File No: NA/583

December 1998

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**CG 33-1136/TKA 40080**

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Director
Chemicals Notification and Assessment

# FULL PUBLIC REPORT

## CG 33-1136/TKA 40080

## 1. APPLICANT

Ciba Specialty Chemicals Pty Limited of 235 Settlement Road, THOMASTOWN VIC 3074 has submitted a standard notification statement in support of their application for an assessment certificate for CG 33-1136/TKA 40080.

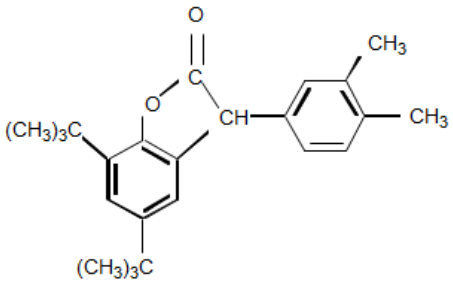
## 2. IDENTITY OF THE CHEMICAL

| | |
|---|---|
| **Chemical Name:** | 2(3H)-benzofuranone, 5,7-(1,1-dimethylethyl)-3-hydroxy-, reaction products with 0-xylene |
| **Chemical Abstracts Service (CAS) Registry No.:** | 181314-48-7 |
| **Other Names:** | CG 33-1136/TKA 40080 (HP 136) |
| **Trade Name:** | HP 136; other Irganox HP series products will contain the notified chemical in quantities $\leq$ 15% |
| **Molecular Formula:** | $C_{24}H_{30}O_2$ |

**Structural Formula:**

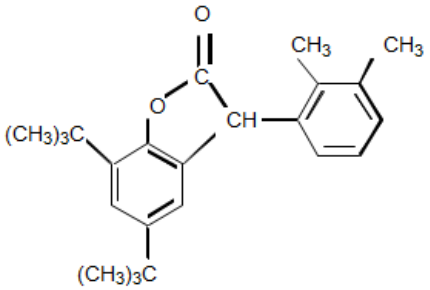
## CG 33-1136 STRUCTURE OF COMPONENTS

**CG 33-0460** (approximately 85%)




$(CH_3)_3C$

**CG 33-1135** (approximately 15%)




| | |
|---|---|
| **Molecular Weight:** | 350.5 |
| **Method of Detection and Determination:** | ultra violet/visible (UV/Vis), infrared (IR), nuclear magnetic resonance and mass spectra were provided; $\lambda_{max}$ in the UV/Vis spectrum was 274.8 nm; assay by gas and high performance liquid chromatography (HPLC) |
| **Spectral Data:** | major characteristic IR peaks identified at the following wavelengths: 875, 900, 1 075, 1 150, 1 175, 1 250, 1 294, 1 376, 1 410, 1 490, 1 605, 1 800 $cm^{-1}$ |

**Comments on Chemical Identity**

The notified chemical CG 33-1136 is a reaction product of 3-hydroxy-5,7-di-t-butyl-furan-2-one with o-xylene, and is a mixture of the two structural isomers CG 33-1135 and CG 33-0460 depicted above. These are present in the approximate molar ratio of 1:6 respectively.

may be cleaved at the reactive CH centre giving rise to free radicals which are stabilised through the partial delocalisation of the free electron around the two aromatic rings. This is the basis for the notified chemical's use as a stabiliser and antioxidant during polymer processing operations.

## 3. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| **Appearance at 20°C and 101.3 kPa:** | white solid |
| **Melting Point:** | 99°C and 124°C (see comments below) |
| **Density:** | 1100 kg/$m^3$ |
| **Vapour Pressure:** | 0.026 kPa at 25°C |
| **Water Solubility:** | < 0.05 mg/L at 25°C |
| **Partition Co-efficient (n-octanol/water):** | Log $P_{ow}$ 8.2 @ 20°C (calculated) |
| **Hydrolysis as a Function of pH:** | no data see (comments below) |
| **Adsorption/Desorption:** | no data see (comments below) |
| **Dissociation Constant:** | no data see (comments below) |
| **Flash Point:** | not applicable |
| **Flammability Limits:** | not flammable |
| **Autoignition Temperature:** | not determined |
| **Explosive Properties:** | not explosive |
| **Reactivity/Stability:** | notified chemical is considered to be stable |
| **Particle Size :** | > 560 μm |

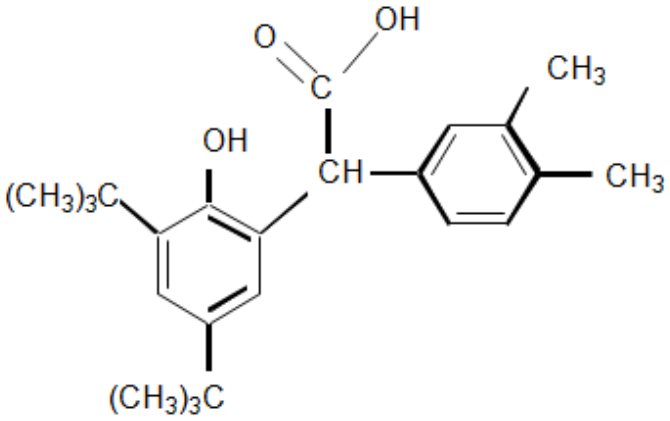
**Comments on Physico-Chemical Properties**

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practices.

The two melting points were determined using differential scanning calorimetry and correspond to the melting points of the two isomers. The lower one (99°C) corresponds to the minor component CG 33-1135, while the higher one (124°C) corresponds to the major component CG 33-0460.

The water solubility is low at less than 0.050 $mg.L^{-1}$ as could be expected of a non-polar species such as the notified chemical, and it was not possible to develop a sufficiently sensitive analytical method for determination of the parent compound or of the products resulting from hydrolytic degradation. However, the lactone ring will be susceptible to hydrolysis, particularly under elevated (alkaline) pH conditions where it is likely to form the compound depicted below. This material contains both phenolic and carboxylate functionalities, and will exhibit acidic properties.

**LIKELY HYDROLYSIS PRODUCT OF CG 33-0460**




The n-octanol/water partition coefficient was calculated which is acceptable given the very low water solubility of the compound. The method employed was based on a "fragmentation" procedure, where the structure of the molecule is broked down to substructures for which reliable Log $P_{ow}$ of the complete molecule is then calculated as the sum of the corresponding fragment values, multiplied by the respective frequency of occurrence. The method also allows for corrections required where intramolecular interactions and/or ionic interactions are operative. For the notified chemical the method gave a calculated Log $P_{ow}$ of 8.2 which is a high value and indicates almost exclusive partitioning into the oil phase. This reflects the lack of significantly polar functionalities within the molecule.

The indicative adsorption/desorption parameter Log $K_{oc}$ was not determined experimentally (due to low water solubility), nor was any calculation of this parameter attempted. However, the low water solubility, high Log $P_{ow}$ and general aromatic hydrocarbon nature of the chemical indicates that it would bind to and become strongly associated with the organic component of soils and sediments.

The material contains no inherently acidic or basic functionalities, and consequently dissociation constant data is not relevant to notification of the chemical.

## 4. PURITY OF THE CHEMICAL

**Degree of Purity:** 96 – 98%

**Toxic or Hazardous Impurities:**

| | |
|---|---|
| *Chemical name:* | o-xylene |
| *CAS No.:* | 1330-30-7 |
| *Weight percentage:* | < 0.1% |
| *Toxic or hazardous properties:* | mildly toxic by ingestion an inhalation<br>an experimental teratogen (1)<br>explosive in the form of vapour when exposed to heat or flame; when heated to decomposition acrid smoke and irritating fumes are given off (1) |

**Other Impurities:**

| | |
|---|---|
| *Chemical name:* | 5,7,5',7'-tetra-terbutyl-3-(3,4-dimethylphenyl)-3H,3'H-[3,3'H-]bi-benzofuranyl-2,2'-dione |
| *CAS No.:* | - |
| *Weight percentage:* | 0.7% |

**Unknown Impurities (> 1% by weight):** 1.4% (seven detected)

**Additives/Adjuvants:** none

## 5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. CG 33-1136/TKA 40080 will be imported in powder form, at a concentration `of approximately 98% as HP 136, and will be used as an additive to impart improved resistance to oxidation and better flow characteristics. The applications will be mainly for polyolefins and to a lesser extent for polycarbonates, styrenics, elastomers and adhesives.

The notified chemical will also be imported as a component of the Irganox HP range of products, which typically contain approximately 15% by weight of HP-136.
It is estimated that 2 to 5 tonnes per annum of the notified chemical will be imported in the

first year increasing to 15 to 20 tonnes per annum by the end of the fifth year.

## 6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported into Australia in plastic 20 kg or one tonne bulk bags. The total imported volume will be transported by road to Ciba production unit in Victoria to be processed into powder blends. There is not expected to be any exposure to the notified chemical during storage and distribution, except in the event of a spill.

*Blending*
The powder blending plant is a state-of-the-art computer managed system, requiring minimal manual handling. The primary source of exposure to the notified chemical during blending will be when emptying bags into the feed hopper of the 350 L blending vessel and during blend discharge operations. Dermal and ocular exposure may occur during these processes. Local exhaust ventilation will be in place over the additive loading area and discharging zone to capture any airborne particles. All processes in between are carried out in a closed system. Ocular exposure is also likely to occur during blend testing. The blending plant is manned by 3 operators and one chemist.

*Processing into Masterbatches*
The blended product will be further processed into masterbatches containing smaller quantities of the notified chemical (up to 15%) eg Irganox HP 2215 FF. It is estimated that on average, there would be two employees potentially exposed at each of the four masterbatch formulating establishments (Sydney, Adelaide and Perth). One worker would be the plant operator and the other a laboratory technican. A maximum of 8 workers is expected to handle the notified chemical up to 50 days per annum.

The primary source of exposure to the powder during masterbatching will be during weighing and batching operations. Exposure by dermal and ocular routes may occur when weighing the ingredients and loading them into solid phase mixers. It is anticipated that all the masterbaching sites will have local exhaust ventilation in place over the additive loading area to capture any airborne particles. The notifier has indicated that blends containing the notified chemical are used only in speciality masterbatch formulating plants. Since these plants handle ingredients with the potential for adverse health effects, adequate safety measures are needed to prevent worker exposure to the notified chemical.

*Further Processing of Masterbatches*
The Masterbatches containing the notified chemical at a level less than 0.1% will be sold to manufacturers of polymer products. The notifier has provied no details regarding these processes.

## 7. PUBLIC EXPOSURE

There is negligible potential for public exposure to the notified chemical arising from use as an additive to impart improved resistance to oxidation and better flow characteristics in polyolefins. The notifier estimates that there will be minimal release of the notified chemical during production of powder blends since any dust and any other residuals containing the notified chemical are removed using vacuum systems and recycled for packing the blended product, and any bags not used in this manner will be disposed of in landfill. There may be widespread public contact with the diverse range of plastic products containing the notified chemical, but the notified chemical is incorporated into the polymer matrix and would not be bioavailable

## 8. ENVIRONMENTAL EXPOSURE

### Release

The manufacture of the powder blends will take place at the Ciba plant alone, and this is an highly automated operation allowing for minimal release of the polymers and other additives used. During production of these blends, measured quantities of the notified material are mixed with the other components in a blending vessel, where they are homogeneously mixed. This mix is then compacted, granulated and packed into bags – some of which may be those in which the material was imported, recycled for containment of the new powder blend granules.

All dust and other residuals (eg in the bags) are removed using vacuum systems and recycled into subsequent batches of the blended products. As a consequence of these automated systems, the notifier anticipates no release during production of the powder blends, and also indicates that similar systems in place at those plants producing masterbatches will lead to minimal release of the notified chemical.

As mentioned above the empty bags will be recycled for packing the new products, and any bags not used in this manner will be disposed of to landfill. However, due to the use of vacuum systems during production, any residual of the imported chemical left in these bags is expected to be insignificant.

The production methods used in all stages of manufacture of the polymer articles into which the new flow modifier/stabiliser will be incorporated mean that almost all the imported material will be firmly encapsulated in polymer matrices with little likelihood for release from the manufactured articles.

### Fate

Since the new material will be firmly incorporated in a polymer matrix, its eventual fate will be associated with that of the polymer articles. It is likely that this will comprise a diverse group of products, but it may be assumed that since these are plastic they will be eventually disposed of into landfill, or possibly be incinerated.
In a landfill there is little possibility of significant leaching of the chemical, since it will be firmly incorporated into the polymer matrix. However, the polymer articles will be very slowly degraded through the agency of various biological and abiotic processes operative in

landfill structures, and it could be expected that the notified chemical will also be destroyed by these processes. In this case it will be degraded to water, methane and carbon dioxide. Incineration of articled containing the chemical will result in its immediate combustion, with formation of water vapour and oxides of carbon.

The material is not readily biodegradable, and a ready biodegradability test [EEC 92/69 C.4] indicated only 1% degradation over a 29-day period.

## 9. EVALUATION OF TOXICOLOGICAL DATA

### 9.1 Acute Toxicity

**Summary of the acute toxicity of CG 33-1136/TKA 40080**

| *Test* | *Species* | *Outcome* | *Reference* |
|---|---|---|---|
| acute oral toxicity | rat | $LD_{50}$ >2 000 mg/kg | (2) |
| acute dermal toxicity | rat | $LD_{50}$ >2 000 mg/kg | (4) |
| skin irritation | rabbit | slight irritant | (5) |
| eye irritation | rabbit | slight to moderate irritant | (6) |
| skin sensitisation | guinea pig | mild sensitiser | (8) |

#### 9.1.1 Oral Toxicity (2)

| | |
|---|---|
| *Species/strain:* | rat/SPF bred |
| *Number/sex of animals:* | 5/sex |
| *Observation period:* | 14 days |
| *Method of administration:* | a single dose of 2 000 mg/kg administered by gavage; vehicle was 0.5% (w/v) carboxymethylcellulose in 0.1% (w/v) aqueous polysorbate 80 |
| *Clinical observations:* | piloerection and reduced locomotor activity was observed in all rats |

| | |
|---|---|
| *Mortality:* | None |
| *Morphological findings:* | None |
| *Test method:* | similar to OECD guidelines (3) |
| *$LD_{50}$:* | > 2 000 mg/kg |
| *Result:* | the notified chemical was of low acute toxicity when administered orally in a limit test in rats |

### 9.1.2 Dermal Toxicity (4)

| | |
|---|---|
| *Species/strain:* | rat/SPF bred |
| *Number/sex of animals:* | 5/sex |
| *Observation period:* | 14 days |
| *Method of administration:* | a dose of 2 000 mg/kg was applied in 0.5% (w/v) carboxymethylcelulose and 0.1% (w/v) aqueous polysorbate 80 to an intact skin site; the site was covered with a semi-occlusive dressing; after 24 hours the dressing and residual test material were removed |
| *Clinical observations:* | there were no signs of systemic toxicity |
| *Mortality:* | None |
| *Morphological findings:* | None |
| *Test method:* | similar to OECD guidelines (3) |
| *$LD_{50}$:* | > 2 000 mg/kg |
| *Result:* | the notified chemical was of low acute toxicity when administered dermally to rats in a limit test |

### 9.1.3 Inhalation Toxicity

Not performed. This is acceptable since the particle size of the notified chemical is greater than 560 µm.

### 9.1.4 Skin Irritation (5)

| | |
|---|---|
| *Species/strain:* | rabbit/New Zealand White |
| *Number/sex of animals:* | 3 females |
| *Observation period:* | 3 days |
| *Method of administration:* | 0.5 g of the test substance moistened with 0.5% (w/v) carboxymethylcellulose in 0.1% (w/v) aqueous polysorbate 80; test substance was maintained under an occlusive patch for 4 hours |
| *Draize scores (Ref):* | all animals showed very slight erythema 60 minutes following application of the test substance; this was accompanied by very slight oedema in 1 of the 3 animals; erythema had cleared by 48 hours and edema had cleared by 24 hours |
| *Test method:* | similar to OECD guidelines (3) |
| *Result:* | the notified chemical was a slight skin irritant in rabbits |

### 9.1.5 Eye Irritation (6)

| | |
|---|---|
| *Species/strain:* | rabbit/New Zealand White |
| *Number/sex of animals:* | 3 males |
| *Observation period:* | up to 7 days |
| *Method of administration:* | 0.1 mL (67 mg) of the notified chemical was placed in the conjunctival sac of the left eye of each rabbit |

*Draize scores (7 ) of unirrigated eyes:*

| | ***Time after instillation*** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Animal*** | ***1 hour*** | | | ***1 days*** | | | ***2 days*** | | | ***3 days*** | | | ***7 days*** | | |
| ***Cornea*** | | | | | | | | | | | | | | | |
| 1 | 0[1] | | | 0 | | | 0 | | | 0 | | | - | | |
| 2 | 0 | | | 0 | | | 0 | | | 0 | | | - | | |
| 3 | 0 | | | 0 | | | 0 | | | 0 | | | - | | |
| ***Iris*** | | | | | | | | | | | | | | | |
| 1 | 0 | | | 0 | | | 0 | | | 0 | | | - | | |
| 2 | 0 | | | 0 | | | 0 | | | 0 | | | - | | |
| 3 | 0 | | | 0 | | | 0 | | | 0 | | | - | | |
| ***Conjunctiva*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** |
| 1 | 2 | 1 | 0 | 2 | 1 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | - | - | - |
| 2 | 2 | 1 | 0 | 1 | 1 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | - | - | - |
| 3 | 2 | 1 | 0 | 1 | 1 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | - | - | - |

[1] see Attachment 1 for Draize scales r=redness c=chemosis d=discharge

*Test method:* similar to OECD guidelines (3)

*Result:* the notified chemical was a slight to moderate eye irritant in rabbits

### 9.1.6 Skin Sensitisation (8)

*Species/strain:* guinea pig/Pirbright White

*Number of animals:* 10/sex (test group), 5/sex (control group)

*Induction procedure:* test animals:
three pairs of intradermal injections (0.1 mL) into the left and right side scapular region:

- Freund's complete adjuvant (FCA) 1:1 with saline
- The notified chemical, diluted to 5% with O*leum arachidis*
- The notified chemical at 5% emulsified in a 1:1 mixture of FCA and saline

one week after the injections, the same region was

treated with 50% notified chemical in vaseline under occlusive dressing for 48 hours

*Challenge procedure:* test animals
two weeks after the topical induction, the left flank of each animal was treated with 30% notified chemical in vaseline under occlusive dressing for 24 hours; the right flank was treated with vaseline alone.

*Challenge outcome:*

| | ***Test animals*** | | ***Control animals*** | |
|---|---|---|---|---|
| ***Challenge Concentration*** | ***24 hours**** | ***48 hours**** | ***24 hours*** | ***48 hours*** |
| 30% | 2/20** | 2/20 | 0/10 | 0/10 |
| 0% | 0/20 | 0/20 | 0/10 | 0/10 |

* time after patch removal
** number of animals exhibiting positive response

10% of the animals of the test group were sensitised 24 and 48 hours the challenge

*Test method:* similar to OECD guidelines (3)

*Result:* the notified chemical was a mild sensitiser to the skin of guinea pigs

**9.2 Repeated Dose Toxicity- 3 Month Oral Toxicity Study in Rats (9)**

*Species/strain:* rat/Sprague-Dawley

*Number/sex of animals:* 70/sex; control and high dose groups: 20/sex/group; low, low-mid and mid dose groups: 10/sex/group
(10/sex/control group and 10/sex/high dose group were assigned to the 4 week recovery group)

*Method of administration:* gavage; vehicle was distilled water containing 0.5% carboxymethylcellulose and 0.1% Tween 80

| | |
|---|---|
| *Dose/Study duration:* | Dose levels were based on the results of a 7-day range finding study in rats<br><br>Test material administered daily for a total of 90 days:<br>Control 0 mg/kg/.day<br>Low dose: 10 mg/kg/day<br>Low-mid dose: 50 mg/kg/day<br>mid dose 200 mg/kg/day<br>high dose: 1 000 mg/kg/day<br><br>all but the recovery group animals were sacrificed at the end of the treatment period; recovery group animals were sacrificed after a further 4 weeks |
| *Clinical observations:* | no treatment related clinical signs of toxicity were noted in any of the animals throughout the study |
| *Clinical Chemistry:* | high dose females showed a minor and reversible increase in plasma protein levels (albumin, globulin and total protein) |
| *Haematology:* | high dose females showed minimally lower and reversible haemoglobin and haematocrit values |
| *Biochemical investigations:* | in a special study to investigate effects on enzymes induced by peroxisome proliferators, female rats in the high dose group showed slightly reduced microsomal protein content, 12-hydroxylase activity and peroxisomal beta-oxidation; these results excluded the test substance as a peroxisome proliferator in rats |
| *Macroscopic examination:* | macroscopic examination revealed mottled livers in 4/10 females of the high dose group at the end of the treatment period; a mottled liver in 1/10 low dose females and a chest wall lesion in 1/10 low dose males were not considered treatment related; a thymic nodule in 1/10 mid dose females was judged of uncertain origin |
| *Histopathology:* | microscopic examination revealed dose-related occurence of hepatic necrosis with accumulation of phagocytic and inflammatory cells in females of high and mid dose groups at the end of the treatment |

period; in the corresponding high dose recovery group hepatic necrosis was not observed however phagocytic and lymphohistiocytic infiltration were present; slight epithelial hypertrophy in high dose males was considered of doubtful relevance

*Organ weights:* females showed an increase in absolute and relative liver weights (high dose) and spleen weights (dose dependent, high and mid dose); these were not seen at the end of the recovery period; effect on spleen weights were not associated with microscopic changes

*Test method:* similar to OECD guidelines (3)

*Result:* the notified chemical did not exhibit any significant organ toxicity in males and exhibited no signs of overt toxicity in females; in high dose females changes observed to haematology and clinical chemistry parameters were reversible; hepatic necrosis observed in high and mid dose females was partially reversible during recovery; effects on liver and spleen weights in female rats were reversible; hepatic lesions observed in the females were not associated with changes of plasma levels of relevant liver enzymes.

the no-observable - effect level (NOEL) for this 90 day rat study of the notified chemical in rats is 1 000 mg/kg for males and 50 mg/kg for females.

## 9.3 Genotoxicity

### 9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (10)

*Strains:* *Salmonella typhimurium* TA 1537, TA 1535, TA 102, TA 100 and TA 98; *Escherichia coli* WP2 *uvr*A

*Concentration range:* the assay was performed in two independent experiments with or without S9 metabolic activation; the test substance and controls were tested in triplicate at the following concentrations:

312.5, 625, 1 250, 2 500 and 5 000 µg/plate

*Test method:* similar to OECD guidelines (3)

*Result:* there were no significant increases in revertant colony numbers at any dose level, either in the presence or absence of metabolic activation.

The notified chemical is not considered to be mutagenic in bacteria.

### 9.3.2 Chromosomal Aberration Assay in Chinese Hamster Ovary Cells (11)

*Dosing schedule:* with S9 mix:
4.69-18.75 µg/mL treatment = 3 hours, recovery = 15 hours; 14.06-28.13 µg/mL treatment = 3 hours, recovery = 39 hours

without S9 mix
4.69-18.75 µg/mL treatment = 18 hours; 14.06-75.0 µg/mL treatment = 42 hours

chromosomes were prepared 18 and 42 hours after the start of treatment with the test material

*Test method:* similar to OECD guidelines (3)

*Result:* no increases in the proportion of cells with structural chromosomal aberrations were seen after treatment with the test material at any of the doses tested in the presence or absence of metabolic activation.

the notified chemical was not considered to be clastogenic under the conditions of this chromosomal aberration test.

### 9.3.3 Gene Mutation Assay in Chinese Hamster Cells *in Vitro*(12):

*Type of cell*: Chinese Hamster cells (V79)

*Concentration range:* 1.48-40.00 µg/mL (original experiment) and 6.25-50.00 µg/mL (confirmatory experiment) with metabolic activation; and 2.96-80.00 µg/mL (original experiment) and 8.75-70.0 µg/mL

(confirmatory experiment) without metabolic activation.

*Metabolic activation:* Aroclor-induced rat liver S9-mix

*Test method:* similar to OECD guidelines (3)

Result: no relevant increases of the mutant frequencies as determined by the screening with 6-thioguanine were found at any of the doses tested in the presence or absence of metabolic activation

the notified chemical was not considered to be mutagenic under the conditions of this test

## 9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low acute toxicity in rats by oral administration ($LD_{50}$ > 2 000 mg/kg) and dermal ($LD_{50}$ > 2 000 mg/kg) administration. The notified chemical was a slight skin irritant and a slight to moderate eye irritant in rabbits. It was a mild skin sensitiser in guinea pigs.

A 90-day repeated-dose study in rats showed a NOEL of 1 000 mg/kg for males (highest dose tested) and 50 mg/kg for females, based on liver and spleen effects.

The notified chemical was found not to be mutagenic by bacterial reverse mutation, in *in vitro* Chinese Hamster V79 cell mutation assays or genotoxic by chromosomal aberration assay in Chinese Hamster Ovary cells. No *in vivo* studies were performed.

According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (13), the notified chemical would not be classified as hazardous, in relation to the toxicological end points measured.

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out using OECD Test Methods.

| ***Test*** | ***Species*** | **Results** |
|---|---|---|
| acute toxicity to fish | Carp<br>*Cyprinus carpio* | $LC_{50}$ (96 h) > 43 mg/L NOEC (96 h) > 45 mg/L<br>See notes below |
| Acute immobilisation<br>(OECD 202) | *Daphnia magna* | $EC_{50}$ (48h) > 45 mg/L<br>See notes below |

| | | |
|---|---|---|
| Growth inhibition | Algae | NOEC (72 h) = 0.61 mg/L |
| (OECD 201) | *Selenastrum capricornulum* | See notes below |
| Respiration inhibition | Aerobic waste water bacteria | EC50 > 200 mg/L |
| (OECD 209) | | See notes below |

* NOEC - no observable effect concentration

The fish toxicity test was performed using a static range finding method and conducted with water containing a nominal 100 mg/L of the notified substance. This loading was well in excess of the water solubility of the substance and consequently the material was dispersed in the water through the agency of a dispersing agent (Cremphor EL), and stirred for 90 hours prior to commencement of the test. During the test the water was continuously agitated through aeration which maintained the dispersion and no gross separation of the notified test material occurred. Two analyses of the dispersion for the notified chemical gave concentrations 43 and 85 mg/L. However, most of the material was associated with the dispersed particles, and not present in true solution.

No mortality or other debilitating symptoms to the fish were observed, and it was therefore concluded that $LC_{50}$ (96 h) > 43 mg/L when the material is present as a dispersion in water. Therefore the chemical is non-toxic to this fish species up to the limits of its solubility.

The tests on immobilisation of daphnia were also conducted using a static method with a dispersion prepared in the same manner as described above for the fish tests, as well as with a filtrate prepared from this dispersion which was analysed and found to contain 19 mg/L of test chemical. The tests were performed in duplicate over a 48 hour period with the water temperatures maintained between 18 and 22 $^{o}$C and the pH between 8.0 (start) and 9.4 (finish). No adverse effect on the mobility of the daphnia was detected after 48 hours exposure to either the dispersion or the filtrate, and consequently the material may be regarded as non-toxic to this species up to the solubility limit.

The tests on inhibition of algal growth were performed with a filtrate prepared by dispersing a nominal 100 mg/L of the test substance in water for 93 hours, then passing the resultant dispersion through a paper filter. The resultant filtrate when analysed was found to contain
1.9 mg/L of the test material. This solution was progressively diluted with water to give concentrations of test material of 0.19, 0.34, 0.61, 1.1 and 1.9 mg/L . The test was run over the standard 72 hour period with the water temperature maintained between 22 and 23 $^{o}$C and pH between 8.1 and 9.0. No statistically significant inhibition of algal growth was observed for water containing < 1.1 mg/L. While a small effect was noted for those tests containing higher loadings of the test material, it was concluded that this was of no biological significance since the nominal loadings were far in excess of the water solubility of the chemical. Again it is concluded that the notified chemical is not toxic to algae up to the limits of its solubility.

No significant inhibition of bacterial respiration (activated sludge bacteria) was observed when the test substance was present at 200 mg/L as a dispersion. This test was performed in duplicate and again it is concluded that the material is non-toxic to activated sludge bacteria up to the limits of solubility.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is considered to be low when it is used in the manner indicated in the notification. The material is not toxic to aquatic species up to the limits of its solubility. Only very small amounts of the chemical are likely to reach the water compartment, and these would rapidly become associated with sediment through adsorption onto the associated organic matter.

Most material will be used in the production of plastic articles where it is incorporated into a polymer matrix giving little possibility for release. However, at the end of their serviceable lives, the plastic articles will be disposed of to landfill or be incinerated. In landfill it could be expected that the notified chemical would be very slowly degraded, while incineration would result in instant and immediate destruction. In either case the chemical will decompose to water and harmless gases.

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

The notified chemical cannot be determined to be hazardous substance on the basis of the toxicological data submitted for this assessment.

During the importation and transportation of the notified chemical, there is unlikely to be any worker exposure, except in the event of a spill. This may be minimised by the recommended practices for spillage given in the Material Safety Data Sheet (MSDS).

Exposure may occur to the notified chemical during initial blending and during masterbatching. There is potential for dermal exposure by direct contact or by dust when the notified chemical is added for blending and the blend is discharged. Details were not provided on discharge operations. Should dermal or ocular contact occur, the notified chemical is unlikely to cause acute systemic toxicity. However, it may cause slight skin and slight to moderate eye irritation and skin sensitisation. Therefore respiratory and dermal exposure should be controlled and workers must be attired with masks, goggles, gloves and industrial clothing as stipulated under recommendations.

Masterbatching is carried out in specialised plants that incorporate engineering controls such as local exhaust ventilation and closed mixing.

The processes involving the manufacture of polymer products containing the notified chemical are not known. The notified chemical is unlikely to pose an occupational health risk to workers because of the low concentration in the final masterbatch (0.1%) and the toxicological profile.

It should be noted that the potential for dust explosion exists when handling the notified chemical in the powdered form. In addition to avoid the adverse health effects of high concentrations of dust in the workplace, airborne dust levels should not exceed the NOHSC exposure standard of 10 $mg/m^3$ (14), measured as inspirable dust.

There is negligible potential for public exposure to the notified chemical arising from use as an additive to impart improved resistance to oxidation and better flow characteristics in polyolefines, polycarbonates, styrenics, elastomers and adhesives. There may be widespread public contact with the notified chemical incorporated into plastic products, but its incorporation within the substrate will preclude adsorption across the skin or other biological membranes.

## 13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- If engineering controls are insufficient to reduce exposure to a safety level: goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (15) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (16); and masks should be selected and fitted in accordance with AS/NZS 1715 (17) to comply with AS/NZS 1716 (18);

- Industrial clothing should conform to the specifications detailed in AS 2919 (19) and AS 3765.1 (20);

- Impermeable gloves or mittens should conform to AS 2161 (21);

- All occupational footwear should conform to AS/NZS 2210 (22);

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;

- NOHSC exposure standard of 10 $mg/m^3$ (14) for dust measured as inspirable dust should be maintained

- A copy of the MSDS should be easily accessible to employees.

## 14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical (HP 136) and products (Irganox HP 2215 FF and Irganox HP 2225 FF) were provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (23).

These MSDS were provided by the applicant as part of the notification statement. They are reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

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## 15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical 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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## Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

| *Erythema Formation* | *Rating* | *Oedema Formation* | *Rating* |
|---|---|---|---|
| No erythema | 0 | No oedema | 0 |
| Very slight erythema (barely perceptible) | 1 | Very slight oedema (barely perceptible) | 1 |
| Well-defined erythema | 2 | Slight oedema (edges of area well-defined by definite raising | 2 |
| Moderate to severe erythema | 3 | Moderate oedema (raised approx. 1 mm) | 3 |
| Severe erythema (beet redness) | 4 | Severe oedema (raised more than 1 mm and extending beyond area of exposure) | 4 |

The Draize scale for evaluation of eye reactions is as follows:

***CORNEA***

| *Opacity* | *Rating* | *Area of Cornea involved* | *Rating* |
|---|---|---|---|
| No opacity | 0 none | 25% or less (not zero) | 1 |
| Diffuse area, details of iris clearly visible | 1 slight | 25% to 50% | 2 |
| Easily visible translucent areas, details of iris slightly obscure | 2 mild | 50% to 75% | 3 |
| Opalescent areas, no details of iris visible, size of pupil barely discernible | 3 moderate | Greater than 75% | 4 |
| Opaque, iris invisible | 4 severe | | |

***CONJUNCTIVAE***

| *Redness* | *Rating* | *Chemosis* | *Rating* | *Discharge* | *Rating* |
|---|---|---|---|---|---|
| Vessels normal | 0 none | No swelling | 0 none | No discharge | 0 none |
| Vessels definitely injected above normal | 1 slight | Any swelling above normal | 1 slight | Any amount different from normal | 1 slight |
| More diffuse, deeper crimson red with individual vessels not easily discernible | 2 mod. | Obvious swelling with partial eversion of lids | 2 mild | Discharge with moistening of lids and adjacent hairs | 2 mod. |
| Diffuse beefy red | 3 severe | Swelling with lids half-closed | 3 mod. | Discharge with moistening of lids and hairs and considerable area around eye | 3 severe |
| | | Swelling with lids half-closed to completely closed | 4 severe | | |

***IRIS***

| *Values* | *Rating* |
|---|---|
| Normal | 0 none |
| Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light | 1 slight |
| No reaction to light, haemorrhage, gross destruction | 2 severe |