File No: NA/214

Date: 27 June 1995

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Alpha Step® MC-48

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Alpha Step MC 48

1. APPLICANTS

The following applicants submitted a joint standard notification for the chemical Alpha Step® MC-48 which will be imported in volumes in excess of 1 tonne per annum.

Amway of Australia Pty Ltd, 46 Carrington Road Castle Hill NSW 2154

Bronson and Jacobs Pty, Parkview Drive Australia Centre, Homebush Bay NSW 2140

2. <u>IDENTITY OF THE CHEMICAL</u>

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

Other name: Alpha sulfo methyl esters

Trade name: Alpha Step® MC-48

Method of detection and determination:

The identity of the major components of the notified chemical may be determined by infrared or NMR spectroscopy. The purity may be determined by potentiometric titration.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: straw coloured waxy solid when dried

Melting Point: 162-179°C (liquid bath method)

Relative Density: 1210.8 kg/m³

Vapour Pressure: 1.0 x 10⁻⁶ kPa at 25°C

Water Solubility: 47.5-50% (flask shaking method)

Partition Co-efficient

(n-octanol/water) log P_{OW}: -3.6 (estimated from solubilities in n-octanol and

water)

Hydrolytic Stability: the extent of hydrolysis of 1.5 g/L solutions over a

5 day period at 50°C was below 10% at pH 4, 7

and 9.

Adsorption/Desorption: adsorption was moderate (soil organic carbon

partition coefficients between 152 and 498) and reversible in duplicate studies on three soils

Dissociation Constant

pKa: 2.12 at 22°C (potentiometric titration technique)

Combustion Products: carbon and sulfur oxides

Autoignition Temperature: no self-ignition was observed below the melting

temperature

Explosive Properties: has no known explosive properties

Reactivity/Stability: may react with strong oxidising or alkali agents

Particle size distribution: not relevant as the chemical is only available in

solution

4. PURITY OF THE CHEMICAL

The notified chemical contains no hazardous impurities at levels necessary to classify it as a hazardous substance (1). Therefore, information on the purity of the chemical has been exempted from publication in the Full Public Report and the Summary Report.

5. <u>INDUSTRIAL USE</u>

The notified chemical will be imported from the USA where it is presently in use. Amway of Australia Pty Ltd will import formulated products containing approximately 4% of the notified chemical. Bronson and Jacobs Pty will import the chemical as a 40% solution and distribute it to manufacturers of household and/or industrial cleaning products. The imported solution will be reformulated into such products as hand dishwashing detergents, light duty household cleaners and laundry products.

Import volumes of the notified chemical will be in excess of 1 tonne/annum for the first 5 years.

6. OCCUPATIONAL EXPOSURE

Amway of Australia will import formulated goods containing the notified chemical which will be sold directly to the public. Exposure of Amway staff to the notified chemical will be negligible as the sealed products contain low concentrations of Alpha Step[®] MC-48 (~4%).

Bronson and Jacobs will import Alpha Step® MC-48 as a 40% solution in sealed unbreakable containers and transport it to their Homebush Bay site for reformulation.

A total of 6 workers will be involved in reformulation. Two handlers/formulators will be involved in handling, transporting and storing containers of imported product as well as preparing mixtures containing the imported product. These activities are expected to take a maximum of 1 hour/day, 4 days/year. Two raw materials testers will sample and test the imported product and mixtures containing the imported product, for a maximum of 4 hours/day, 4 days/year. Two packers will dispense the formulated products into plastic bottles, and pack them into cardboard boxes, for a maximum of 4 days a year. Workers will wear eye protection (eg. goggles), PVC gloves, protective clothing (eg. industrial overalls and PVC apron) and protective footwear to limit exposure.

7. PUBLIC EXPOSURE

The notified chemical is to be used as a surfactant. It will be imported as a 40% aqueous solution and reformulated into such products as hand dishwashing detergents, light duty household cleaners and laundry products, or will be imported as formulated products containing ~4% of the notified chemical. The products containing the notified chemical will be made available to both the household and industrial markets, and as a result public exposure is likely to be extensive. Although no information was provided on the products reformulated from the 40% solution, presumably those would contain similar levels of notified chemical.

The applicants have stated that the substance is not classified under the Australian Code of Transport of Dangerous Goods by Road or Rail. The chemical will be stored in closed unbreakable containers. Once formulated, the products will be transported in customer packaging (usually plastic containers) which in turn will be stored and transported in corrugated cardboard boxes.

8. <u>ENVIRONMENTAL EXPOSURE</u>

- . Release
- Formulation, handling and disposal

Reformulation of the aqueous solution into cleaning products will be undertaken by Bronson and Jacobs Pty Ltd, Homebush Bay, NSW. Blending into cleaning products is not expected to generate significant quantities of waste. Spills will be contained with suitable inert material, collected and contained in drums for disposal. Finished products will be packed in plastic bottles, in turn packed in cardboard cartons for distribution.

Use

Cleaning products (detergents, household cleaners, laundry products) containing Alpha Step® MC-48 will be diluted with water before use by the consumer, and discharged to sewer as diluted solutions after cleaning.

. Fate

The main pathway for removal of Alpha Step® MC-48 from effluent streams and the environment is expected to be biodegradation. Testing of radiolabelled palmitate (methyl ester) at a concentration of 0.1 mg/L in the presence of activated sludge from a Swiss sewage treatment plant revealed rapid degradation and mineralisation, with no starting material remaining after 5 days and 62-67% $^{14}\text{CO}_2\text{evolved}$ within 28 days (2). Metabolism involved oxidative degradation of the alkyl chain, followed by desulphonation and ester scission. Mineralisation reached 55-62% over a 28 day period, after an initial lag of 2-6 days, at higher concentrations (1 and 5 mg/L).

The degree of mineralisation of methyl ester and disodium salt reached around 50% in a model plant with 3 hour hydraulic retention time fed continuously at 10 mg/L. Much less than 1% of intact surfactant was found in plant effluent. These results are said to be similar to those obtained for tallow fatty acid, ester sulfonates. No significant biodegradation could be observed under anaerobic conditions, consistent with the proposed mechanism, the first step of which (ω -oxidation) requires molecular oxygen.

Rapid mineralisation of the palmitate also occurred on various soils, with cumulative CO₂ production reaching 49-66% and 64-76% in 28 days at methyl ester concentrations of 10 and 1 mg/kg, and 31-79% at disodium salt concentrations of 300 mg/kg (2).

Testing of the notified mixture at a concentration of 20 mg/L dissolved organic carbon resulted in 54% degradation as measured by carbon dioxide evolution (3). This falls slightly short of the strict criterion (60%) adopted by the OECD (Test Guideline 301B) for defining ready biodegradability.

In summary, primary biodegradation of Alpha Step® MC-48 in sewage treatment should exceed 99%. Ultimate biodegradation of residues and metabolites in plant effluent is expected to follow rapidly in receiving waters. The hydrophilic surfactant is not expected to bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

The test material used in the following toxicological reports was neat dried Alpha Step® MC-48.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Alpha Step® MC-48

Test	Species	Outcome	Reference
Oral	Rat	LD ₅₀ > 2000 mg/kg	4
Dermal	Rat	LD ₅₀ > 2000 mg/kg	5
Skin irritation	Rabbit	non-irritant	6
Eye irritation	Rabbit	severe irritant	7
Skin sensitisation	Guinea pig	non-sensitising	8

9.1.1 Oral Toxicity (4)

This study was conducted in accordance with OECD guideline No: 401 (9).

Alpha Step® MC-48 was administered by the oral route to Sprague-Dawley rats (5/sex), at a single dose of 2000 mg/kg in dimethyl sulphoxide (DMSO). The animals were observed for the following 14 days. Necropsy was performed on animals which died. All remaining animals were sacrificed on day 15 and necropsy performed.

Two female animals were found dead one day after dosing. All surviving animals showed the following clinical signs: hunched posture, lethargy, decreased respiration rate and laboured respiration, noisy respiration and increased salivation. These effects disappeared 2-4 days after dosing. Bodyweight gains of the surviving animals were unaffected by treatment.

Necropsy on the female animals that died revealed haemorrhagic lungs, dark kidneys, as well as haemorrhage of the gastric mucosa, small intestines and large intestines. Two of the sacrificed animals (one of each sex) showed sloughing of the gastric mucosa. All other animals showed no significant macroscopic lesions.

The results of this study indicate an acute oral LD₅₀ of>2000 kg/mg in rats of both sexes for Alpha Step $^{\circ}$ MC-48.

9.1.2 Dermal Toxicity (5)

This study was conducted in accordance with OECD guideline No: 402 (10).

A single dose of undiluted Alpha Step® MC-48 was administered by semi-occlusive dermal application (24 hour contact) to 10 Sprague-Dawley rats (5/sex) at a dose of 2000 mg/kg. Clinical observations were made for 14 days after the day of treatment. No deaths occurred during the observation period. All rats were sacrificed on day 15 and necropsy performed. Bodyweight gains of the treated animals were unaffected by treatment in all but one female which showed a bodyweight decrease in the first week after treatment. Necropsy on sacrificed animals revealed no significant macroscopic lesions.

Skin effects were noted up to seven days after treatment. These effects included very slight to well-defined erythema (all animals), very slight oedema (2 males), slight haemorrhage of dermal capillaries (1 male, 2 females), desquamation (2 females) and loss of skin elasticity (1 male).

The results of this study indicate an acute dermal LD₅₀ of >2000 kg/mg in rats of both sexes for Alpha Step® MC-48.

9.1.3 Inhalation Toxicity

Inhalation toxicity data were not provided. This is acceptable as the chemical has low vapour pressure (1.0 x 10⁻⁶ kPa at 25°C) and exposure via inhalation will be unlikely.

9.1.4 Skin Irritation (6)

This study was conducted in accordance with OECD guideline No: 404 (11).

A single 4-hour semi-occluded application of 0.5 g Alpha Step® MC-48 (moistened with 0.5 ml distilled water) was made to the closely-clipped dorsa of 3 New Zealand White rabbits (1 male and 2 females). Four hours later the dressings were removed and the test site wiped with cotton wool soaked with distilled water. Skin reactions were assessed 1, 24, 48 and 72 hours after dressing removal. All animals showed very slight erythema at the 1 and 24 hour observations, which persisted in the one animal through 48 hours. Two animals showed very slight oedema at 1 hour only.

The results of this study indicate that Alpha Step® MC-48 is not a skin irritant in rabbits.

9.1.5 Eye Irritation (7)

This study was conducted in accordance with OECD guideline No: 405 (12).

A single application of Alpha Step® MC-48 (0.1 g) was instilled in the conjuctival sac of the right eye of one male New Zealand White rabbit. The left eye served as the control. Ocular damage/irritation was assessed at 1, 24, 48 and 72 hours after treatment.

The test agent produced vocalisation in the animal approximately 15 seconds after instillation.

Corneal effects were reported throughout the study: dulling of normal corneal luster at 1 hour; areas of diffuse corneal opacity at 24 and 48 hours; areas of translucent corneal opacity at 72 hours. Iridial inflammation was observed at all observation times. Conjunctival redness, chemosis and discharge were observed throughout the study (severe at 1 and 72 hours, moderate at 24 and 48 hours). Haemorrhage of the nictitating membrane was observed at 24, 48 and 72 hours. At 72 hours the nictitating membrane was pale in appearance and discharge was blood stained.

The results of this study suggest that Alpha Step® MC-48 is a severe eye irritant in rabbits.

9.1.6 Skin Sensitisation (8)

This study was conducted in accordance with OECD guideline No: 406 (13).

Female albino guinea pigs (20 test, 10 control, 8 pretest) were used in the Magnusson-Kligman Maximisation Test.

Pretest

Four animals were injected intradermally with Alpha Step® MC-48 at concentrations ranging from 0.15 to 5% (w/v in distilled water). An intradermal induction concentration of 0.1% was selected (highest concentration which did not cause local necrosis, ulceration or systemic toxicity).

Two animals (intradermally injected with Freund's Complete Adjuvant eight days earlier) were treated with 48-hour occlusive applications of Alpha Step® MC-48 at concentrations ranging from 10 to 75% (w/w in distilled water). An induction concentration of 10% was selected (highest concentration producing mild to moderate dermal irritation).

Two animals were treated with 24-hour occlusive applications of Alpha Step® MC-48 at concentrations ranging from 1 to 10% (w/w in distilled water). Challenge concentrations of 2 and 5% were selected (the highest non-irritant concentrations).

Induction

On day one, 20 test animals were injected intradermally (on either side of a 4 x 6 cm clipped area of the dorsal scapula) with 0.1 ml Freund's Complete Adjuvant (FCA) diluted 50:50 with distilled water (50:50 FCA), 0.1% w/v Alpha Step® MC-48 in distilled water and 0.1% w/v Alpha Step® MC-48 in 50:50 FCA. Similar injections were made in the control animals however test material was excluded. Skin reactions were assessed by the Draize method at 24 and 48 hours.

On day 7, all test animals were induced with a 48-hour occluded application of 10% Alpha Step® MC-48 (0.2-0.3 ml). Control animals were treated with vehicle alone. Skin reactions were assessed 1 and 24 hours after patch removal.

Challenge

On day 21, 24-hour occluded applications of 2 and 5% Alpha Step® MC-48 were made to the clipped right flank of both test and control animals. The left flank was treated with vehicle alone. Sensitisation reactions were assessed 24 and 48 hours after patch removal.

Results

After intradermal induction, all test animals showed very slight to well-defined erythema (24 and 48 hours) and 5 control animals showed very slight erythema (24 hours).

One test animal was found dead on day 10. The cause was unknown.

Skin reactions in test animals after topical induction included very slight to well-defined erythema at 1 hour (20/20) and 24 hours (17/19), as well as very slight oedema at 1 hour (13/20) and 24 hours (6/19). No reactions were observed in the control group after topical induction.

Twenty-four hours after challenge with 5% Alpha Step® MC-48 very slight erythema was observed in 2/19 test animals. By 48 hours, no animals in this group showed any skin

reactions. Animals treated with 2% Alpha Step® MC-48 and control animals showed no reactions at either observation time.

The results of this study suggest that Alpha Step® MC-48 is not a skin sensitiser in guinea pigs.

9.2 Repeated Dose Toxicity (14)

A 28-day oral toxicity study was conducted in accordance with OECD guideline No: 407 (15).

Alpha Step® MC-48 (in distilled water) was administered daily by gavage to Sprague-Dawley rats at 0 (control group), 15 (low dose), 150 (mid dose) or 1000 (high dose) mg/kg/day for 28 days. The study utilised a total of 40 rats (5/sex/dose).

All animals survived to scheduled necropsy. Clinical signs were observed in high dose animals only. These included increased salivation, lethargy, fur wetting, noisy respiration and red brown staining of the external body surface. Two females showed more severe signs during the first week (including hunched posture, pilo-erection, decreased respiratory rate, diuresis, diarrhoea) but improved by day 6.

Slight effects in bodyweight increases were seen in high dose males only. Water consumption was slightly greater in high dose females. Food consumption was unaffected by treatment.

There were no treatment-related effects in haematology or blood chemistry.

There were no treatment-related organ weight changes in any of the treatment groups.

Gross pathology revealed abnormalities in the stomach, liver, lungs and adrenals of the high dose animals only. Gastric abnormalities were in the non-glandular region of the stomach (thickening, sloughing, multiple raised white foci, a small dark focus and multiple light brown adhesions) and the limiting ridge of the stomach (multiple raised white foci) of animals of both sexes. An accentuated lobular pattern of the liver and dark patches on the lungs was seen in one female. Small or pale adrenals was seen in 2 males.

Histopathology revealed epithelial acanthosis (with or without hyperkeratosis) in the nonglandular region of the stomach in high and mid dose animals of both sexes.

Based on the histopathological findings, the target organ for toxicity was found to the stomach.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium and Escherichia coli Reverse Mutation Assay (16)

This study was conducted in accordance with OECD guidelines No: 471 (17) and No: 472 (18).

Alpha Step® MC-48 was tested by the Ames plate incorporation procedure using *Salmonella typhimurium* strains TA 98, TA 100, TA 1535 and TA 1537, as well as *Escherichia coli* strain WP2uvrA, with and without metabolic activation.

Two experiments were conducted with Alpha Step® MC-48 at concentrations ranging from 0 to 5000 µg/plate. The reference mutagens N-ethyl-N'-nitro-N-nitrosoguanidine (TA 100, TA 1535, WP2uvrA; - S9), 4-nitroquinoline-1-oxide (TA 98; - S9), 9-aminoacridine (TA

1537; - S9), 2-aminoanthracene (TA 1535, WP2uvrA; + S9) and benzo(a)pyrene (TA 98, TA 100, TA 1537; + S9) were used as positive controls.

Alpha Step® MC-48 produced no significant increases in the number of revertant colonies in any of the tester strains, with or without metabolic activation.

Under the experimental conditions reported, Alpha Step® MC-48 is not mutagenic.

9.3.2 Chromosome Aberrations in Human Lymphocytes (19)

This study was conducted in accordance with OECD guideline No: 473 (20).

Experiments were conducted in duplicate with a 4 h treatment interval. Human lymphocytes were exposed to Alpha Step® MC-48 with and without exogenous metabolic activation. Cultures incubated with S9 were treated with Alpha Step® MC-48 at concentrations ranging from 0 to 156.25 μ g/ml. Cultures without S9 mix were treated with 0 to 625 μ g/ml Alpha Step® MC-48. Harvest times were 20 hours in the first experiment and 20 and 44 in the second. Cultures which served as positive controls were treated with ethylmethanesulfonate in the presence of S9 or cyclophosphamide in the absence of S9. Stained chromosome preparations were examined for chromosomal aberrations (100 metaphases per treatment group).

Experiment 1 showed a statistically significant increase in the number of cells with aberrations in cultures incubated with 312.5 and 625 μ g/ml in the presence of metabolic activation. This effect was not apparent in both of the duplicate cultures and was not reproduced in experiment 2. The positive controls gave the expected increases in frequency of aberrant cells. The number of polyploid cells remained unchanged for all treatment groups.

Alpha Step® MC-48 was shown to be non-clastogenic in human lymphocytes.

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (21)

This study was conducted in accordance with OECD guideline No: 474 (22) using albino CD1 mice (5/sex/dose/harvest time).

Test mice were given Alpha Step® MC-48 intraperitoneally at concentrations of 50 (low), 100 (mid) or 200 (high dose/maximum tolerated dose) mg/kg. Control mice were given distilled water by the same route. Positive animals were given cyclophosphamide. High dose test and negative control animals were harvested 24 and 48 hours after dosing. Other dose groups were harvested at 24 hours only. Stained bone marrow smears were prepared at harvest (1 slide per animal) and examined for micronuclei frequency.

One thousand polychromatic erythrocytes (PCE) were scored per animal, and the number of micronucleated PCEs/1000 PCEs recorded. The ratio of PCE to normochromatic erythrocytes (NCE) was recorded as a measure of cytotoxicity.

The frequency of micronucleated PCEs was unaltered by treatment with Alpha Step® MC-48 at any of the concentrations tested. Cyclophosphamide produced a significant increase in the micronuclei frequency. PCE/NCE ratios remained unchanged after any of the Alpha Step® MC-48 doses.

The results of this study suggest that Alpha Step® MC-48 is not clastogenic *in vivo*.

9.4 Overall Assessment of Toxicological Data

Animal tests suggest that Alpha Step® MC-48 has low acute oral and dermal toxicity in rats (LD₅₀ >2000 mg/kg by both routes), is not irritating to the skin of rabbits and is not

sensitising to the skin of guinea pigs. When applied to the eye of one rabbit, severe irritation resulted.

A 28-day repeated oral toxicity study in rats revealed gastric effects in animals of both sexes after administration of 150 and 1000 mg/kg/day.

The chemical was shown to be non-mutagenic in bacteria (*Salmonella typhimurium* and *Escherichia coli*) as well as being non-clastogenic in cultured human lymphocytes and in the mouse micronucleus assay.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Testing on aquatic fauna used semi-static conditions with results expressed as nominal concentrations, which did not generally differ significantly from those measured. Some losses observed after day 11 in the *Daphnia* reproduction test were thought to reflect biodegradation from the build up of bacteria introduced with algal cells used as feed for the test organisms. Results indicate moderate to high toxicity. The tabulated end-point in the *Daphnia* reproduction test reflects immobilisation. For reproduction, the EC_{50} was between 0.25 and 0.80 mg/L.

Test	Species	Result	Reference
96 h acute	Rainbow trout	LC ₅₀ = 1.7 mg/L	23
48 h immobilisation	Daphnia magna	$EC_{50} = 2.5 \text{ mg/L}$	24
21 d reproduction	Daphnia magna	$EC_{50} = 0.48 \text{ mg/L}$	25
72 h growth inhibition	Scenedesmus subspicatus	$EC_{50} = 45 \text{ mg/L}$	26

The algal test result, expressed as final measured concentration (59-81% of nominal), indicates slight toxicity.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Based on the estimated levels of imports, worst case concentrations of Alpha Step® MC-48 entering treatment works may reach levels of about 0.16 mg/L in city locations and 0.5 mg/L in country areas. Given high levels of removal (>99%) in model treatment systems, levels entering aquatic environments are expected to be reduced below 1% of aquatic end-points before further dilution and biodegradation in receiving waters.

The new surfactant is expected to compete in the market with linear alkylbenzenesulphonates (LAS), which have similar environmental properties (27). It is stated in the submission that improved detergency allows replacement of LAS surfactants by smaller amounts of the new detergent mixture, thus reducing the total organic load per wash and providing justification for the introduction of Alpha Step® MC-48.

12. <u>ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS</u>

The notified chemical is in use in the USA, however no information is available on its effects on humans. It is a severe eye irritant in rabbit. Other animal studies have shown it to have low acute oral and dermal toxicities, as well as being non-irritating and non-

sensitising to skin. Genotoxicity studies have shown the chemical to be neither mutagenic or clastogenic.

The chemical is combustible, forming oxides of carbon and sulfur. Under normal use conditions, the chemical will be stored in sealed containers designed to minimise breakage in the event of accident. Imported product will be stored away from sources of ignition such as heat, sparks or open flame.

The potential for worker exposure is limited to 4 days a year for a total of 6 personnel. Given the personal protective equipment which these workers will be required to wear during reformulation procedures, the risks associated with eye irritation should be minimal. Under normal use conditions the risk to workers is expected to be minimal.

Since products containing the notified chemical will be available to the public as hand dishwashing detergents, light duty household cleaners and laundry products, public exposure to the notified chemical is expected to be high. However, the levels of the notified chemical in such household products will be relatively low. Although the undiluted compound is a severe eye irritant (consistent with its surfactant properties), products containing Alpha Step® MC-48 are not expected to pose any greater hazard than comparable products already available to the public.

In the case of accidental spillage during transport, the public may be exposed to more concentrated forms of Alpha Step® MC-48. However, with the recommended practices for storage and transportation in place, this should not pose a significant risk to workers.

13. **RECOMMENDATIONS**

To minimise occupational exposure to Alpha Step® MC-48 the following guidelines and precautions should be observed.

- . If engineering controls and work practices are insufficient to reduce exposure to a safe level, the following personal protective equipment should be used:
 - chemical-type goggles conforming to Australian Standards 1336 (28) and 1337 (29);
 - . impervious gloves conforming to Australian Standard 2161 (30); and
 - . protective clothing conforming to Australian Standards 2919 (31).
- . Good work practices should be implemented to avoid splashing and spillages.
- Spills should be cleaned up promptly.
- . Good personal hygiene practices, such as washing of hands prior to eating food, should be observed.
- . A copy of the Material Safety Data Sheet for products containing the notified chemical should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for Alpha Step® MC-48 (Attachment 1) was provided in Worksafe Australia format (32). The MSDS was provided by Bronson and Jacobs Pty 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 Bronson and Jacobs Pty.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Alpha Step® MC-48 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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- 3. Project No: 625/18. Assessment of the Ready Biodegradability of Alpha Step [®]MC-48 using the CO2 Evolution Test (Modified Sturm Test), Safepharm Laboratories Ltd, 1994.
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- 5. Project No: 625/6. *Alpha Step MC-48 Acute Dermal Toxicity (Limit Test) in the Rat*, Safepharm Laboratories Ltd, 1994.
- 6. Project No: 625/7. *Alpha Step MC-48: Acute Dermal Irritation Test in the Rabbit*, Safepharm Laboratories Ltd, 1994.
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- 8. Project No: 625/9. *Alpha Step® MC-48: Magnusson and Kligman Maximisation Study in the Guinea Pig*, Safepharm Laboratories Ltd, 1994.
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- 25. Project No: 625/16. Assessment of the Effect of Alpha Step® MC-48 on the Reproduction of Daphnia magna, Safepharm Laboratories Ltd, 1994.
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