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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

FLAMTARD H

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.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

FLAMTARD H

1. APPLICANT(S)

Fidene Corporation Pty Ltd, 52 Frenchs Road, Willoughby, NSW 2068.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, Flamtard H is not considered to be hazardous. Therefore, the details of chemical name, CAS number, molecular formula, spectral data, purity, use, appearence and import volume have been exempted from publication in the Full Public Report

Trade name: Flamtard H

Molecular weight: 286.11

Method of detection and determination:

Inductively-coupled plasma mass spectroscopy (ICP-MS) was used to determine zinc, tin, sodium, chlorine and water content of the chemical. The identity of the chemical was confirmed by UV/visible spectroscopy, Fourier transformed infra red spectroscopy (FTIR) and X-ray diffraction spectrophotometry.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearence at 20°C and 101.3 kPa:	powder
Odour:	odourless
Melting Point:	decomposes at 200°C and does not possess a precise melting point
Boiling Point:	not determined
Density:	3300 kg/m^3
Vapour Pressure:	< 0.01 kPa at 25°C
Water Solubility:	0.001 g/L at 20°C (approximately)
Fat Solubility:	< 7 mg/kg at 37°C
Hydrolysis:	not applicable

Partition Co-efficient (n-octanol/water) log $P_{O/W}$:	< -1.05
Hydrolysis as a function of pH:	Not determined
Adsorption/Desorption:	not determined
Dissociation Constant pKa**:**	not applicable
Flash Point:	not applicable for solids
Flammability Limits:	not flammable, when formed into a pile and heated
Combustion Products:	metal oxide fumes
Explosive Properties:	not explosive
Pyrolysis Products:	if involved in a fire, may give off metal oxide fumes
Decomposition Temperature:	200°C
Decomposition Products:	not applicable
Autoignition Temperature:	> 400°C
Reactivity/Stability:	stable under ambient conditions; not oxidising
Particle size distribution:	1 to 15 µm (97.6%)

· **Comments on physico-chemical data**

In general, stannate compounds are stable in solution with only the alkali metal salts being significantly soluble in water. Heavy metal stannates are usually insoluble compounds (1).

The water solubility results are based largely on the levels of zinc as the levels of tin were below the limit of detection in the majority of samples. The notifier speculates that this could be because the hydroxystannate ion may precipitate tin oxides, leading to a lower than anticipated tin level in solution, for example [$(Sn(OH)_6)^{2-}$ -----> $SnO_2.3H_2O$]. This appears to contradict the known stability in solution.

The chemical is expected to be immobile in soil due to its low solubility.

4. PURITY OF THE CHEMICAL

Degree of purity: approximately 94%

5. INDUSTRIAL USE

Flamtard H is a flame retardant which is added to polymers. It may sometimes be used with other flame retardents such as aluminium hydroxide. Flamtard H will be incorporated into polymers used in the manufacture of cable sheathing, refrigerator gaskets, electrical conduit, junction boxes and other plastic components. The estimated import is not expected to exceed 150 tonnes per year and not more than 300 tonnes over the next five years.

6. OCCUPATIONAL EXPOSURE

Flamtard H will be imported to Australia in 25 kg multiwall paper sacks. The chemical will be used at 30 sites throughout Australia. At each site 2 workers will be exposed to Flamtard H during compounding of plastics. The magnitude and duration of exposure will depend on the feed mechanism employed. Flamtard H will be added manually or automatically to a Banbury or Henschel high speed mixer. The mixed material is extruded and chopped into pellet form. The pellets are then fed into injection moulding and/or extrusion machine hoppers. It is envisaged that workers will be exposed for approximately 30 minutes a day for 12 days per year, if using the manual feed technique. Work environments are expected to be well ventilated and worker exposure minimised by the use of local exhaust ventilation during mixing, good work practices and personal protective equipment. Exposure will also be less at sites where an automatic feed line is utilized. Approximately 68 persons will be exposed to Flamtard H during its use.

7. PUBLIC EXPOSURE

Under normal conditions, there will be low potential for public exposure to Flamtard H during manufacturing operations. Widespread public contact with finished plastic articles containing Flamtard H may arise from either use or disposal. However, by this stage the notified chemical will be encapsulated within the polymer, from which it is very unlikely to be absorbed into the body.

8. ENVIRONMENTAL EXPOSURE

. Release

Unused, cured material and associated containers will be disposed to landfill as non-hazardous waste. Since the chemical is an inorganic salt and a fire retardant, incineration is not a suitable method of disposal.

. Fate

Of the amount of zinc hydroxystannate imported only negligible amounts (< 1%), will be designated waste, resulting from the manufacture of plastic products. This waste is in the form of dust which remains in the hoppers after mixing of the various ingredients. The remainder of the chemical will be incorporated into the cured polymer matrix of items such as cable sheathing and electrical conduit.

As zinc hydroxystannate will be incorporated into plastic compounds, it is unlikely to present a hazard to the environment at any stage of its use. In the event of a spillage before processing, the chemical's low vapour pressure and water solubility suggest that it would not readily enter environment systems.

In aquatic systems it should quickly sink to the sediment/sludge layers and on land, it could be collected for disposal in an approved landfill.

The bioaccumulation potential of zinc hydroxystannate was not investigated because of the very low partition coefficient (log P_{ow} < -1.05) and lipid solubility (< 7 mg kg^{-1}). Also, because of the known stability of these stannate compounds, it can be anticipated that the chemical will not undergo abiotic or biotic degradation.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1Summary of the acute toxicity of Flamtard H

Test	Species	Outcome	Reference
Oral	rats	LD_{50} >5000 mg/kg	(2)
Dermal	rats	LD_{50} >2466 mg/kg	(4)
Inhalation	rats	LC_{50} >4.35 mg/L	(6)
Skin irritation	rabbit	non-irritant	(8)
Eye irritation	rabbit	slight irritant	(11)
Skin sensitisation	guinea pig	non-sensitiser	(14)

9.1.1 Oral Toxicity (2)

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 401 (3).

A single dose of 5000 mg/kg of Flamtard H in distilled water was administered by gavage to Sprague-Dawley rats (5/sex). The animals were observed at 1 and 4 hours after dosing and subsequently once daily for 14 days. No deaths were noted during the study. All animals showed the expected gain in body weight over the study period. No abnormalities were noted at necropsy.

The results of this study indicate an oral LD_{50} of >5000 mg/kg for Flamtard H in male and female rats.

9.1.2 Dermal Toxicity (4)

This study was carried out in accordance with OECD Guidelines for Testing of Chemicals No: 402 (5).

A single dose of 2466 mg/kg of Flamtard H was administered by semi-occlusive application to the shaved skin of Sprague-Dawley rats (5/sex) for 24 hours. The animals were observed for 14 days after removal of the bandage. No deaths were noted during the study. All animals showed expected gain in body weight during the study. No evidence of systemic toxicity or skin irritation was noted. No abnormalities were noted at necropsy.

The results of this study indicate a dermal LD_{50} of >2466 mg/kg for Flamtard H in male and female rats.

9.1.3 Inhalation Toxicity (6)

This study was carried out in accordance with OECD Guidelines for Testing of Chemicals No: 403 (7).

Sprague-Dawley rats (5/sex) were treated with a single 4-hour continuous snout-only exposure to Flamtard H dust (mean atmospheric concentration = 4.35 mg/L, 72.2% of particles with particle size < 4μm). The animals were observed for a period of 14 days after treatment.

There were no deaths or treatment related clinical signs. Body weight, food and water consumption were not affected. Necropsy did not reveal any treatment related effects.

The inhalation LC_{50} of Flamtard H was >4.35 mg/L in rats.

9.1.4 Skin Irritation (8)

This study was carried out in accordance with OECD Guidelines for Testing of Chemicals No: 404 (9).

A single dose of 0.5 g Flamtard H moistened with water was administered by occlusive application to the clipped flank of three male New Zealand White rabbits for four hours. The site of application was examined approximately 60 minutes and 1, 2 and 3 days after removal of the dressing. Skin reactions were assessed according to Draize (10). There were no signs of erythema or oedema in any of the animals.

The results of this study indicate that Flamtard H is non-irritant to the skin of rabbit.

9.1.5 Eye Irritation (11)

This study was carried out in accordance with OECD Guidelines for Testing of Chemicals No: 405 (12).

Three New Zealand White rabbits (one male and two females) were used in the study. Initially, a single dose of 0.1 g of Flamtard H was instilled into the conjunctival sac of the right eye of each rabbit. The other eye which remained untreated, served as the control. Immediately after instillation of the test substance, the initial pain reaction of the rabbit was assessed using a six point scale (11). Ocular reactions were assessed according to Draize (13) after 1 hour and 1, 2 and 3 days post-exposure. Slight to moderate reactions indicative of pain, were noted in all animals after dosing.

Slight conjunctival redness and chemosis were observed in all animals after 1 hour post-exposure and slight conjunctival redness persisted in all animals up to 1 day. Slight conjunctival discharge was observed in both females. On day 2 all treated eyes appeared normal.

The results of this study indicate that Flamtard H is a slight eye irritant in rabbits.

9.1.6 Skin Sensitisation (14)

This study was carried out according to the OECD Guidelines for Testing of Chemicals No: 406 (15).

The maximisation test (16) was used to assess skin sensitisation potential of Flamtard H. Skin reactions were assessed according to a four-point scale (14). The sensitivity of the strain of guinea pig used in this study is periodically tested with a known skin sensitiser, 2,4-dinitrochlorobenzene. Positive sensitisation responses were observed in the animals tested with 2,4-dinitrochlorobezene.

Preliminary study

To determine the concentration for intradermal injection in the study, four dose levels of Flamtard H (1%, 5%, 10% and 25% w/v in distilled water) were administered to four albino Dunkin-Hartley

guinea pigs. Skin reactions were assessed at 24, 48 and 72 hours post-exposure. The dose level selected was 25% w/v as this dose is considered to be the minimum irritating dose.

To determine the dose level for topical induction in the main study, four dose levels of Flamtard H (10%, 20%, 50% and 75%) in distilled water were administered to a group of two animals which had been injected with Freund's Complete Adjuvant previously. Skin reactions were assessed 1, 24 and 48 hours post-exposure. There was no evidence of skin irritation in any of the dose levels tested. Therefore, the dose level selected for topical application was 75% w/w.

To determine the dose level for topical challenge in the main study, two dose levels of Flamtard H in distilled water (50% and 75%) were administered to a group of two animals which had been injected with Freund's Complete Adjuvant previously. Skin reactions were assessed 1, 24, and 48 hours post-exposure. As there was no skin irritation, the dose level selected for topical challenge was 75% (w/w) as this was the maximum irritating dose.

Induction

Thirty eight female albino Dunkin-Hartley guinea pigs (20 test and 10 control) were used.

A row of three injections of: 1) Freund's Complete Adjuvant and distilled water 1:1; 2) a 25% w/v suspension of the test substance in distilled water; and 3) a 25% w/v suspension of test material in a 1:1 preparation of Freund's Complete Adjuvant and distilled water, was made on each side of the mid-line of the test animals. One week later, a single dose of 75% w/w of the test substance in distilled water was administered by occlusive application to the clipped scapular area of each test animal for 48 hours. Twenty-four hours after the removal of the dressing, the application sites were examined for reactions. Control animals were similarly treated but without the test substance.

Challenge

Two weeks after induction, both the test and control animals were challenged with a single dose of 75% w/v of the test substance in distilled water by occlusive application for 24 hours on the right flank of each animal. Only the vehicle was applied to the left flank of each animal.

One control group animal was found dead on day twenty one of the study. twenty-four hours after application, scattered mild redness was noted after the challenge at the site of application in one test group animal. A similar observation was noted at the test material sites of two control group animals during the same period. These reactions were, therefore, considered to be skin irritation rather than skin sensitisation. No adverse skin reactions were noted at 48 hours after application. Gain in body weight was unaffected in all animals.

The results of this study indicate that Flamtard H is not a skin sensitiser in guinea pigs.

9.2 28-Day Repeated Dose Toxicity (17)

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 407 (18).

Flamtard H in distilled water was administered by gavage once daily to groups Sprague Dawley CD rats (5/sex) at dose levels of 50, 250 or 1233 mg/kg/day over 28 days. The control group received only distilled water. The volume of test and control material administered to each animal was base on the most recent body weight and was adjusted at weekly intervals.
One female from the intermediate dose group was killed on day 28 of the study due to an eye injury caused during blood sampling. The remaining animals survived the entire study period.

Food consumption and body weight gain in test animals were comparable with that seen in controls.

There were no clinical chemistry and haemotology changes observed in the study.

At necropsy there were no organ weight changes attributable to treatment with the test material, treatment-related macroscopic abnormalities and histopathological changes observed in the study.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (19)

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 471 (20).

Flamtard H at dose levels of 5000, 1000, 200, 40, or 8 µg/plate was tested for gene mutation using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 both in the presence or absence of metabolic activation (S9-mix). The experiment was also conducted using Flamtard H at dose levels of 5000, 2500, 1250, 625, or 312.5 µg/plate. Positive controls used were N-methyl-N'-nitro-N-nitrosoguanidine, 9-aminoacridine, 4-nitro-O-phenylenediamine (without S-9 mix) and 2-aminoanthracene (with S-9 mix). Distilled water was used as the diluent for the test substance and as the negative control.

In both experiments, the test substance did not induce statistically significant dose-related increases in the number of revertant colonies of *Salmonella typhimurium* strains both in the absence or presence of S-9 mix. The positive controls induced the expected increases in all strains tested.

The results of this study indicate that Flamtard H is not mutagenic.

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

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 474 (22).

The maximum tolerated dose was determined by administering Flamtard H in a single oral dose of 5000 mg/kg in distilled water to a group of fourteen (7/sex) albino BKW mice. Animals were observed 1 and 4 hours after dosing and thereafter, once daily for 3 days. No deaths were noted during the study. No clinical symptoms or premature mortalities were observed. As no significant effects of treatment were observed, the maximum tolerated dose selected was the limit dose for the assay of 5000 mg/kg.

In the main test, three groups of ten (5/sex) albino BKW mice treated at 0 (distilled water) or 5000 mg/kg test substance. A separate group was treated with the positive control, cyclophosphamide. Bone marrow smears were prepared 24, 48 and 72 hours after dosing for the solvent control and test animals, and at 24 hours after dosing for the positive control animals. The number of polychromatic erythrocytes (PECs)/smear counted was 1000.

No clinical signs were observed in any of the animals treated with the test substance. When compared to the solvent control, no statistically significant increases in the mean incidence of micronucleated PECs were seen in any of the animals treated at any of the sampling times. The positive control, when compared with the solvent control, induced statistically significant increase in the frequency of micronucleated PECs.

The results of this study suggest that under the test conditions reported Flamtard H does not exhibit clastogenic effects.

9.4 Overall Assessment of Toxicological Data

Flamtard H has low acute oral, dermal and inhalation toxicity in rats. It is a slight eye irritant. It is not a skin irritant in rabbits or a skin sensitiser in guinea pigs. A 28-day repeated study showed no treatment-related effects at doses of up to 1233 mg/kg/day. Flamtard H was found to be non-mutagenic in the *Salmonella typhimurim* reverse mutation assay and non-clastogenic in the mouse bone marrow cells micronucleus assay.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The ecotoxicity studies were conducted according to the OECD Test Guidelines using technical grade zinc hydroxystannate. Full test reports were provided by the notifier and the results are summarised below:

Test	Species	Result
96 h acute	Rainbow trout(*Salmo gairdneri*)	LC_{50} >0.1 ppm* NOEC > 0.1 ppm*
48 h	Daphnia (*Daphnia magna*) immobilisation	EC_{50} > 0.1 ppm* NOEC > 0.1 ppm*
30 min & 3 h respiration & inhibition	activated sludge (mixed sewage bacterial culture)	IC_{50} > 1000 ppm# for 30 min & 3 h

* Because of the low solubility of zinc hydroxystannate it was only possible to demonstrate that the chemical was not toxic to fish and *Daphnia* at the highest concentration which could be prepared. In both situations the results represent nominal concentrations. The average test concentration ranged between 23% and 79% (0.023-0.079 $mg.L^{-1}$) of the nominal concentration.

\# Due to the low water solubility of the test material the test vessels contained a fine dispersion of the test material in water and not a true solution.

It was noted that the maximum, nominal test concentration of zinc hydroxystannate used in the ecotoxicity studies was only one tenth of the chemical's solubility in water. Presumably this was due to either changes in water quality or, what is more likely, to a decrease in the time taken to prepare true test solutions.

Aquatic toxicity tests indicate that zinc hydroxystannate is unlikely to be toxic to aquatic fauna, due to its low solubility in water. While reproduction tests for daphnids were not conducted, the apparent lack of acute toxicity, and the probability that the chemical, given its low solubility, will not be absorbed in significant quantities by living cells, indicate that reproductive effects are unlikely to be observed. Similar comments apply to toxicity to algae.

The influence of zinc hydroxystannate on respiration and nitrifying ability of activated sludge was tested under aerobic conditions according to OECD Test Method 209. A concentration of 1000 $mg.L^{-1}$ exerted no inhibition over bacterial respiration processes although, as noted above, a true solution of zinc hydroxystannate was not possible.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Wastes containing the chemical will not be released to the environment until it has been fully incorporated into the solid polymer matrix. Any off-cuts of cured material are reground and added to virgin material in small amounts. However, in the event of the disposal of cured waste, leaching from landfill is not expected due the chemical being bound within the plastic matrix.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

There is no information on the effects of Flamtard H on human health. It has been shown in animal studies to have low acute oral, dermal and inhalation toxicities. However, it is a slight eye irritant. Therefore, eye contact should be avoided. It is not a skin irritant or a sensitiser to skin.
Flamtard H has low vapour pressure and low partition coefficient, not flammable, not explosive and non-reactive under normal use conditions.

The maximum exposure of each worker to the notified chemical during compounding of plastics is 30 minutes per day for 12 days per year. Under normal use conditions, given the toxicological profile of the notified chemical, this exposure is unlikely to result in any adverse health effects.

There is potential for widespread public contact with plastic articles containing Flamtard H. However, negligible absorption of the notified chemical is anticipated, since it will be encapsulated within the polymer matrix.

13. RECOMMENDATIONS

To minimise occupational exposure to Flamtard H the following guidelines and precautions should be observed:

. the work place should be well ventilated and local exhaust ventilation should be used during mixing;

. good work practices to avoid generation of dust;

. airborne dust levels should be kept below 10 mg/m^3 (nuisance dust); and

. if engineering controls and work practices are insufficient to reduce exposure to a safe level, the following personal protective equipment which complies with Australian Standards should be worn such as respiratory protection devices (AS 1715-1991 (23), AS 1716-1992 (24)), safety spectacles (AS 1336-1982 (25), AS 1337-1982 (26)) gloves (AS 2161-1978 (27) and overalls (AS 3765.1-1990 (28), AS 3765.2-1990 (29)); and

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

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Flamtard H (Attachment 1) was provided in Worksafe Australia format (30). This MSDS was provided by Fidene Corporation 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 Fidene Corporation Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Flamtard H 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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