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# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

# FULL PUBLIC REPORT

BENZENEPROPANOIC ACID, 3-(2H-BENZOTRIAZOL-2-YL)-5-(1,1-DIMETHYLETHYL)-4-HYDROXY-, C7-9-BRANCHED

AND LINEAR ALKYL ESTERS (TK 13336)

This Assessment has been compiled in accordance with the provisions of the Industrial Chemicals (Notification and Assessment) Act 1989, as amended and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. 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.

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Director

Chemicals Notification and Assessment

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BENZENEPROPANOIC ACID, 3-(2H-BENZOTRIAZOL-2-YL)-5-(1,1-DIMETHYLETHYL)-4-HYDROXY-, C7-9-BRANCHED AND LINEAR ALKYL ESTERS (TK 13336)

#### 1. APPLICANT

CIBA Australia Ltd of 140 Bungaree Road, Wentworthville, NSW 2145

## 2. <u>IDENTITY OF THE CHEMICAL</u>

Chemical Abstracts name: Benzenepropanoic acid, 3-(2H-

benzotriazol-2-yl)-5-(1,1-

dimethylethyl)-4-hydroxy-, C7-9branched and linear alkyl esters

Chemical Abstracts Service

(CAS) Registry No.: 127519-17-9

IUPAC name:
Mixture of branched and linear

C7-9 ester of [3-2h-benzotriazol-2-

yl)-5-(1,1-dimethylethyl)-4hydroxyphenyl)]-propionic acid

Other name(s): CG 25-384, CGL 384

Trade name(s): TK 13336, Tinuvin 384 (product

containing 4-7% xylene)

**Empirical formula:** C27H37N3O3

Structural formula:

Molecular weight: 451.61 (Cg alkyl ester)

Method of detection and determination: GC assay and

microanalysis were

provided

# 3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: Pale yellow liquid

Odour: Almost no odour

**Boiling Point:** 451°C at 101.3 kPa (extrapolated)

Freezing Point: -29.4°C

**Density:**  $1078.3 \text{ kg/m}^3 \text{ at } 20^{\circ}\text{C}$ 

**Vapour Pressure:** 3 x  $10^{-6}$  Pa at 25°C

Water Solubility: <0.3 mg/L (detection limit) at 20°C

 $8.2 \times 10^{-7} \text{ g/L (calculated)}$  (1)

Fat Solubility: 99.6 g/100g fat simulant HB 307

Surface Tension: 67.0 - 63.9 mN/m at 20°C

(Concentration 10,000 mg/L)

**Viscosity:** 16900±400 mPa.s (20°C)

1290±20 mPa.s (40°C)

Partition Co-efficient

(n-octanol/water) log  $P_O/W$ : 9.2 (calculated)

Flash Point: 148°C

Flammability Limits: Not flammable

Autoignition Temperature: 415°C

**Explosive Properties:** Not explosive

Reactivity/Stability: Stable between ambient

temperature and 150°C

Comments on physico-chemical properties:

## Hydrolysis as a Function of pH:

Whilst the notified substance has an ester functionality and is therefore susceptible to hydrolysis, no results were available. This is acceptable, since attempts were made to determine the level of hydrolysis as a function of pH but were unsuccessful due to the very low solubility of the notified substance in water (< 300 ppb measured, 820 ppt calculated). No suitably sensitive analytical method is available and hydrolysis is unlikely under environmental conditions.

## Partition Coefficient:

The octanol water partition coefficient was experimentally determined as log P >>4 in preliminary testing using the shake flask method [OECD No.107]. This method is only effective over the log P range of -2 to 4. A log P of 9.16 was calculated for the notified substance using a computer model (CLOGP) which made allowances for tautomeric structures, charges, dissociation and H-bonds.

# Adsorption/desorption:

No adsorption/desorption data was provided due to the low solubility of the notified substance in water. However, the high log P indicates that it is likely to sorb to sediment particulates.

#### Dissociation constant:

Dissociation tests were not conducted due to the low solubility and relatively high MW of the notified substance. The weak acidity of the phenolic functionality of the notified substance would suggest some solubility in highly basic media.

#### 4. PURITY OF THE CHEMICAL

Degree of purity (of the notified chemical alone): 96-99%

Toxic or hazardous impurity/impurities:

Tin Concentration 15 μg/g (Maximum)

Non-hazardous impurity/impurities: (> 1% by weight)

. Chemical name: Methyl 2-[3-(2H-benzotriazol-2-yl)-

5-tert-butyl-4-hydroxyphenyl]-

propionate

**CAS No.:** 84268-33-7

Weight percentage: 2%

. Chemical name: 2-[3-(2H-benzotriazol-2-yl)-5-

tert-butyl-4-hydroxyphenyl]-

propionic acid

Weight percentage: 1%

. Chemical name: Mixed isomers of octanol

Weight percentage: 1%

# Additive(s)/Adjuvant(s):

Chemical name: Xylene
CAS No.: 1330-20-7
Weight percentage: 4 - 7%

#### 5. <u>INDUSTRIAL USE</u>

TK 13336 will be imported and used as an UV light absorbent material in surface coatings and plastics. The main use of the chemical will be for high quality clear coatings, which are widely used on new motor vehicles, aircrafts or trains. The product may also be used in paints for refinishing and repair work. Small quantities may be used on boats and for general timber protection. Another possible application may be to provide a clear finish over exterior signs.

The notified substance is similar to other UV stabilisers currently marketed in Australia (e.g. Tinuvin 900). TK 13336 belongs to the benzotriazole class of UV light stabilisers. It has been developed as a replacement for UV stabilisers which are used in powder form.

The estimated import volume is 1-5 tonnes in the first year and up to 20 tonnes per year by the fifth year of operations.

# 6. OCCUPATIONAL EXPOSURE

## Manufacture of Paints

It is anticipated that TK 13336 will be shipped in 50 kg and 200 kg lined steel drums and distributed to reformulators without repackaging.

TK 13336 will be added into the paint at a late stage in the paint manufacturing process, prior to final testing and filling. The notified chemical will be weighed and added to blending vessels, not usually in a closed system. However, engineering controls will be employed to reduce worker exposure.

The number of industrial paint manufacturing sites which will be using the notified chemical is between 20 to 30. It is estimated that 5 workers (3 plant operators and 2 laboratory technicians) will be handling the chemical at each site.

# Vehicle Refinishing and Repair workers

Worker exposure is also possible among paint applicators. Worksafe has estimated that there are 8,400 spray-painters and 30,000 repair workers in Australia. The notifier has indicated that there has been a rapid move towards the use of robotic spraying equipment by original equipment manufacturers. Implementation of this new technology should lead to a reduction in overspray and worker exposure.

#### Manufacture of Plastics

When TK 13336 is used in the manufacture of formulated thermoplastics, it is likely to involve a maximum of 12 additional manufacturers. An estimated 20 to 40 operators will be involved in the preparation of masterbatch concentrates.

# 7. PUBLIC EXPOSURE

There will be low potential for public exposure to the notified chemical during distribution, reformulation and disposal.

The supply of the notified chemical for use in surface coatings will only be as a component of formulated products. While no specific information has been provided on how the formulated

paint products will be applied, it is anticipated that conventional air-pressurised sprayers in horizontal or downdraft spray booths will be used. Overspray will be exhausted through an aqueous scrubber, which removes the waste paint as sludge. The use of conventional exhaust scrubbers would result in minimal public exposure to the notified chemical.

Although the use of the notified chemical may be extended to plastics, no information is available on how it is supplied or how it is incorporated into plastics. However, at the levels proposed, the manufacturing of plastic products containing the notified chemical would not be expected to result in significant public exposure. The notified chemical will not be recommended for use as an additive in contact food plastics.

Due to the notified chemical's low vapour pressure and low water solubility, it is expected to remain encapsulated within cured surface coats and plastic products. The risk of public exposure to the notified chemical from the use of these cured products would be minimal.

## 8. **ENVIRONMENTAL EXPOSURE**

#### . Release

TK 13336 will be formulated at a level of 1-2% in surface coatings.

It is stated that formulation will not generate any waste stabiliser, but this appears unrealistic as process equipment must be routinely cleaned to prevent product contamination and maintain operational efficiency (2). However, wastage from such operations is likely to be low since most of the residues are likely to be collected for use in other batches.

Incineration or disposal to landfill are the recommended methods of disposal, with incineration being the preferred method. Spillages of the notified substance (liquid) will be adsorbed on an inert material before disposal in a suitable manner. The notifier has stated that metal drums used for transport of the stabiliser are expected to be washed (multiple rinsing) with solvents used in the production process which are later used in further formulations. Disposal instructions for empty containers

indicate that after suitable rinsing, the drums should be holed or crushed before disposal.

The notifier indicates that the stabiliser may eventually be used as an additive in selected thermoplastics (PVC, polystyrene and polyolefins). If this use is pursued, it would entail blending of the stabiliser at comparable concentrations to those used for surface coatings.

The following three possible routes via which TK 13336 may enter the environment are identified in the submission:

- gradual weathering of coatings containing the notified substance;
- · discard of coated articles to landfill; and
- · volatilisation during accelerated curing.

None of these routes is likely to give rise to significant environmental exposure to the free stabiliser, which is expected to remain encapsulated in paint matrices by virtue of its low vapour pressure and minimal water solubility. However, the most significant route for entry into the environment, disposal of paint sludge from spraying operations, is not adequately addressed by the notifier.

Conventional liquid spray technology relies on air-pressurised sprayers and is usually conducted in a horizontal or downdraft spray booth (2). Transfer efficiencies are typically rather poor (in the order of 50%) and overspray in the air is often exhausted through an aqueous scrubber, which removes the waste paint as a sludge. Scrubber water tends to be recycled, and solids are drummed for disposal as hazardous waste, either through incineration or secure landfill.

#### . Fate

TK 13336 is expected to remain encapsulated within the cured formulation after curing. The low water solubility and high log P of the notified substance indicated that it will be adsorbed onto sediment particulates. Similarly, leaching from wastes disposed in landfill is considered unlikely. Significant exposure of air or water is not expected, with wastes expected to be either destroyed by incineration or consigned to landfill where they will remain immobile.

Ready biodegradability was investigated in a modified Sturm test (OECD guideline No.301 B) at nominal concentrations (in presence of TWEEN 80) of 10.0 and 21.1 ppm. The amount of carbon dioxide evolved in 28 d was 9 and 3% respectively. The low rate of mineralisation indicates that TK 13336 is not readily biodegradable.

A summary sheet for an aquatic bioaccumulation test was provided. The original report was in Japanese and a translation of the full report was unavailable. The testing was conducted on carp over an 8 week period using two concentration levels, 1.0 and 0.1 ppm. For both concentrations the BCF did not exceed 3.0. This indicates that the potential for bioaccumulation in aquatic species is low.

#### 9. EVALUATION OF TOXICOLOGICAL DATA

# 9.1 Acute Toxicity

Table 1: Summary of the acute toxicity of TK 13336

Test	Species	Outcome	Reference
Acute oral	Rat	LD <sub>50</sub> >2,000 mg/kg	3
Acute dermal	Rat	LD <sub>50</sub> >2,000 mg/kg	4
Skin irritation	Rabbit	Non-irritating	5
Eye irritation	Rabbit	slightly irritating	6
Skin sensitisation	Guinea pigs	Non-sensitising	7

## 9.1.1 Oral Toxicity (3)

TK 13336 at a single dose of 2000 mg/kg was administered by gavage to adult albino rats (Tif:RAI f(SPF)), 5 rats of each sex. The animals were observed for 14 days. There were no deaths. Clinical signs were observed for up to 4 days post-dosing and included piloerection, hunched posture, and dyspnea. Normal

bodyweight gain was observed during the observation period. At necropsy, macroscopic examination showed normal morphology.

This study indicates that the oral LD50 of TK 13336 is >2000 mg/kg.

## 9.1.2 Dermal Toxicity (4)

TK 13336 was applied at a dose level of 2000 mg/kg (undiluted liquid) to the clipped skin of albino rats (Tif:RAI f(SPF)) under semiocclusive dressing for 24 hours. Five rats of each sex were used. The animals were observed for a period of 14 days after dosing. There were no deaths. Clinical signs were apparent for up to 5 days post-dosing and included piloerection, abnormal body positions, and dyspnea. Normal bodyweight gain was observed during the observation period. At necropsy, macroscopic examination showed normal morphology.

This study indicates that the dermal LD50 of TK 13336 is >2000 mg/kg.

#### 9.1.3 Skin Irritation (5)

The potential for TK 13336 to cause skin irritation was studied in 3 female New Zealand white rabbits. An area was clipped free of hair on both flanks of the animals. The test article (0.5 mL undiluted liquid) was applied under occlusive dressing to the right flank, and the left flank served as a control. The dressing was removed after 4 hours and the application site was examined at 1, 24,48 and 72 hours after removal of the dressing. Slight erythema was observed in all 3 animals and slight oedema in 1 animal at 1 hour. Only slight erythema was apparent in 2 of the animals at 24 hours and all signs had disappeared by 48 hours.

This study indicates that TK 13336 is not irritating to the skin.

# 9.1.4 Eye Irritation (6)

Tinuvun 384 was tested for potential ocular irritant effects in 3 male New Zealand white rabbits. The test substance (0.1 mL undiluted liquid) was placed into the conjunctival sac of the left eye of each animal. The right eye served as a control. The eyes were examined at 1, 24, 48 and 72 hours after the

instillation of TK 13336. Slight, diffused erythema and slight oedema of the conjunctiva were observed in all animals at 1 hour but this was reduced to only some hyperaemic blood vessels remaining from 24 hours onwards.

This study indicates that TK 13336 is not irritating to the eye.

#### 9.1.5 Skin Sensitisation (7)

The potential for TK 13336 to cause skin sensitisation was studied in albino guinea pigs using the maximisation method. In the first week of the induction phase, three pairs of intradermal injections (0.1 ml each) were made simultaneously into the clipped neck of the guinea pigs (10 of each sex) containing the following:

- . adjuvant/saline mixture (1:1)
- . test article in sesame oil; or
- . test article in the adjuvant/saline mixture.

During the second week of induction, TK 13336 in vaseline was applied to the clipped area of each animal under occlusive bandage for a period of 48 hours. The application site had been treated with 10% sodium lauryl sulfate the day before the application of the test material.

A separate control group (10 of each sex) was treated with adjuvant and vehicle (sesame oil) during the induction phase.

The animals did not received any further treatment during weeks 3 and 4.

In the fifth week the animals were challenged with TK 13336 in vaseline applied to the clipped area for 24 hours under occlusive bandage. The application site was scored for erythema and oedema at 24 and 48 hours after removal of the bandage. No signs of erythema or oedema were noted in any of the treated animals.

TK 13336 did not cause skin sensitisation under the conditions of this experiment.

# 9.2 Repeated Dose Toxicity (8)

TK 13336 was administered orally by gavage to albino rats (Tif:RAIf(SPF)) at a dose of 0 (Vehicle: Distilled water containing 0.5% carboxymethyl cellulose and 0.1% Tween 80), 2, 50 or 500 mg/kg/day for 28 days. The treatment period was followed by a 28 day recovery period. Twenty animals of each sex were used per dose group and half of the animals were killed at the end of the treatment period and the other half were used in the recovery study.

There were no deaths or treatment-related clinical signs during this study. A decrease in the rate of bodyweight gain was observed in both the males and the females of the high dose group from weeks 2 to 4. Food consumption was also decreased in the high dose males during weeks 1 and 2 and in the females of this group throughout the treatment period.

Neurological investigation consisting of measurement of body temperature, forepaw and hindpaw grip strengths and landing foot splay was conducted 5 days prior to the treatment and on days 17, 28 and 52 of the study. This investigation did not reveal any treatment-related effects.

Haematology showed slight but dose-dependent decreases in red blood cell count, haemoglobin and haematocrit in the mid and high dose groups. These decreases were statistically significant in the high dose group. However, the reticulocyte levels were not decreased, but increased in the high dose group, suggesting that erythropoiesis was not impaired in these animals. The number of platelets was increased in the mid and high dose males, and the prothrombin time was slightly increased in the high dose males. These haematological parameters were comparable to control values by the end of the recovery period.

Clinical chemistry revealed a dose-dependent and statistically significant increase in the albumin to globulin ratio in the mid and high dose groups. This was mainly due to a decrease in globulin levels. Cholesterol and triglyceride levels were slightly increased in the mid and high dose groups. Potassium levels were increased in the mid and high dose males. Increased alkaline phosphatase activities were measured in the mid and high dose group, being up to 2.5-fold higher than control levels in the high dose males. Aspartate aminotransferase activity was also slightly increased in the high dose group. These clinical chemistry parameters were comparable to control values at the end of the recovery period.

At necropsy, absolute and relative liver weights were increased in the mid dose males and in both sexes in the high dose group. Organ weights in at the end of the recovery period were comparable to controls. Macroscopic and histological examinations were conducted on half of the animals and the other half were subjected to a neuropathological examination. Macroscopic examination showed enlarged liver in 2/5 mid dose males and 5/5 of the males and females in the high dose group. Histology revealed minimal to marked hypertrophy of hepatocytes in 5/5 the males of the mid and high dose groups and in 4/5females of the mid dose group and 5/5 females of the high dose The incidence of foci of necrotic hepatocytes was also increased in the mid dose females and in both sexes in the high dose group. Minimal hypertrophy of the thyroid follicular epithelial cells had occurred in 2/5 males and 1/5 female in the mid dose group and in 2/5 high dose males. No data were presented on the incidence of the liver and thyroid changes in the recovery animals. The neuropathological examination did not reveal any treatment related effects.

These data show that the target organ for oral toxicity of TK 13336 following repeated exposure in rats is the liver.

## 9.3 Genotoxicity

## 9.3.1 Mutagenicity Assay in Bacteria (9)

The potential for TK 13336 to cause point mutations was investigated in Salmonella typhimurium (strains TA98, TA100, TA1535 and TA1537) and Escherichia Coli (strain WP2uvrA) reverse mutation assays. A dose ranging study showed that concentrations of TK 13336 of up to  $5,000 \mu g/0.1 \text{ mL}$  were not cytotoxic toward TA100. Consequently, the dose levels were chosen as 312, 625, 1,250, 2,500 and  $5,000 \mu g/0.1 mL$ . TK 13336 was found not to increase the number of revertant colonies of S. typhimurium or E. Coli at any of the dose levels, when tested both in the presence or absence of rat liver microsomes (S9). Positive controls used in the absence of S9 were 2-nitrofluorene (for TA98), sodium azide (for TA100 and TA1535), 9-aminoacridine (for TA1537) for S. typhimurium and 4-nitroquinoline-N-oxide for E. Coli. presence of S9, positive controls used were 2-aminoanthracene (for TA98, TA100 and TA1537), cyclophosphamide (for TA1535) for S. typhimurium and 2-aminoanthracene for E. Coli.

 ${\tt TK}\ 13336$  was found not to cause mutations under the conditions of this experiment.

# 9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (10)

The potential for TK 13336 to cause clastogenic effects was evaluated in the mouse micronucleus assay. TK 13336 in Arachis oil was administered intraperitoneally to mice (Tif:MAGf(SPF)) at a dose of 5,000 mg/kg. Eight mice/sex /dose/sampling time were dosed and 5/sex/dose/sampling time were evaluated. The animals were killed at 16, 24 or 48 hours after dosing and bone marrow samples were taken and examined histologically for the presence of micronuclei. There was no increase in the number of micronucleated polychromatic erythrocytes as compared to vehicle controls at any of the sampling times. Cyclophosphamide was used as a positive control.

TK 13336 was found not to cause a clastogenic response under the conditions of this experiment.

#### 9.4 Overall Assessment of Toxicological Data

TK 13336 was tested for acute oral toxicity in rats and was found to have an LD50 >2,000 mg/kg. The dermal acute toxicity study showed that the LD50 in rats treated by this route was also >2,000 mg/kg. These results indicated that TK 13336 had low oral and dermal acute toxicity. The notified chemical did not cause skin or eye irritation in rabbits. TK 13336 was tested for skin sensitisation in guinea pigs and was found to be negative. A 28-day repeat dose toxicity study, where rats were dosed at 2, 50 or 500 mg/kg/day showed that the target organ for toxicity of this compound in the rat was the liver. A reverse mutation assay conducted in S. typhimurium and E. Coli showed that the notified chemical was devoid of mutagenic activity. TK 13336 was also shown to lack clastogenic activity when tested in the mouse bone marrow micronucleus assay.

#### 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The concentration recorded in the various aquatic tests listed below were all significantly higher than the water solubility of the notified substance (< 0.3  $\rm mg.L^{-1}$ ). These higher concentrations were achieved with the aid of a solubilising agent (unidentified).

#### Zebra-fish:

A static acute toxicity study (OECD guideline No. 203) with zebra-fish ( $Brachydanio\ rerio$ ) was performed in dechlorinated tap water maintained at a constant water temperature of 23°C and pH of 8.0. Testing revealed a 96 h LC50 > 9.9 ppm (actual).

The concentration used in the study are listed in the table below. A significant difference between the nominal dose and the measured dose is clearly evident, in addition to a > 50% reduction between the initial measure concentration (0 h) and the final concentration corresponding to 96 h. During these aquatic tests it was observed that "small parts" of the notified substance were "swimming" at the surface of the test solutions corresponding to nominal concentrations of 58 and 100 mg.L $^{-1}$ . Further at the conclusion of the testing all solutions were homogeneously mixed with strong turbidity evident at 58 and 100 mg.L $^{-1}$ .

Nominal concentration  $(mg.L^{-1})$  10 18 32 58 100 Measured conc. 0 h  $(mg.L^{-1})$  4.10 8.50 11.70 21.90 33.60 Measured conc. 96 h  $(mg.L^{-1})$  2.0 3.7 5.5 7.2 9.9

#### Daphnia:

Static acute toxicity testing on Daphnia magna (OECD guideline No. 202) revealed a calculated EC50 of 3.2 ppm (measured) after 48 h exposure.

The nominal and measured concentrations used are given below and again illustrate the significant difference between corresponding concentrations. At 0 h homogeneous distribution of the test substance was only noted in solution corresponding to measured concentration of  $< 0.5 - 3.8 \text{ mg.L}^{-1}$  inclusive, after 48 h homogeneity of solution was only noted up to 1.15 mg.L<sup>-1</sup>. At higher concentrations particulates from the notified substance were seen to be "swimming" at the surface of the test solutions, and after 48 h deposits of the test substance were noted.

Nominal  $(mg.L^{-1})$  1.0 1.8 3.2 5.8 10 18 32 58 100 Measured  $(mg.L^{-1})$  <0.5 0.8 1.15 1.7 3.8 6.0 11.7 11.3 21.2

# Activated sludge:

An activated sludge from a sewage treatment plant was used to assess the effect of the test substance on micro-organisms from a measure of the oxygen consumption. Testing protocol was as per OECD guideline No. 209 except that a settled sludge was used instead of a centrifuged sludge. After 3 h testing the EC50,  $EC_{20}$  and  $EC_{80}$  were all determined to be > 100 ppm. A result indicating that the notified substance had no inhibitory effect on micro-organisms at the concentration studied.

#### Algal growth:

Algal growth inhibition data were not submitted since the water solubility of the notified substance was below the limit of detection (LOD  $0.006~\rm g.L^{-1}$ ). Significant exposure appears unlikely in view of the low solubility and routes of disposal for waste products containing the substance.

#### 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Up to 50% of the paint used in spray painting operations is waste and requires disposal. However, TK 13336 will represent a small proportion (< 2%) of waste paint sludges consigned to landfill, and is expected to remain associated with such wastes.

The proposed uses of the notified substance (ie. surface coatings and possibly plastics) will result in the encapsulation of the stabiliser within polymer matrices. Therefore the potential for the release of notified substance to the environment is minimal.

The high log Pow (calculated, 9.2) and high lipid solubility (96.6 g/100 g fat) indicate that the notified substance has a potential for bioaccumulation, particularly in the aquatic compartment. However, the very low solubility of TK13336 (< 300 ppb) in water clearly indicates that water does not provide an effective transport vehicle for the mobilisation of the notified substance. Therefore, the potential impact of the notified substance on the sensitive aquatic species is limited. The summary report of the bioaccumulation data confirm this

scenario, indicating an experimentally determined BCF in fish of <3.0.

The notified substance appears to be moderately to slightly toxic towards the aquatic species tested (Daphnia and zebra-fish). However, in view of the very low solubility of the notified substance and its encapsulation during its proposed usage pattern, significant contamination of the aquatic compartment is not expected and hazard appears minimal.

# 12. <u>ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY</u> <u>EFFECTS</u>

The toxicity profile of TK 13336 indicates that the it has low acute toxicity via the oral and dermal routes. It is non-irritating to the skin and eyes and does not cause skin sensitisation. However, the short term repeated exposure study indicates that at relatively high levels TK 13336 may be hepatotoxic. Therefore, prolonged exposure to the chemical should be minimised.

The notified chemical is a viscous liquid with low volatility. Therefore, it is expected that inhalational exposure would not be significant during the paint manufacturing process. The use pattern indicates that the most likely route of exposure during the manufacturing process would be dermal. During the application of paint containing TK 13336, inhalational exposure as well as dermal exposure may be possible.

Based on the toxicity profile and the likely exposure pattern of TK 13336, it is unlikely that this chemical will pose a significant hazard to workers and the public.

#### 13. RECOMMENDATIONS

To minimise occupational exposure to TK 13336 the following guidelines and precautions should be observed:

. If engineering controls are insufficient to reduce exposure to a safe level, the following personal protection equipment should be worn, as the notified chemical may cause liver damage with prolonged exposure:

- safety glasses or goggles (AS 1336, AS 1337) (11, 12);
- . impervious gloves (AS 2161) (13); and
- protective clothing (AS 3765.1, AS 3765.2) (14,
  15);

Good work practices should be implemented to avoid spillages; and

Good personal hygiene should be observed.

# 14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for TK 13336 was not provided as it will be imported as the product Tinuvin 384. The MSDS for Tinuvin 384 (Attachment 1) was provided in Worksafe Australia format (16). This MSDS was provided by CIBA-GEIGY Ltd as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of CIBA-GEIGY Ltd.

#### 15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals* (Notification and Assessment) Act 1989 (the Act), secondary notification of TK 13336 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

Full bioaccumulation data will be required in subsequent submissions if exposure to the aquatic compartment is high.

## 16. REFERENCES

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