

File No: NA/185

Date: 1 September, 1994

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION  
AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989*, 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****HOSTACOR V4205****1. APPLICANT**

Hoechst Australia Limited, 606 St. Kilda Road, Melbourne, Victoria.

**2. IDENTITY OF THE CHEMICAL**

Based on the nature of the chemical and the data provided, is not considered to be hazardous. Therefore, the details of chemical name, molecular and structural formulae, molecular weight, spectral data, impurities, exact manufacture and import volume have been exempted from publication in the Full Public Report and the Summary Report.

**Other name(s) :** Salt of an alkenyl succinic acid derivative

**Trade name:** Hostacor V4205

**Method of detection and determination:**

The identity of the chemical was confirmed by Fourier transformed infra red, Nuclear magnetic resonance (NMR) and UV/Visible spectroscopy and High pressure liquid chromatography (HPLC).

**3. PHYSICAL AND CHEMICAL PROPERTIES**

The notified chemical will be imported in a formulation with sodium hydroxide (< 10%) and water (10-30%) known as Hostacor V4205. All properties listed below are those of the formulation unless otherwise specified.

**Appearance at 20°C and 101.3 kPa:** Red-brown, clear, viscous gel

**Odour:** Weak, but characteristic

<b>Boiling Point:</b>	143.1°C @ 101.3 KPa
<b>Density:</b>	1040 kg/m <sup>3</sup>
<b>Vapour Pressure:</b>	1.1x10 <sup>3</sup> kPa at 100°C
<b>Water Solubility:</b>	> 1000 g/L at 20°C
<b>Fat Solubility:</b>	0.3 g/100g fat at 37°C
<b>Partition Co-efficient (n-octanol/water) log P<sub>O/W</sub>:</b>	<u>&lt; 0</u>
<b>Hydrolysis as a function of pH:</b>	Hydrolytically stable at pH 7 and 9 (half life >1 year at 25°C)
<b>Adsorption/Desorption:</b>	Not determined
<b>Dissociation Constant pKa:</b>	Not determined (the substance is a reaction product of several dissociated compounds)
<b>Surface Tension:</b>	30.1x10 <sup>-3</sup> N/m @ 20°C
<b>Flash Point:</b>	> 160°C
<b>Flammability Limits:</b>	Not determined
<b>Combustion Products:</b>	Not determined
<b>Pyrolysis Products:</b>	Oxides of carbon and nitrogen
<b>Decomposition Temperature:</b>	Not determined
<b>Decomposition Products:</b>	Not determined
<b>Autoignition Temperature:</b>	335°C
<b>Explosive Properties:</b>	Not explosive

**Stability:** Stable under ambient conditions;  
not oxidising

**Particle size distribution:** Not applicable

. **Comments on physico-chemical properties**

All tests were apparently conducted according to Hoechst Laboratory standard procedures.

A discrete melting point could not be defined, as the substance has a honey-like consistency, which varies in viscosity with temperature. As such, the omission of data in this regard is acceptable.

As the substance was found to be of low solubility in buffers of pH 4, a test for hydrolysis in the acidic range was not possible. This is acceptable. For solutions of pH 7 and 9, the decomposition of solutions was less than 10% in 5 days, and as such the substance is considered stable at these pH levels. While the mixture contains esters, amides and succinimide linkages, hydrolysis at pH 4 would also not be expected.

The company submits that surface active substances, and mixtures of several dissociated compounds are unsuitable for partition coefficient testing using OECD procedures No. 107 and 117, under the Nernst Partition Law. Recommended HPLC procedures are only valid for undissociated and non-surface active substances (the surface tension results indicate that the substance will be surface active). Therefore the partition co-efficient for Hostacor V4205 has been calculated using the solubility of the substance in both pure water and pure octanol. This is acceptable.

The company claims that no data have been received from the manufacturer regarding adsorption/desorption, other than the statement that the substance is composed of a mixture of several dissociated compounds. Given the high solubility of the substance, this is acceptable. As a surface active substance, adsorption of the notified substance to soils may be expected.

#### **4. PURITY OF THE CHEMICAL**

**Degree of purity :** 99% (w/w)

#### **5. INDUSTRIAL USE**

Hostacor V4205 is an emulsifier/corrosion inhibitor added to coolants/lubricants used in car and whitegood manufacture. The notified chemical will be blended into concentrate products containing the notified chemical at a concentration of 10-30%. This product is diluted with a high viscosity index paraffin oil for sale to end-users containing the notified chemical at a concentration of < 10%. This is further diluted with water for use as a metal working fluid where the approximate concentration of the notified chemical is < 1%.

#### **6. OCCUPATIONAL EXPOSURE**

The notified chemical will be imported into Australia in 200L steel drums. Hostacor V4205 containing the notified chemical will be reformulated at six sites in Australia and distributed to 25 outlets.

Approximately 400 workers will be exposed to the chemical during storage, handling, reformulation, production support activities and end-use.

In the reformulation plant 40 workers will be exposed to the notified chemical only during pumping of fluids in and out of sealed mixing vessels due to vessel containment. 25 laboratory personnel involved in quality control operations will be exposed to the notified chemical during blended formulations. 150 workers will be exposed to the metal cutting fluids containing the notified chemical during metal working operations.

#### **7. PUBLIC EXPOSURE**

Due to the unavailability of Hostacor V4205 to the general public, there should be minimal public health effects resulting from its use.

## 8. **ENVIRONMENTAL EXPOSURE**

Hoechst Australia Limited have provided the following details for the treatment of wastes in their Melbourne manufacturing facilities.

Spills from formulation and blending vessel rinsings all pass to on-site effluent treatment pits which have a capacity of 40 000 L. Effluents from the final pit are constantly trickling into a larger interceptor pit (capacity 60 000 L), which ultimately flows into sewers.

For each batch of product containing Hostacor V4205 produced, approximately 200 L of water is used to rinse the mixing vessels. Hoechst estimate that 0.57 kg of Hostacor V4205 will be disposed of this way per batch, with an anticipated 15 batches per year (ie 8.55 kg per year).

The Hoechst triple interception pit system is cleaned annually by an EPA licensed waste company. Liquid waste is passed into sewers with the semi-liquid sludge being disposed of to a registered landfill.

Hoechst is unable to provide exact details on the amount of sludge removed from lubricant baths, as the amount will vary with the size of the bath, the type and frequency of metal working and so on. Similar variability exists for the amounts of liquid waste. The largest anticipated user, has effluent lagoons of 500 000 L capacity, with lubricant bath contents being emptied into the lagoon approximately every two years.

### **. Disposal**

The company anticipates that only small amounts of spilled substance would require disposal, in the course of routine formulation. Any spillage during production runs will be contained within the bunded areas of the plant. Adsorption of spills onto liquid binding substances is recommended, with such substances then going to landfill, or incineration. The remains of spills will be rinsed into drains that will flow to effluent pits prior to release to sewage systems.

Tank rinsings following a blending run are also to be discharged to effluent pits. Air-borne effluent retrieved from the scrubber systems will also be placed in effluent pits. Using the notifiers

estimated 6 blending sites, and assuming that each site will produce approximately 9 kg of waste, **a total disposal to effluent pits of 54 kg per year** is expected.

All water-borne effluent will pass through a triple interceptor pit and be neutralised before release to the sewage system.

During normal use, metalworking fluids are removed from baths approximately every 12 months. The liquids removed from drained baths are treated with inorganic acids to break down the oil/water emulsion. The water fraction from this treatment is discharged to the sewage system. The water-insoluble non-ionic acid derivatives present in the oil phase are disposed of by registered liquid waste contractors.

Solids present in the baths are periodically removed and consigned to landfill. The notifier claims that only minimal amounts of Hostacor V4205 will be present in this sludge (approximately 1 kg per year), due to the low concentration of the substance in the final formulation.

#### . **Fate**

The notified substance is highly soluble and hydrolytically stable, and thus will disperse into the water column if it reaches waterways.

Sludge removed from effluent pits that is placed in landfill may potentially leach, given the high water solubility of the substance. However, the use of licensed disposal services should ensure that the landfill sites are secure, and thus minimal loss is expected from this source. In addition the surface activity should mean that at least some of the substance will adsorb to soils.

Sludge removed from lubricant baths is expected to contain minimal amounts of the notified substance and is expected to remain in landfill sites for the reasons given above.

#### . **Biodegradation**

A biodegradation study was conducted following TG 301A (OECD) and EEC directive 92/69/EEC (Part C.4-A). The dissolved organic carbon was used to determine the biodegradability over 28 days. A decrease of dissolved organic carbon on average of 68.3% over the test period indicated that the substance is biodegradable, but does

not meet the definition of ready biodegradability of > 70% within the designated time period.

## . **Bioaccumulation**

The notified substance is not expected to rapidly degrade under environmental conditions. However, the substance is not expected to bioaccumulate, despite its predicted persistence in the aquatic compartment, due to its high water and low fat solubility.

## 9. **EVALUATION OF TOXICOLOGICAL DATA**

### 9.1 **Acute Toxicity**

Table 1 Summary of the acute toxicity of Hostacor V4205

Test	Species	Outcome	Reference
Oral	rats	LD <sub>50</sub> >2000 mg/kg	(2)
Dermal	rats	LD <sub>50</sub> >2000 mg/kg	(4)
Skin	rabbit	moderate-severe irritant	(6)
Eye irritation	rabbit	moderate-severe irritant	(9)
Skin sensitisation	guinea pig	non-sensitiser	(11)

#### 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 2000 mg/kg of Hostacor V4205 in deionised water was administered by gavage to Wistar 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<sub>50</sub> of >2000 mg/kg for Hostacor V4205 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 2000 mg/kg of Hostacor V4205 was administered by semi-occlusive application to the shaved skin of Wistar 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 the expected gain in body weight during the study. There was no evidence of systemic toxicity but skin irritation was noted. No abnormalities were noted at necropsy.

The results of this study indicate a dermal LD<sub>50</sub> of >2000 mg/kg for Hostacor V4205 in male and female rats.

#### **9.1.3 Skin Irritation (6)**

This study was carried out in accordance with OECD Guidelines for Testing of Chemicals No.: 404 (7).

A single dose of 0.5 g Hostacor V4205 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 30 to 60 minutes and 1, 2 and 3 days after removal of the dressing. Because of the persistent erythema in some animals additional examinations were done on 7 and 14 days. Skin reactions were assessed according to Draize (8).

In one animal moderate to severe erythema was observed up to day 2 which persisted as well-defined erythema up to day 7. In other two animals well-defined erythema observed up to day 2 persisted as slight erythema in one animal up to day 3 and in the other animal up to day 7. Oedema observed in all three animals at 30 to 60 minutes after application persisted in two animals up to day 1 and in the other animal up to day 2.

Erythema was found to be reversible by day 14

The results of this study indicate that Hostacor V4205 is a moderate-severe skin irritant in rabbits.

#### **9.1.5 Eye Irritation (9)**

This study was carried out in accordance with OECD Guidelines for Testing of Chemicals No.: 405 (10).

Three New Zealand White rabbits (one male and two females) were used in the study. Initially, a single dose of 0.1 g of Hostacor V4205 was instilled into the conjunctival sac of the left eye of each rabbit. The other eye, which remained untreated, served as the control. Ocular reactions were assessed according to Draize (8) after 1 hour and 1, 2, 3, 7 and 14 days post-exposure.

In all eyes, severe erythema and moderate chemosis of the conjunctivae with considerable discharge was noted 3 days after treatment. In one animal, severe erythema, moderate chemosis and discharge persisted up to day 7. In other two animals moderate erythema persisted up to day 7 and was reversible in one animal on day 14, while slight chemosis and slight discharge was observed in only one animal.

Slight to moderate opacity was observed covering more than half the corneal area up to day 3 in one animal and up to day 7 in the other two animals.

Changes to the iris were observed during first three days after treatment in one animal and on days 7 and 14, respectively in other two animals.

The results of this study indicate that Hostacor V4205 is a moderate-severe eye irritant in rabbits.

#### **9.1.6 Skin Sensitisation (11)**

This study was carried out according to the OECD Guidelines for Testing of Chemicals No: 406 (12).

The maximisation test (13) was used to assess skin sensitisation potential of Hostacor V4205 reactions assessed according to a four-point scale (14). The sensitivity of the strain of guinea pig used in this study was periodically tested with a known skin sensitiser, 2,4-dinitrochlorobenzene. Positive sensitisation responses were observed in the animals tested with 2,4-dinitrobenzene.

### Preliminary study

To determine the concentration for intradermal injection in the study, three dose levels of Hostacor V4205 (0.2%, 1.0% and 5% w/v in isotonic saline) were administered to three Pirbright-White guinea pigs. Skin reactions were assessed at 24, 48 and 72 hours post-exposure. The dose level selected was 0.2% 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 Hostacor V4205 (0.2%, 1.0%, 5.0% and 25.0%) in isotonic saline were administered to a group of six animals which had been injected with Freund's Complete Adjuvant previously. Skin reactions were assessed 1, 24 and 48 hours post-exposure. Well defined to moderate erythema and very slight oedema were observed with 5 and 25% concentration. As there was no reaction observed with 1.0%, this concentration was selected for topical application.

To determine the dose level for topical challenge in the main study, 0.2% Hostacor V4205 in (this dose level was selected since Freund's Adjuvant can lower the threshold value for primary irritation determined in preliminary tests) isotonic saline was administered to group of five 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 the topical challenge was 0.2% (w/w).

### Induction

Thirty female Pirbright-White guinea pigs (20 test and 10 control) were used.

A row of three injections of: 1) 50% Freund's Complete Adjuvant, 2) a 0.2% w/v suspension of the test substance in isotonic saline; and 3) a 0.2% w/v suspension of test material in a 1:1 preparation of Freund's Complete Adjuvant, was made on each side of the mid-line of the test animals. One week later, a single dose of 1% w/w of the test substance in isotonic saline 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.

Forty-eight hours after induction, erythema and oedema, indurated and encrusted skin and necrosis were observed at the sites previously treated with Freund's Adjuvant. The injection sites treated with the test substance in the vehicle showed well-defined erythema, slight oedema and indurations and encrustations. No effects were observed with the control groups.

### Challenge

Two weeks after induction, both the test and control animals were challenged with a single dose of 0.2% w/v of the test substance in isotonic saline 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.

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 Hostacor V4205 is not a skin sensitiser in guinea pigs at the concentration tested. Even though skin irritation was observed after induction.

## **9.2 28-Day Repeated Dose Toxicity (14)**

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 407 (15).

Hostacor V4205 in deionised water was administered by gavage once daily to groups Wistar rats (5/sex) at dose levels of 62.5, 250 or 1000 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 based on the most recent body weight and was adjusted at weekly intervals.

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

Clinical chemistry examinations revealed a slight increase in glutamic pyruvate transaminase activities in both sexes of the high dose group. No haematology changes observed in any animal in the study.

At necropsy there were no organ weight changes attributable to treatment with the test material, treatment-related macroscopic

abnormalities or histopathological changes. However, a spotted spleen was observed in one female of the high dose group.

### **9.3 Genotoxicity**

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

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 471 (17).

Hostacor V4205 at dose levels of 10000, 2500, 500, 100, 20 or 4 µg/plate were tested for gene mutation using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 and *Escherichia coli* strain WP2uvrA both in the presence or absence of metabolic activation (S9-mix). The experiment was also conducted using Hostacor V4205 at dose levels of 5000, 2500, 500, 100, 20, or 4 µg/plate. Positive controls used were sodium azide with TA100 and TA1535, 9-aminoacridine with TA1537, 2- nitrofluorene and MNNG with WPuvrA (without S-9 mix) and 2-aminoanthracene (with S-9 mix). Deionised 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* or *Escherichia coli* strains either in the absence or presence of S-9 mix. The positive controls showed the expected increases in all strains tested.

The results of this study indicate that Hostacor V4205 is not mutagenic in bacteria.

#### **9.3.2 Chromosome Aberration Assay in Chinese Hamster V79 Cells *in vitro* (18)**

This study was carried out according to OECD Guidelines for Testing of Chemicals No: 473 (19).

Hostacor V4205 was investigated for its potential to cause chromosomal aberrations in the chinese hamster V79 cell.

Preliminary experiments were performed in order to determine the toxicity of Hostacor V4205 to the cells. Cytotoxicity was not observed in the presence and absence of liver S9 mix at 100 µg/ml. The culture medium and culture medium with solvent were used as

negative controls; ethylmethanesulphonate (1500 µg/ml) without metabolic activation and cyclophosphamide (5 µg/ml) with metabolic activation dissolved in nutrient medium were the positive controls utilized.

Two experiments were performed using cultures in the absence and presence of S9 metabolic activation. A single cell suspension of V79 was prepared from 2 day old, exponentially growing stock. Cells were subsequently treated with Hostacor V4205 and chromosomes prepared 18 hours or 28 hours after treatment. Cultures with the S9 mix were treated for 6 hours and cultures without the S9 mix were treated for the 6, 28 or 48 hour period between the start of treatment and fixation.

The results indicate the test substance does not show a reproducible enhancement of chromosomal aberrations at concentrations of 10, 50 and 100 µg/ml tested with S9 mix and 10, 25, 50 and 100 µg/ml without S9 mix.

The positive control substances both elicited a significant increase in chromosomal aberrations.

In conclusion, Hostacor V4209 was found to be non-clastogenic *in vitro* in the V79 chinese hamster Cell line.

#### **9.4 Overall Assessment of Toxicological Data**

Hostacor V4205 has low acute oral and dermal toxicity in rats. It is a moderate-severe skin and eye irritant but not a skin sensitiser. A 28-day repeated dose study showed no treatment-related effects at doses of up to 1233 mg/kg/day. Hostacor V4205 was found to be non-mutagenic in the *Salmonella typhimurim* and *Escherichia coli* reverse mutation assay and non-clastogenic in the chinese hamster V79 cell assay.

### **10. ASSESSMENT OF ENVIRONMENTAL EFFECTS**

The ecotoxicity studies were conducted using a specially prepared batch of the new substance, which was free of solvents and other additives. The following ecotoxicity results were provided by the notifier.

Test	Species	Test Guidelines	Result
96 hour Acute *	<i>Brachydanio rerio</i> (Zebra fish)	OECD 203; EEC Guideline 79/831/EEG	LC <sub>50</sub> =14.8 mg.L <sup>-1</sup>
48 hour Acute	<i>Daphnia magna</i> (Water flea)	OECD 202; EEC Guideline 79/831 Annex V	EC <sub>50</sub> =5.14 mg.L <sup>-1</sup>

\* - complete lethality was observed at 22 mg mg.L<sup>-1</sup>, with symptoms, but no lethality at 10 mg.L<sup>-1</sup>

The above test results indicate that the substance is slightly toxic to fish and moderately toxic to *Daphnia*. No *Daphnia* reproduction or algal tests were conducted. The company submits that these tests are not required, as the *Daphnia* test shows toxicity to aquatic invertebrates, and that the proposed method of use and disposal of the notified substance will preclude major release to waterways. This is acceptable.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

All the expected re-formulation sites are located in either metropolitan Melbourne or Sydney. The predicted environmental concentrations following release after formulation and use are shown in the tables below. The information for these calculations was supplied in addition to that supplied by the company in the original notification package.

**Table 1. Predicted Environmental Concentrations following release from typical formulation processes. Calculations have been made both with and without the effects of biodegradation.**

Factor	Given Value	Concentration ★	Concentration ★★
Amount of waste anticipated per batch (splashes and rinsings)	0.6 kg	-	-
Total discharge to effluent pits per year (assuming 15 batches per year)	9.0 kg	-	9
Effluent pit capacity	40 000 L	225.00 ppm	72.00ppm
Final interceptor pit capacity	60 000 L	150.00 ppm	48.00 ppm
Dilution in sewage treatment	500 ML	1.80 ppb	0.57 ppb

works (Melbourne)

\* Assuming no biodegradation, \*\* assuming 68 % degradation (as given in submission Ready Biodegradability Tests)

The biodegradation potential of the notified substance will further ensure that the substance breaks down in effluent pits prior to removal to sewage systems. Discharge from Melbourne sewage treatment works is to Port Phillip Bay, and still further dilution is expected. Therefore release of the chemical should ensure that there is virtually no risk to aquatic organisms associated with the use of this substance. Should the substance be formulated in Sydney, similar PECs are expected.

Much smaller releases are expected from the end-users of the notified substance. The notifier estimates that approximately 1 kg per year will result from splash cleanup and general cleaning of tanks (eg. cleaning/discharge of lubricant baths etc.).

**Table 2. Predicted Environmental Concentrations following release from typical users plant. Calculations have been made both with and without the effects of biodegradation.**

Factor	Given Value	Concentration	Concentration
Amount of waste anticipated from baths per year	0.5 kg	-	-
Effluent pit cappacity	500 000 L	0.1 ppm	0.032 ppb
Dilution of 30 000 L in sewage treatment works (Geelong) <sup>#</sup>	5 ML	6 ppb	1.9 ppb

#30 000L per day is removed from effluent pit and treated with acid prior to disposal of liquid fraction to sewers. These calculations are made assuming that acid treatment removes none of the chemical. As this is not the case, the above example represents an extreme worst case scenario.

\* Assuming no biodegradation, \*\* assuming 68 % degradation (as given in submission Ready Biodegradability Tests)

The two examples outlined in the above tables demonstrate that the proposed release concentrations, from both formulation and typical use are three orders of magnitude below the levels of concern to aquatic fauna. Therefore, use of the notified substance in the prescribed manner should ensure that there is little risk to aquatic organisms. No toxicity test results were submitted for



algae. Such tests should be conducted if conditions and/or volumes and areas of use of the notified substance change significantly.

## **12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS**

There is no information on the effects of Hostacor V4205 on human health. It has been shown in animal studies to have low acute oral and dermal toxicities. However, it is a moderate-severe skin and eye irritant. Therefore, skin and eye contact should be avoided. It is not a skin sensitiser and is not genotoxic.

Hostacor V4205 has a low vapour pressure, is not explosive and non-reactive under normal use conditions.

Workers at the reformulation plant will be exposed to the chemical only for a very short time during filling and emptying of the mixing tank. Laboratory personnel will be exposed to small quantities of the chemical in blended formulations.

Workers in metal working operations being the largest group of workers handling the product containing the chemical will not be exposed to more than 1% of the notified chemical. Given this exposure profile and with good work practices exposure to the notified chemical should be negligible

There is low potential for public exposure to the notified chemical. Therefore there should be negligible risk to public health.

## **13. RECOMMENDATIONS**

To minimise occupational exposure to Hostacor V4205 the following guidelines and precautions should be observed:

- . the work place should be well ventilated and local exhaust ventilation should be used during filling and emptying the mixing vessel;
- . good personal hygiene should be observed;
- . good work practices to avoid contact with the chemical;

- . 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 safety spectacles (AS 1336-1982 (20), AS 1337-1982 (21)) gloves (AS 2161-1978 (22) and overalls (AS 3765.1-1990 (23), AS 3765.2-1990 (24));
- . any spillages should be promptly cleaned up and disposed according to local or state regulations; 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 the product Hostacor V4205 (Attachment 1) was provided in Worksafe Australia format (25). 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* (the Act), secondary notification of Hostacor V4205 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. A secondary notification should be made if the substance were to be used in a manner resulting in either increased quantities released to water, or in areas where there is a significantly lower expected effluent dilution (such as country areas). Such a notification should include algal toxicity testing.

#### **16. REFERENCES**

1. RTECHS Data Base - US Department of Health and Human Services (NIOSH), 1992.
2. Pharma Development Central Toxicology, "Hostacor V4205: Acute Oral Toxicity to the Rat". Data on file, Report No: 93.0276, July 1993.

3. OECD Guidelines for Testing of Chemicals, "Acute Oral Toxicity" No: 401, 1981.
4. Pharma Development Central Toxicology, "Hostacor V4205": Acute Dermal Toxicity to the Rat". Data on file, Report No: 93.0277, June 1993.
5. OECD Guidelines for Testing of Chemicals, "Acute Dermal Toxicity" No: 402, 1987.
6. Pharma Development Central Toxicology, "Hostacor V4205: Skin Irritation to the Rabbit". Data on file, Report No: 93.0450, July 1993.
7. OECD Guidelines for Testing of Chemicals, "Acute Dermal Irritation/Corrosion" No: 404, 1981.
8. Draize, J.H., et. al., "The Appraisal of Chemicals in Food, Drugs and Cosmetics", Association of Food and Drug Officials of the United States, Austin, Texas, 1959.
9. Pharma Development Central Toxicology, "Hostacor V4205: Eye Irritation to the Rabbit". Data on file, Report No: 93.0451, July 1989.
10. OECD Guidelines for Testing of Chemicals, "Acute Eye Irritation/Corrosion" No: 405, 1987.
11. Pharma Development Central Toxicology, "Hostacor V4205: Skin Sensitisation to the Guinea Pig". Data on file, Report No: 93.0372, June 1993.
12. OECD Guidelines for Testing of Chemicals, "Skin Sensitisation" No: 406, 1981.
13. Magnusson B. and Kligman A.M., "Allergic Contact Dermatitis in the Guinea Pig" Thomas Publ, USA 1970.
14. Pharma Development Central Toxicology, "28-day Oral Toxicity to the Rat". Data on file, Report No: 93.0619, September 1993.
15. OECD Guidelines for Testing of Chemicals, "Repeated Dose Oral Toxicity - Rodent: 28-day or 14-day Study" No: 407, 1981.

16. Pharma Development Central Toxicology, "Hostacor V4205: An Evaluation of Mutagenic Potential Using Salmonella typhimurium & Eschericia coli". Data on file, Report No:93.0271, June 1993.
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