be imported in 200 L sealed drums. After importation, it will be warehoused at the notifier's site and delivered to the customer site by road transport. Waterside, transport and warehouse workers will handle the sealed product, so occupational exposure for these workers is negligible unless an accident occurs.

Formulation and plant operation
At the customer site, laboratory technicians will collect quality control (QC) samples for testing. A formulator will manually weigh the notified chemical in a container and transfer it into a stainless steel vessel containing water and other ingredients for mixing. The final product (concentrate) will contain a maximum of 35% of the notified chemical. After QC testing the product is transferred to storage containers which in turn are transferred to filling machines via hoses. The final product containing the notified chemical is dispensed to 30 mL containers. Approximately 10 batches are manufactured per annum. Workers could be exposed to the notified polymer through dermal contamination during quality control analysis, weighing, transfer to the mixing vessel and storage vessels and during the connecting and disconnecting of the filling hoses. The workers will wear gloves, overalls and safety glasses.

End use product exposure
Workers in hairdressing salons will dilute the concentrate to <11% in waving lotion, before applying it to hair. These workers may or may not wear gloves and would experience dermal and may be inhalation exposure to the chemical. The notifier claims that the chemical is inactivated when dilute hydrogen peroxide solution is added to client's hair at the end of the treatment process, before the hair is rinsed.

7. PUBLIC EXPOSURE

There is considerable potential for intermittent exposure of the public to the notified chemical in permanent wave hairdressing solutions. Accidental exposure of the notified chemical will only occur in the event of a spill.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier estimates that up to 10 kg of the notified chemical may be lost through accidental spills and equipment washings during reformulation. All of the permanent wave concentrate will to be used at hairdressing salons around Australia and the chemical is expected to enter the sewers to be treated before release to the environment. Approximately 50% of the product will be absorbed onto towels, which are cleaned through commercial launderettes. The other 50% will be reacted with hydrogen peroxide whilst on the clients' hair before being

rinsed from the hair and washed from the basin into the sewer.

The notifier also estimates that approximately 0.1 g residue of the notified chemical will remain in the 'empty' concentrate bottles disposed of to landfill after use. Annual production of the final product is expected to be 45,000 units. This equates to 4.5 kg of the chemical being released to the environment via landfill.

The notifier has indicated that the 'empty' 200 L drums that contained the 58 - 70% ammonium thiolactate solution will be disposed to landfill but has not estimated the amount of residue that would remain in these drums. However, based on past experience, this is estimated at 1%.

Fate

Considering the high water solubility, low molecular weight and expected low partition coefficient the chemical is expected to be mobile in soils. All the chemical released to the sewer is expected to remain in the water fraction, with none associated with sediments.

The 4.5 kg of chemical disposed of to landfill from used concentrate containers is likely to leach out in very low concentrations and in a diffuse manner. The notified chemical is expected to eventually be broken down by chemical and microbiological degradation in the environment. It is not expected to bioaccumulate due to its very high water solubility.

9. EVALUATION OF TOXICOLOGICAL DATA

The chemical has been notified as a limited notification. Part C of the schedule is not required, however available data should be submitted. The notifier has submitted reports of two toxicological tests, which are summarised below.

9.1 Acute Toxicity

Summary of the acute toxicity of

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} = l518 mg/kg (Bliss method) LD_{50} < l522 mg/kg (Litchfield & Wilcoxon method)	(Lheritier, 1990)
skin sensitisation	guinea pig	weak sensitiser	(Kaufmann, 1991)

9.1.1 Oral Toxicity (Lheritier, 1990)

Species/strain:	rat/Sprague-Dawley CD
Number/sex of animals:	5/sex (five groups)
Observation period:	15 minutes after intubation; 1, 2 and 4 hours; daily for 14 days
Dosages:	0, 1 125, 1 415, 1601 and 1 786 mg/kg
Method of administration:	0.97 to 1.54 mL/kg in distilled water by gavage
Test method:	OECD TG 401
Mortality:	20% at 1 415 mg/kg; 80% at 1 601 mg/kg; 90% at 1 786 mg/kg
Clinical observations:	at 1 125mg/kg animals showed low activity up to 4 hours but normal on day following treatment; at 1 415 mg/kg absence of motor function noted in all animals up to 4 hours, one animal exhibited tremors up to 1 hour and all surviving animals were normal the day following treatment; at 1 601 mg/kg clonic convulsions, loss of motor functions and tremors were observed up to 4 hours and 2 surviving animals were normal on day 2; at 1 786 mg/kg absence of motor function and clonic (incoordinate "thrashing" type) convulsions were observed in all animals up to 4 hours, 2 animals exhibited lethargy day following treatment, in a few animals tremors were noted and the surviving animal was normal on day 2;
Morphological findings:	Animals that died during the study showed congestion in the lungs; no abnormalities were observed at necropsy
Comment;	LD50 calculated according to Bliss' method (Bliss, 1938) = 1518 mg/kg; and that calculated according to Litchfield & Wilcoxon's method (Litchfield & Wilcoxon, 1949) = 1522 mg/kg
LD_{50}*:*	1522 mg/kg (1421-1630 mg/kg) (Litchfield & Wilcoxon method) 1518 mg/kg (1435 – 1606 mg/kg) (Bliss method)
Result:	the notified chemical was of low acute oral toxicity in rats

9.1.6 Skin Sensitisation (Kaufmann, 1991)

Species/strain:	guinea pig/Pirbright white
Number of animals:	10/sex: 20 test, 10 controls
Induction procedure:	The test article was applied undiluted to clipped skin of left anterior quadrant of the back of each test animal and kept for 6 hours and dermal irritation was assessed after 24 hours; procedure repeated on the same site once weekly for 3 weeks
Challenge procedure:	Two weeks after the final induction exposure, test and control animals were challenged on a previously untreated site with 58.23 and 20.38% of the test article. Method of application and duration of exposure were similar to the induction process. 18 – 22 hours after patch removal allergic responses were evaluated at 24 and 48 hours
Test method:	OECD TG 406

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
20.38%	**0/20	***3/20	0/10	0/10
58.23%	0/20	***3/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response
*** slight patchy erythema or slight, but confluent or moderate, patchy erythema

Comment:	at 58.23% challenge 3 animals exhibited slight patchy erythema at the 24 hour time interval which was persistent in 2 animals and increased to slight, but confluent or moderate, patchy erythema in the other
Result:	the notified chemical was a weak sensitiser to the skin of guinea pigs

9.4 Overall Assessment of Toxicological Data

The notified chemical, ammonium thiolactate, exhibited low acute oral toxicity in rats with an $LD_{50} \leq 1\ 522$ mg/kg and was a weak sensitiser to guinea pig skin.

Under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) ammonium thiolactate is classified as a hazardous substance on the basis of its acute oral toxicity ($LD_{50} \leq 1\ 522$ mg/kg) and requires the risk phrase R22 Hazardous if swallowed.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided which is acceptable for chemicals submitted as limited notifications.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard presented by the importation and use of the chemical is expected to be low. The products containing the notified chemical will be used throughout Australia. The major environmental exposure to the substance will come from discharge of water from hairdressing salons to the sewers.

As the product will be used nation-wide, and sent to sewage treatment plants in both city and country locations, a Predicted Environmental Concentration (PEC) based on continental use has been calculated:

Import Volume per annum	1 tonne
Amount discharged to sewer	100%
Volume discharged per day	3.0 kg
Sewer output per day*	2 700 ML
Concentration in Sewage Treatment Plant	1.0 μg/L (pp.)

*Sewer output based on an Australian population of 18 million, each using 150 L water per day.

PEC calculations show that the exposure to aquatic organisms will be at very low level, 1 ppb in sewage effluent further diluted to 0.1 ppb by receiving waters. Adsorption to sludge, soil and sediment is unlikely to occur and the substance will eventually be broken down by chemical and microbiological degradation in the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical exhibited low acute oral toxicity in rats with an $LD_{50} \leq 1\ 522$ mg/kg. Ammonium thiolactate was a weak sensitiser to guinea pig skin.

The notified chemical is classified as a hazardous substance in accordance to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999) on the basis of its acute toxicity ($LD_{50} \leq 1\ 522$ mg/kg) and will carry the risk phrase R22.

The imported solution (58 – 70% chemical) and product concentrate (35% chemical) are also hazardous substances. Hazardous substances labelling will apply to the concentrate label, which will require the risk phrase R22 Harmful if swallowed.

Occupational health and safety
Under normal working conditions, waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical, as they will be handling sealed drums containing the notified chemical. Therefore occupational health risk for the workers is considered to be low.

During formulation, workers involved in QC testing, manual weighing and transfer of the notified chemical to the mixing vessel, are likely to experience dermal and may be eye exposure to the notified chemical. Workers involved in other processes, such as connecting and disconnecting filling lines and QC testing the final product, may also experience dermal and eye exposure to a lower concentration of notified chemical. Workers will need to avoid skin contamination, and should wear the safety gloves, overalls and safety glasses as stated in the notification statement. Exhaust ventilation should be provided.

Workers in hairdressing salons will also handle the concentrate, at 35% chemical, and the diluted perming solution applied to hair (11% chemical). Exposure in the salon may be frequent, consequently hairdressing workers should also avoid skin contact, particularly as the chemical is a mild sensitiser. The notification statement states that these workers will wear gloves, but does not indicate whether disposable gloves are included in the end use packet. In practice, gloves use is likely to be variable.

Public health

There is considerable potential for public exposure to the notified chemical arising from its use as an ingredient in permanent waving solutions in the hairdressing industry. Given the use pattern and the limited toxicological information supplied, any information on skin and eye irritancy, skin absorption and dermal toxicity studies would have assissted in the public health assessment. However, the low import volume and the concentration of the notified chemical in the final product (11%) may indicate a low risk to public health.

13. RECOMMENDATIONS

Ammonium thiolactate may be recommended to the National Occupational Health and Safety Commission for consideration for inclusion in the NOHSC List of Designated Hazardous Substances.

End use products used in the workplace and containing ammonium thiolactate at $\geq$ 25% will require labelling under hazardous substances regulations.

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

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);

- Industrial clothing should conform to the specifications detailed in AS 2919 (Standard Australia, 1987) and AS 3765.1 (Standards Australia, 1990);

- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australian/Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australian/Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the material safety data sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commssion, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Secondary notification under section 64(1) of the Act shall be required if the method of use changes in such a way as to greatly increase the environmental exposure of the notified chemical, particularly to natural waters, or if additional information becomes available on adverse environmental effects of the chemical. Ecotoxicity results including for algae and chronic exposure to daphnia would be required if the import volume exceeds 1 tonne. Secondary notification under section 64(1) of the Act shall be required if conditions of use are varied such that greater public exposure to the notified chemical may occur. Secondary notification of the notified chemical shall also be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

16. REFERENCES

Hansch C and Leo AT (1979) Substituent Constants for Correlation Analysis in Chemistry and Biology, John Wiley, New York.

Kaufmann K (1991) Skin Sensitisation in the Guinea-Pig, Project Nos. 1-05-1879-90, IBR Forschungs Gmbh, Germany.

Lheritier M (1990) Acute Oral Toxicity to the Rat, Project Nos. 071404 – PO1 and 071404 – DO1, Hazleton, France.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Canberra, Australian Government Publishing Service.

National Occupational Health and Safety Commission (1994b) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Canberra, Australian Government Publishing Service.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Sydney, Standards Association of Australia.

Standards Australia (1990) Australian Standard 3765.1-1990, Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals. Sydney, Standards Association of Australia.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Sydney, Standards Association of Australia.

Standards Australia (1998) Australian Standard 2161.2:1998, Occupational Protective Gloves, Part 2: General Requirements. Sydney, Standards Association of Australia.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Sydney/Wellington, Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Sydney/Wellington, Standards Association of Australia/Standards Association of New Zealand

Attachment 1

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

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

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

CORNEA

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

CONJUNCTIVAE

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

IRIS

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