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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

HOSTAVIN N30

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

HOSTAVIN N30

1. APPLICANT

Hoechst Australia Limited of 606 St. Kilda Road, Melbourne, Victoria 3004, have submitted a limited notification for the assessment of Hostavin N30.

2. IDENTITY OF THE CHEMICAL

Hostavin N30 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical identity, formulation and exact import volume have been exempted from publication in the Full Public Report and the Summary Report.

Other name: Hostavin N30

Number-average molecular weight: > 1000

Maximum percentage of low molecular weight species (molecular weight < 1000): 20%

Method of detection and determination:

IR spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: White powder, fine grain or yellowish granules

Melting Point/Boiling Point: Softening point > 148°C

Density: 1100 kg/m^3 at 20°C

Vapour Pressure: 6.9 x 10^{-6} kPa at 100°C
3.3 x 10^{-5} kPa at 149°C

Water Solubility: < 0.1 g/L at 23°C

Partition Co-efficient (n-octanol/water) log P_{ow}: > 6

Flash Point: > 260°C (Pensky-Martens Closed cup)

Flammability Limits: Combustibility: burns for a short time without spreading

Exposive Properties: risk of dust explosion, dust explosion data - lower limit, 200 mg/m^3 Hostavin N30 dust

Reactivity/Stability: no known chemical reactions take place

Particle size distribution: 95% < 500µm
7-8% < 32µm

Comments on Physico-Chemical Properties

Since the polymer is a high molecular weight species, its partition co-efficient is estimated to be > 6 (because of its compact structure and molar mass over 600), and as it has a large molecular cross-section (>950 pm), it is not expected to cross biological membranes. Dissociation in water is unlikely on the basis of chemical structure.

The adsorption/desorption rates were not determined but their relevance is reduced by the polymer's low water solubility and use pattern.

4. PURITY OF THE CHEMICAL

Degree of purity: ? 96%

Toxic impurities: none

Non-toxic impurities (> 1% by weight): < 4%

Maximum content of residual monomers: < 0.2%

Additives/Adjuvants: none

5. INDUSTRIAL USE

Hostavin N30 is intended to be used in plastics applications as a UV light stabiliser which also possesses antioxidant properties, especially for use in polyolefins (polyethylene, both low density and high density, and polypropylene). Hostavin N30 is to be used in cases where precautions against the harmful influence of UV radiation during outdoor exposure have to be adopted. Additionally, Hostavin N30 can be used as a stabiliser against thermal degradation during processing. Typical applications are films, fibres, car bumpers, bottle crates, garden furniture, etc

The estimated import of Hostavin N30 containing the notified chemical is greater than 1 tonne per annum in the first five years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported into Australia in 25 kg polyethylene bags within fibreboard cartons.

A number of additives, including Hostavin N30 at levels normally up to 1%, are added to a mixer together with the appropriate powdered polyolefin grade. Additives may be

automatically preweighed into heat-sealed plastic bags from closed hoppers at pre-weighing facilities under local exhaust ventilation prior to transport to granulation plants. Alternatively, at granulation plants, additives are weighed into a container immediately prior to addition to vented mixing vessels.

The polyolefin mixture passes through a closed system requiring further blending with weighed quantities of the polyolefin grade until the additives are mixed to the required final concentration in the extruder. At the extruder, the mixture is mixed, melted and extruded through a cutter to form granulated, stabilised polyolefin. Water is used to cool the extruded polyolefin prior to cutting to granules. At this stage all additives, including Hostavin N30, will be immobilised in a polymer matrix and not extracted by contact with the cooling water. The water is recycled after granules pass through a drier. After drying, granules will be automatically packaged into polyethylene bags (25 kg) and palletised before being held in store. Samples of blended powder mix and granulated polyolefin will be retained for subsequent analysis of additive levels and confirmation of technical characteristics of the production grade.

Approximately 350 workers will be exposed to the chemical and they are as follows: 60 warehouse personnel; 8 pre-weighing operators, 60 granulation plant operators, 24 maintenance personnel and 200 moulding plant operators. For those workers likely to be exposed to Hostavin N30 powder, the duration is expected to be 250 hours per year for weighing operators and 120 hours per year for granulation plant operators.

7. PUBLIC EXPOSURE

The public may come in contact with thenotified chemical in plastics such as films, fibres, car bumpers, bottle crates and garden furniture. However, the chemical will be immobilised in the polyolefin carrier and, as such, public exposure from this source will be minimal. Minor public exposure may result from accidental spillage of the notified chemical during transport and storage and during reformulation.

8. ENVIRONMENTAL EXPOSURE

. Release

The formulation of the polymer into plastic granules will involve the mixing of ingredients under an air extraction system. The air exhausted in this process will be filtered, and the filter is disposed of by a licensed solid waste disposal firm (see below). An accurate estimate of the loss of polymer cannot be made because of other residues, but it is expected to be much less than 1 kg/day (for 120 days of production, this is << 1% of volume imported in year 5).

The process involves further mixing and blending of the reactants in a closed system. After blending, the hot formulation is extruded and granulated, water cooled, and dried. The cooling water is re-used and does not extract any additive from the plastic matrix. The granulated material is packaged for use by granulation plants.

. Fate

Residues that might occur in the moulding of granules into articles are cleaned from equipment by passage of natural grade polyolefin, or another production batch of

polyolefin grade that will not be affected by the residues. The natural grade polyolefin is retained for recycling.

Trimmings from moulding of articles are regranulated or reground and used with virgin polymer at a level of up to 30%. Any remaining granulated material is re-used on other projects or sold for re-working.

Disposal of any granules not recycled will be through a licensed waste disposal contractor to a regulated land fill or by incineration in an approved incinerator. It is expected that landfill, incineration or recycling will be the ultimate fate at the end of the life of the finished moulded articles and other products. Hostavin N30 is expected to remain bound in polyolefin when finished articles are in landfills. Due to the expected low exposure of the polymer, biodegradation and bioaccumulation are not relevant. Combustion would expect to yield carbon dioxide, water and traces of nitrogen oxides, and no significant quantities of any hazardous combustion products.

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicological data are required for polymers of NAMW > 1000 according to the *Act*. However, data for acute oral toxicity, skin and eye irritation and mutagenicity in bacteria were supplied and are evaluated below.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Hostavin N30

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 2000 mg/kg	(1)
Skin Irritation	Rabbit	non-irritant	(2)
Eye irritation	Rabbit	slight irritant	(3)

9.1.1 Oral Toxicity (1)

This study was carried out according to OECD Guidelines for Testing of Chemicals (4) No.: 401.

A single dose of 2000 mg/kg of Hostavin N30 in sesame oil was administered by gavage to Wistar rats (5/sex). The animals were observed at 1 and 6 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 > 2000 mg/kg for Hostavin N30 in male and female rats.

9.1.2 Skin Irritation (2)

This study was carried out in accordance with OECD Guidelines for Testing of Chemicals (4) No: 404.

A single dose of 500mg of Hostavin N30 moistened with polyethylene glycol was administered by occlusive application to the shaved dorsal area of three male New

Zealand White rabbits for four hours. The site of application was examined approximately 30-60 minutes, 24, 48 and 72 hours after removal of the plaster.
One hour after removal of the plaster, one animal had barely detectable erythema. 24 hours and later times after removal of the plaster all animals were free of any symptoms of irritation.

The results of this study indicate that Hostavin N30 is not irritating to the skin of rabbits.

9.1.5 Eye Irritation (3)

This study was carried out in accordance with OECD Guidelines for Testing of Chemicals (4) No.: 405.

A single dose of 100 mg of Hostavin N30 was instilled into the conjunctival sac of the left eye of each of three New Zealand White rabbits. Twenty four hours after application of the test substance and at each evaluation time point where secretion was observed or when corneal examination with sodium fluorescein was conducted, the treated eyes were thoroughly rinsed with physiological sodium chloride solution at 37°C.

From 1 to 24 hours after application the conjunctivae were a diffuse crimson red and were slightly swollen. The lids were approximately half closed. In addition there was a clear, colourless discharge. Forty eight and 72 hours after application the conjunctivae of two animals still had marked injected blood vessels. Seven days after application all symptoms of irritation had resolved.

The results of this study indicate that Hostavin N30 is a slight eye irritant in rabbits.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (5)

Hostavin N30 at dose levels from 0.16 - 5000 μg/plate was tested for induction gene mutations using *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, TA 1538 and *Escherichia coli* strain WP2*uvrA* in either the presence or absence of metabolic activation provided by rat liver S9.

Hostavin N30 did not cause a significant increase in the number of revertant colonies with any of the tester strains either in the presence or absence of S-9 mix.
Negative controls gave the expected background levels of mutants for each strain and positive control mutagens exhibited the expected mutagenic potencies.

It is concluded that Hostavin N30 is not mutagenic in the bacterial test system either in the presence or in the absence of an exogenous metabolizing system.

9.4 Overall Assessment of Toxicological Data

Hostavin N30 has low acute oral toxicity in rats. It is not a skin irritant in rabbits but is a slight eye irritant. Hostavin N30 was found to be non-mutagenic in bacteria. It would not be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (6) in relation to Acute lethal effects (oral) or Irritant effects (skin, eye).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although no ecotoxicological data has to be provided for polymers of NAMW > 1000 according to the Act, the company did provide data for a 96h LC_{50} fish test. The species used was the zebra fish *Brachydanio rerio,* with the test giving a LC_{50} range of 2500 - 3000 mg/L based on the nominal concentration. The polymer was insoluble and test solutions were homogenised giving obvious turbid solutions. The results appear inconclusive as to whether the physical presence of the polymer caused mortality or the polymer in solution caused mortality. (7)

Due to its high NAMW the polymer is not expected to cross biological membranes.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The polymer is being imported for use in plastic mouldings and will act to stop the deterioration of these mouldings. The main release to the Australian environment will be through disposal of finished moulded products. While this amounts to a significant total, the polymer is an additive in cured polyolefin products and is expected not to leach from the finished product. If the finished product is burnt, no significant quantities of any hazardous combustion products are expected. Further, any monomers or low molecular weight species are expected to share the same fate as the polymer. Therefore, it is considered that the polymer does not pose a significant hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer has a NAMW > 1000 and is, therefore, unlikely to be able to cross biological membranes and cause adverse health effects. The polymer may contain a significant proportion (up to a maximum of 20%) of low molecular weight species (NAMW < 1000) of unknown toxicity. However, on the basis of the toxicological data, neither the polymer nor the low molecular weight species are expected to contribute to acute oral toxicity, skin or eye irritancy or mutagenicity. The low level of residual monomer (< 0.2%) is not expected to present a health hazard. The notified polymer is in the form of a powder or granules with a low respirable fraction so that dust particles are unlikely to enter the lungs.

The notified polymer will be imported into Australia in 25 kg polyethylene bags within fibreboard cartons at a rate of greater than one tonne per annum for the first five years. It is used at a low level (<1%) as an antioxidant and/or light stabiliser in plastics so that the exposure of workers or the public to the polymer in the final plastic is expected to be negligible. Addition of the polymer to the polyolefin either directly or from preweighed additive packages is carried out under local exhaust ventilation and exposure to the polymer is expected to be low. Preweighing of the polymer into sealed plastic bags containing various additives is also carried out under local exhaust ventilation so that exposure to the notified polymer is expected to be low during this process also. Mixing of the additive package with the polyolefin and all subsequent procedures are carried out in closed systems so that exposure to the notified polymer is expected to be negligible.

The notified polymer is to be imported in sturdy polythene lined cardboard boxes. The risk of adverse occupational or public health effects occurring as a result of transport,

storage or use of the notified polymer or during use of the plastic containing it is expected to be low.

13. RECOMMENDATIONS

To minimise occupational exposure to Hostavin N30 the following guidelines and precautions should be observed:

. if engineering controls and work practices are insufficient to reduce exposure to Hostavin N30 to a safe level, then personal protective devices which conform to and are used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS 1337) (8,9), impermeable gloves (AS 2161) (10) and protective overalls (AS 2919) (11) and footwear (AS 2210) (12) should be worn;

. precautions for organic dust and the Worksafe Australia exposure standard for nuisance dust ($10mg/m^3$ (13)) should be observed;

. good work practices should be implemented to avoid spillages;

. good personal hygiene should be observed; and

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

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Hostavin N30 was provided in Worksafe Australia format (14).

This MSDS was provided by Hoechst Australia Limited 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 Hoechst Australia Limited.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Hostavin N30 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

1. Pharma Development Central Toxicology, 1992, ' Hostavin N30 Testing for Acute Oral Toxicity in the Male and Female Wistar Rat' , data on file, Hoechst Aktiengesellschaft, Frankfurt, Germany.

2. Pharma Research Toxicology and Pathology, 1988, ' Hostavin N30 Test for Skin Irritation in the Rabbit' , data on file, Hoechst Aktiengesellschaft, Frankfurt, Germany.

3. Pharma Research Toxicology and Pathology, 1988, ' Hostavin N30 Test for Eye Irritation in the Rabbit' , data on file, Hoechst Aktiengesellschaft, Frankfurt, Germany.

4. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris, France[1].

5. Pharma Research Toxicology and Pathology, 1988, ' Hostavin N30 Study of the Mutagenic Potential in Strains of *Salmonella typhimurium* (Ames Test) and *Escherichia coli*' , data on file, Hoechst Aktiengesellschaft, Frankfurt, Germany.

6. National Occupational Health and Safety Commission, 1994, *Approved Criteria for Classifying Hazardous Substances* [NOHSC: 1008], Australian Government Publishing Service.

7. Pharma Research Toxicology and Pathology, 1989, ' Hostavin N30 96-hours Acute Toxicity Study in Zebra fish (*Brachydanio rerio*) data on file, Hoechst Aktiengesellschaft, Frankfurt, Germany.

8. Standards Australia, 1994, Australian Standard 1336-1994*, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, Australia.

9. Standards Australia, 1992, Australian Standard 1337-1992, *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Australia.

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

11. Standards Australia, 1987, Australian Standard 2919 - *1987 Industrial Clothing*, Standards Association of Australia Publ., Sydney, Australia.

12. Standards Australia, 1994, Australian Standard 2210 - 1994 *Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications*, Standards Association of Australia Publ., Sydney, Australia.

[1] The Guidelines relevant to the current notification are as follows:

- No. 203 Fish, Acute Toxicity Test
- No. 401 Acute Oral Toxicity
- No. 404 Acute Dermal Irritation/Corrosion
- No. 405 Acute Eye Irritation/Corrosion
- No. 471 *S. typhimurium,* Reverse Mutation Assay
- No. 472 *E. coli*, Reverse Mutation Assay

13. National Occupational Health and Safety Commission, *Exposure Standards for Atmospheric Contaminants in the Occupational Environment*, 2rd Edition, Australian Government Publishing Service Publ., Canberra, 1991.

14. National Occupational Health and Safety Commission, 1994 *, National Code of Practice for the Preparation of Material Safety Data Sheets.* [NOHSC:2011 (1994)] AGPS, Canberra ,1994.