File No: NA/17

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

HOSTAMER V3212

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Acting Director
Chemicals Notification and Assessment

20 September 1991

FULL PUBLIC REPORT

HOSTAMER V3212

1. IMPORTER

Hoechst Australia Ltd., 606 St. Kilda Road, Melbourne, Victoria 3004

2. IDENTITY OF THE CHEMICAL

Chemical name: 1-propanesulphonic acid, 2-methyl-2-[(1-oxo-2-propenyl) amino]-, monoammonium salt, polymer with N-ethenyl formamide, 2-propenamide and ethenyl phosphonic acid, ammonium salt

Chemical Abstract Services Registry Number (CAS No): 132834-24-3

Trade name: Hostamer V3212

Molecular formula: $(C_7H_{13}NO_4S.H_3NC_3H_5NO.C_3H_5NO.C_2H_5O_3P.\ x\ H_3N)y$

Spectral data: an infra-red spectra was included in the notification statement

Number-average molecular weight: approximately 1×10^6

Monomers:

1-Propanesulphonic acid, 2-methyl-2-[(1-oxo-2-propenyl)amino]-, monoammonium salt (37.1% w/w)
CAS No: 58374-69-9

Formamide, N-ethenyl (3.5% w/w)
CAS No: 13162-05-5

2-propenamide (acrylamide) (58.3% w/w)
CAS No: 79-06-1

Phosphonic acid, (1.1% w/w)
ethenyl-, ammonium salt
CAS No: 133445-36-0

Maximum content of residual monomers:

2-propenamide (acrylamide) (< 0.1% w/w)
CAS No: 79-06-1

There is no information on low molecular weight polymers, degradation products or whether the polymer undergoes loss of monomers.

3. PHYSICAL AND CHEMICAL PROPERTIES

At room temperature and atmospheric pressure, Hostamer V3212 is an odourless white crystalline powder of low volatility. Its physical and chemical properties include:

Melting point:	280^{O}C
Density:	604 kg/m^3 (at 20^{O}C)
Water solubility:	soluble at concentrations below 20 g/L (at 20^{O}C)
Partition coefficient (log $P_{(o/w)}$):	- ?
Particle size:	100% > 45 u 93% > 212 u
Flash point:	> 260^{O}C (open cup)
Flammability:	combustible
Autoignition temperature:	> 360^{O}C
Explosion potential:	capable of a dust explosion
Reactivity:	stable under normal and acid conditions

Comments on Physical/ Chemical Properties

No data was provided for vapour pressure but this is not relevant as a large polar polymer of this nature will have negligible vapour pressure.

No data was provided for hydrolysis but the chemical is stated to be stable under both acid and alkaline conditions. It is further stated that as the polymer is anionic, acid hydrolysis is the most likely hydrolytic process but this appears to refer to ionization rather than hydrolysis. From the structure, hydrolysis is unlikely to be important under environmental conditions.

The notifier claims that the chemical will not dissociate but it contains sulphonic acid (major) and phosphonic acid (minor) groups both of which have appreciable acidity.

4. METHOD OF DETECTION AND DETERMINATION

Detection and characterisation of the new polymer is by infra-red spectroscopy.

5. PURITY OF THE CHEMICAL

Purity: active ingredient approx. 98% w/w
water approx. 2% w/w

Toxic or hazardous impurities: acrylamide
approx. < 0.1% w/w

No information is available on the degree of purity of the dried substance.

6. INDUSTRIAL USE

It is estimated that up to 500 kg of the polymer will be imported per year for the first 5 years. The polymer will be used exclusively as a thickener in a domestic biodegradable toilet cleaner at a concentration of 0.2% w/w.

7. OCCUPATIONAL EXPOSURE

Hostamer V3212 will be imported and transported in 25 kg sealed polyethylene bags which are kept in closed containers, therefore, exposure during transit and storage is unlikely except in the event of an accidental spillage.

It is stated in the notification that Hoechst Australia Ltd. will only be involved with the importation and transportation of the polymer to the user i.e. the toilet cleaner manufacturer (Pax Australia Pty. Ltd.). Therefore, potential worker exposure will take place only at one site i.e. at the user's premise where production of the toilet cleaner will be carried out.

In the notification, it is stated that at the user's premise, one warehouse person will mechanically transfer the packaged polymer powder to the production area where it will be pre-weighed in a designated dispensary featuring full fume extraction, before being compounded into a domestic toilet cleaner at a concentration of 0.2% w/w. The polymer powder will be transferred to the compounding equipment by two workers (compounders). After compounding, the liquid toilet cleaner containing the polymer will be mechanically packed into 500 ml polyethylene bottles fitted with polypropylene caps. Seven packaging operators will supervise the packaging of the toilet cleaner. One laboratory technician will be responsible for assaying the batches of liquid toilet cleaner. Quality assurance of the packaged toilet cleaner will be performed by one quality assurance officer.

Production is scheduled to run for up to 50 days per year and in that time, 10 personnel (two compounders, seven packaging operators and one laboratory technician) may be exposed to the polymer. Exposure of the compounders who handle the polymer powder will be high if control and personal protection procedures and good work practices are not implemented. Worker exposure to the polymer will be greatly reduced following the first compounding stage in the production process, as the notifier notes that by then the polymer would have been incorporated in the liquid phase of the toilet cleaner at a very low concentration of 0.2% w/w. Due to the low concentration of the polymer in the finished product, the exposure of the packaging operators and laboratory technician to the polymer will be low.

8. PUBLIC EXPOSURE

Public accessibility to Hostamer V3212 polymer is high due to its incorporation into a domestic toilet cleaner but, the potential for public exposure is low due to its low concentration (0.2% w/w) in and the use pattern of the end-use product. The end-use product is to be packaged in 500 ml polyethylene bottles and is

to be used undiluted by squeezing the liquid from the bottle onto the toilet bowl.

The polymer is a stable, high molecular weight polymer and it is to be reformulated at one site only in Australia. No release of the polymer into the environment is expected at the reformulation site.

The polymer is stored and transported as layers of 25 kg polyethylene bags on a single pallet, and is not expected to result in environmental discharge under normal circumstances. Less than one tonne of the substance would be transported per year by road.

Disposal is to be by regulated land fill or incineration. The end-use product was stated to have been designed to comply with OECD Biodegradability Guidelines for household products.

9. ENVIRONMENTAL EXPOSURE

Release

The polymer will be imported in 25 kg polyethylene bags with valve (resealable filler/ pourer opening). Reformulation will take place at Pax (Australia) Pty. Ltd., Ingleburn, NSW. The process involved suggests that release to the environment from the reformulation site will be minimal and will be limited to that spilt or remaining in the bags. The compounding activities for production of a 10000 kg batch of toilet cleaner, involving 20 kg of the polymer will include transfer of the polymer from storage and placement in the compounding equipment. The product is to be packaged in 500 mL polyethylene squeeze bottles with polyethylene caps. Waste from cleaning, spills, spoilage etc. will not be reformulated. The notifier states that waste substance should be disposed through a licensed waste disposal contractor to a regulated landfill or by incineration in an approved incinerator. From the low amount to be imported and the low environmental hazard this is acceptable.

Fate

The retailer of the toilet cleaner recommends that 50 to 60 mL of the product would be used per toilet bowl treatment. The product is recommended for domestic purposes, to be used undiluted by removing the cap and squeezing the liquid from the bottle around

the bowl of the toilet and under the rim. It should be left for 10 minutes or overnight, if possible, before flushing of the toilet. Treatment is estimated to be once a week.

The product contains 0.2% w/w Hostamer V3212 and with 2L of water in the toilet bowl, a concentration of 0.005% of the polymer is present prior to flushing. The bowl concentration is further diluted by cistern flush by a factor of 10-fold before being flushed into the sewer resulting in a polymer concentration of 5 ppm. Assuming that there is a 100-fold dilution in the sewer system and a further 100-fold dilution at the sewerage treatment plant, the resulting discharge into receiving waters will have polymer concentration of less than 1 ppb.

The only available data on environmental fate, a result of a biological decomposition test, show no measurable degradation (< 10%) over 28 days, using the DIN Static Test (no further details).

10. ASSESSMENT OF TOXICOLOGY DATA

10.1 Acute Toxicity Studies

Table 1 Summary of acute toxicity of Hostamer V3212

Test	Species	Outcome	Ref.
Oral	Rat	LD_{50}: > 5000 mg/kg	1
Skin irritation	Rabbit	non-irritant	2
Eye irritation	Rabbit	non-irritant	3

10.1.1 Acute Oral Toxicity (1)

This study was performed according to the OECD Guidelines for the Testing of Chemicals No: 401 (1981) (4).

In a range-finding study, a single dose of 5000 mg/kg of Hostamer V3212 in polyethylene glycol 400 was administered by gavage to two male and two female Sprague-Dawley albino rats. These animals were observed for five days. No deaths were noted during the study period.

In the main study, a single dose of 5000 mg/kg of Hostamer V3212 in polyethylene glycol 400 was administered by gavage to five male and five female Sprague-Dawley albino rats. These animals were observed for 14 days. No deaths were noted during the study period. An abnormal body carriage (hunched posture) and pilo-erection were observed in all animals up to 24 hours post dosing but these animals were normal from Day 2 of the study. Gain in bodyweight was unaffected by treatment. Necropsy on animals killed on Day 14 revealed congestion of the lungs in three rats but no macroscopic abnormalities were observed in the remaining animals. Results from this study indicate an LD_{50} > 5000 mg/kg for Hostamer V3212.

10.1.2 Dermal Irritation (2)

This study was performed according to the OECD Guidelines for Testing of Chemicals No: 404 (1981) (5)

A single dose of 0.5 g of Hostamer V3212 was administered to the clipped backs of each of three New Zealand White rabbits and was held in place with an occlusive patch for four hours. The test sites were examined for irritation 1, 24, 48 and 72 hours post treatment. The skin responses were graded according to the Draize scoring system (6). Very slight erythema was observed in one animal an hour after treatment. This reaction had totally disappeared at 24 hours. The remaining animals were unaffected by treatment. Results from this study indicate that Hostamer V3212 is non-irritant to rabbit skin.

10.1.3 Eye irritation (3)

This study was performed according to the OECD Guidelines for Testing Chemicals No: 405 (1981) (7).

A single dose of 0.1 ml (55 mg) of Hostamer V3212 was introduced to one eye of each of three New Zealand White rabbits. The eyes were examined 1, 24, 48 and 72 hours post treatment and the ocular responses were graded according to the Draize scoring

system (6). In one animal, "expanded test material" obscured the cornea and iris precluding evaluation in the first hour following treatment. Moderate iridial inflammation (1/3) and conjunctivitis characterised by slight to moderate redness (3/3) or slight to moderate chemosis (2/3) were observed during the study. The intensity of these reactions decreased with time and two animals were normal 48 hours following treatment whilst the third animal was normal at 72 hours. No evidence of corneal damage was recorded over 72 hours. The mean values of the reactions indicate that Hostamer V3212 is not an eye irritant in rabbits.

11. OVERALL ASSESSMENT OF TOXICOLOGY DATA

Hostamer V3212 has low acute oral toxicity (oral LD_{50} in rats: > 5000 mg/kg). Tests on rabbits show that it is not a skin or eye irritant. There are no chronic exposure data.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

According to the notifier, the polymer is not known to cause any health conditions or to affect any existing health conditions and no work-related effects on health have been reported. It is stated in the notification that the polymer has not previously been produced in large quantities nor used for any commercial purposes, therefore, it should be noted that human exposure to this polymer has been limited. Due to the stability of the polymer, its high molecular weight (> 1000), large particle size (> 10 u) and very low volatility, the polymer is not likely to be absorbed across biological membranes such as the skin or via inhalation. Therefore, physiological effects are unlikely. Acrylamide, the residual monomer, is a known neurotoxicant (8) but, as this chemical is present in a very small quantity (< 0.1%), it is not likely to adversely affect human health.

The polymer powder is combustible and is capable of a dust explosion. However, good-housekeeping and the implementation of control measures in the workplace such as, adequate ventilation, the elimination of ignition sources, hot surfaces and high temperatures, and the earthing and dustproofing of all electrical fittings, machinery and equipment, will minimise the possibility of a dust explosion.

The polymer is hygroscopic and in the presence of water, at concentrations > 20 g/L it forms a slippery gel. Therefore, spillage of the polymer onto wet surfaces may be hazardous to workers. However, good work practices such as careful handling and storage of the polymer powder will help prevent such accidents from taking place. In addition, cleaning up of spills with water should be avoided.

Under normal use conditions when control and precautionary measures are implemented, it is unlikely that the polymer will present any significant acute health or safety hazard to workers. The recommendations listed in Section 14 should be sufficient to minimise exposure and health and safety hazards in the workplace.

The use pattern outlined by the notifier suggests that Hostamer V3212 presents a low public health hazard. If the conditions of use are varied, greater exposure of the public may occur. In such circumstances, further information may be required to assess the hazards to public health.

13. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Environmental effects testing is not required for small volume polymers, but results of some tests were provided. The full reports of the biodegradation test, the bacterial toxicity test and the fish toxicity test are stated to be unavailable.

The test results are tabulated as follows:

Table 2 Summary of ecotoxicity of Hostamer V3212

Test	Organism	Result
Acute toxicity	fish (golden orfe)	LD_{50} > 500 mg/L
Fermentation tube	bacteria-toxicity test	EC_0 > 2500 mg/L
Acute toxicity	bacteria (unspecified)	> 1000 mg/L

The above-mentioned results and the low acute oral toxicity in rats (oral LD_{50} in rats: > 5000 mg/kg), indicate that the polymer is practically non-toxic to the test organisms. Due to the lack of details of test methods and reports relating to ecotoxicity, no firm conclusions about the aquatic toxicity of Hostamer V3212, a polyanionic (polyaliphatic sulphonate) polymer, can be drawn.

14. ASSESSMENT OF ENVIRONMENTAL HAZARD

The predicted environmental concentration is at least four orders of magnitude less than the indicated acute toxicity concentration of golden orfe fish and bacteria.

The notified chemical would not be expected to exhibit toxic characteristics because large polymers of this nature are not readily absorbed by biota. In addition, as the polymer is water rather than lipid soluble, it is unlikely to be retained in biota. The expected environmental hazard is low.

15. RECOMMENDATIONS FOR THE CONTROL OF OCCUPATIONAL EXPOSURE AND OCCUPATIONAL HAZARDS

To minimise occupational exposure and health and safety hazards, the following guidelines should be observed:

. the workplace should be well ventilated and local exhaust ventilation should be employed to collect all foreseeable escapes of dust;

. good housekeeping and maintenance should be practised to avoid the accumulation of dust in the workplace. Spillages should be cleaned up promptly using the most appropriate method in order to avoid the generation of a dust cloud;

. storage of the polymer in robust sealable containers and in dry well ventilated places away from heat and sources of ignition, is essential;

. good work practices should be implemented to avoid the generation of a dust cloud or spillage;

. suitable personal protective equipment which comply with Australian Standards (AS) should be used such as:

. safety glasses (AS 1337) - *Eye Protectors for Industrial Applications* (9), in situations when the polymer powder may contact the eyes,

. rubber protective gloves (AS 2161) - *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)* (10),

. appropriate protective clothing and

. in situations when ventilation is insufficient, appropriate dust respirators (AS 1716) - *Respiratory Protective Devices* (11);

. all sources of ignition, hot surfaces or high temperatures should be eliminated in areas where the polymer powder will be handled. Electrical fittings, machinery and equipment should be earthed and dust-proof;

. personal hygiene should be observed;

a copy of the Material Safety Data Sheet (MSDSs) for the polymer and the toilet cleaner should be easily accessible to employees.

16. RECOMMENDATIONS FOR MATERIAL SAFETY DATA SHEET (MSDS)

The MSDS for Hostamer V3212 (Attachment 1) has been compiled according to Worksafe Australia format (12).

17. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act), secondary notification of Hostamer V3212 shall be required by Hoechst Australia Ltd. if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

18. REFERENCES

1. Acute Oral Toxicity in the Rat - Project No: 10/12. Data on file, Hoechst Australia Ltd., (1985).

2. Acute Dermal Irritation/ Corrosion Test in the Rabbit - Project No: 10/13. Data on file, Hoechst Australia Ltd., (1985).

3. Acute Eye Irritation/ Corrosion Test in the Rabbit - Project No: 10/14. Data on file, Hoechst Australia Ltd., (1985).

4. OECD Guideline for Testing of Chemicals - *Acute Oral Toxicity* No: 401 (1981).

5. OECD Guideline for Testing of Chemicals - *Acute Dermal Irritation/ Corrosion* No: 404 (1981).

6. Draize, J.H. et. al., *The Appraisal of Chemicals in Foods, Drugs, and Cosmetics*, Association of Food and Drug Officials of the United States, Austin, Texas (1959).

7. OECD Guideline for Testing Chemicals - *Acute Eye Irritation/ Corrosion* No: 405 (1981).

8. *Dangerous Properties of Industrial Materials*, 7th. Edition, Ed. N. Irving Sax and R.J. Lewis SR., Van Nostrand Reinhold Publ., New York, 2, (1989).

9. Australian Standard 1337-1984 *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, (1984).

10. Australian Standard 2161-1978 *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, (1978).

11. Australian Standard 1716-1984 *Respiratory Protective Devices*, Standards Association of Australia Publ., Sydney, (1984).

12. National Occupational Health and Safety Commission *Guidance Note for the Completion of a Material Safety Data Sheet*, 2nd. Edition, Australian Government Publishing Service Publ., Canberra, (1990).