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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

TINOGARD TL (Benzotriazole Dodecyl p-Cresol)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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FULL PUBLIC REPORT

TINOGARD TL (Benzotriazole Dodecyl p-Cresol)

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba (Australia) Pty Ltd (ABN 97 005 061 469)
235 Settlement Road
THOMASTOWN VIC 3074

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Name, CAS Number, Molecular Formula, Structural Formula, Molecular Weight, Spectral Data, Purity, Impurities, Import Volume, Identity of Recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

NOTIFICATION IN OTHER COUNTRIES
EU, USA, Canada, China, New Zealand, Philippines.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Tinogard TL

OTHER NAME(S)
Benzotriazolyl Dodecyl p-Cresol (INCI Name)
CA 23-071
TK 12215

MOLECULAR WEIGHT
Majority < 500 g/mol

ANALYTICAL DATA
Reference IR, NMR, LC-MS and GC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Light yellow, oily liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-54°C	Measured
Boiling Point	415°C at 101.3 kPa	Measured
Density	1003 kg/m^3 at 20°C	Measured
Vapour Pressure	2.4x10^{-8} kPa at 25°C	Measured
Water Solubility	0.13 µg/L at 20°C	Measured
Hydrolysis as a Function of pH	Expected to be stable.	Inferred from structure

Partition Coefficient (n-octanol/water)	log Pow = 8.9 at 20ºC	Calculated
Surface Tension	71.5 mN/m at 20ºC	Measured
Adsorption/Desorption	log K_{oc} > 5.6 at 40°C	Measured
Dissociation Constant	pKa = 8.9	Calculated
Flash Point	> 200ºC at 97.8 kPa	Measured
Autoignition Temperature	410ºC	Measured
Explosive Properties	Not explosive	Measured

DISCUSSION OF PROPERTIES
The notified chemical has a low water solubility and low molecular weight. For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity
The MSDS for the notified chemical states that the notified chemical can form a volatile vapour/air mixture.

Dangerous Goods classification
The notified chemical is classified as follows according to the Australian Dangerous Goods Code (NTC, 2007): Environmentally hazardous substance (aquatic environment).

According to the MSDS for the notified chemical, it is classified as Class 9, Packing Group III due to toxicity to aquatic organisms and ability to cause long-term adverse effects in the aquatic environment.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported at > 90% as the product Tinogard TL.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 2	< 2	< 2	< 2	< 2

PORT OF ENTRY
MELBOURNE

IDENTITY OF RECIPIENTS
Ciba (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported by sea in 20 L plastic canisters and transported by road from the wharf to the notifier's warehouse in Thomastown, Victoria. The containers will be unloaded and stretch-wrapped pallets will be transported to various customers for reformulation into finished products.

USE
The notified chemical will be used in home and personal care products (≤ 0.05%) as a UV light stabiliser to prevent fading or discolouration upon exposure to light.

OPERATION DESCRIPTION
Reformulation
Canisters of the notified chemical will be transported by forklift to the blending vessel where a dip-tube will be inserted into the canister and a pre-determined amount pumped into the blending vessel where it will be mixed with other ingredients such as water, emollients, surfactants, colours and fragrances to form the finished product. The finished products will be filled and packaged into containers of various sizes for retail sale.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Warehouse	1-5	0.5	50-100
Process Operator	3-6	2	50-100
Quality Control	3-6	0.5	50-100
Packaging	3-6	1	50-100

EXPOSURE DETAILS

Reformulation

The most likely exposure scenario to the notified chemical (> 90%) will be via the dermal and ocular routes from spills, drips and splashes to workers involved in reformulation during processes such as: connection and disconnection of dip tubes to canisters containing the notified chemical, cleaning of blending vessels, quality control and packaging. Exposure is not anticipated to be significant given blending and packaging will be carried out using closed, automated systems and workers are anticipated to wear impervious gloves, overalls and safety glasses.

The notified chemical has a low vapour pressure and although blending may create aerosols, these are expected to be contained within the closed blending vessel and therefore, inhalation exposure is not expected.

Professional use in hair salons

Frequent dermal exposure to the notified chemical in shampoo, soap, skin care and detergent products (≤ 0.05%) is expected during professional use in hair salons. Personal protective equipment is not expected to be used by these professionals.

6.1.2. Public exposure

The public will experience frequent dermal exposure to home and personal care products such as shampoos, soaps, skin creams, fragrances and detergents containing the notified chemical at concentrations up to 0.05%. Based on the use of multiple products containing the notified chemical at 0.05%, the level of exposure to the notified chemical is estimated to be ≤ 9 mg/kg bw/day based on the Scientific Committee on Consumer Products' (SCCP's) Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation (SCCNFP, 2003).

Accidental ocular exposure may also occur from spills, drips and splashes during use of products containing the notified chemical.

Since products containing the notified chemical are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50 > 5000 mg/kg bw low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test.	*no evidence of sensitisation based on the study provided
Rat, repeat dose oral toxicity – 28 days.	NOAEL > 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro*, chromosome aberration	non genotoxic

* Maximum concentration used for induction was not clear in the study and therefore a definitive conclusion was not able to be reached.

Toxicokinetics, metabolism and distribution
The notified chemical has a low water solubility and high partition coefficient and as such is not expected to be readily absorbed across biological membranes despite its low molecular weight. Studies on a similar chemical indicated that it was absorbed, distributed, metabolised and excreted albeit in small amounts

Acute toxicity
The notified chemical was found to be of low acute oral toxicity in rats according to OECD TG 401 (Biomedizinische Forschungsgesellschaft mbH, 1986). There were no mortalities or adverse findings reported in any of the treated rats (5 male, 5 female) and the oral LD50 was determined to be > 5000 mg/kg bw.

The notified chemical was found to be of low acute dermal toxicity in rats according to OECD TG 402 (Ciba-Geigy Ltd, 1986k). There were no mortalities and adverse findings were limited to dyspnea, ruffled fur and abnormal body position. The dermal LD50 was determined to be > 2000 mg/kg bw.

Irritation and Sensitisation
The notified chemical was found to be slightly irritating in a skin irritation test conducted in 3 rabbits according to OECD TG 404 (see Appendix B for further details). Slight erythema was observed for up to 72 hours in 1 rabbit and slight oedema was observed in 1 animal 1 hour after treatment only (with no oedema present at the 24 hour observation). The effects observed were not sufficient for the chemical to be classified as a skin irritant according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The notified chemical was found to be slightly irritating in an eye irritation test conducted in 3 rabbits according to OECD TG 405 (see Appendix B for further details). Slight redness was observed in all animals 1 hour following treatment and persisted in 1 animal until the 72 hour observation. One animal also displayed slight chemosis but this had cleared by the 24 hour observation. The effects observed were not sufficient for the chemical to be classified as an eye irritant according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

No evidence for sensitisation potential of the notified chemical was found in a Skin Sensitisation – Guinea Pig Maximisation Test according to OECD TG 406 when 10% was used as an induction concentration (see Appendix B for details). The study report did not identify whether 10% was the maximum concentration that could be used for induction. Therefore, although not likely to be a potent sensitiser, the potential for skin sensitisation cannot be ruled out entirely.

Repeated Dose Toxicity
In a 28-day repeat dose oral toxicity study, no significant adverse clinical observations, laboratory findings or effects on the organs were observed in animals treated with the notified chemical at 50, 250 or 1000 mg/kg bw/day. Therefore, the No Observed Adverse Effect Level (NOAEL) was established as > 1000 mg/kg bw/day in this study, based on the absence of adverse effects at the highest dose level (Biomedizinische Forschungsgesellschaft mbH, 1987).

Genotoxicity
The notified chemical (dissolved in acetone) failed to induce an increase in revertant colonies in a bacterial reverse mutation assay (Ames test), conducted both with and without metabolic activation analogous to the method described in OECD TG 471 (Ciba-Geigy Ltd, 1986o). No evidence of reduction of the background lawn or cytotoxicity was reported.

The notified chemical was found not to be cytotoxic nor induce an increase in the frequency of structural or numerical chromosome aberrations in Chinese hamster lung fibroblasts under the conditions of the study conducted according to “Guideline on toxicity study data for application of new chemical standards (Notice 237 of Kanpogyo, notice 306 of Yaku and notice 303 of 62 Kikyoku) (Japan) (see Appendix B for further details).

Health hazard classification
Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Workers involved in reformulation may experience accidental dermal and ocular exposure to the notified chemical at > 90% from spills, drips and splashes. Exposure is expected to be minimised by the use of coveralls, safety glasses and impervious gloves. Although the notified chemical caused minor irritation to the skin and eye of rabbits and the sensitisation could not be ruled out, irritation or sensitisation is not expected to be a significant risk for workers given the anticipated low level of exposure.

Professionals in hair salons will frequently experience dermal exposure to products containing the notified chemical at ≤ 0.05%, such as shampoos, soaps, skin creams, fragrances and detergents. However, given the low concentration of the notified chemical in the products, the level of exposure is expected to be low and the risk of irritation is not considered to be unacceptable.

The notified chemical was found to have a NOAEL > 1000 mg/kg bw/day in a 28-day repeat dose oral toxicity study in rats. Therefore, the notified chemical is not expected to pose a risk to reformulation workers or workers in hairdressing salons following the anticipated low level of repeated exposure.

6.3.2. Public health

The public will encounter frequent dermal exposure and infrequent accidental ocular exposure to the notified chemical at ≤ 0.05% in a range of products, such as shampoos, soaps, skin creams, fragrances and detergents. Despite signs of minor irritation in animal tests at a concentration > 90% and inconclusive sensitisation data, irritation or sensitisation is not anticipated at the level of exposure encountered during use of products containing the notified chemical at ≤ 0.05%.

The estimated systemic exposure for the notified chemical from the use of multiple home and personal care products is ≤ 9 mg/kg bw/day. Given the NOAEL in a repeat dose oral toxicity study was > 1000 mg/kg bw/day, no systemic toxicity is anticipated during use of products containing the notified chemical at ≤ 0.05%.

Overall, the risk to the public from use of products containing the notified chemical at ≤ 0.05% is not considered unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Since the notified chemical will not be manufactured locally, there will be no environmental exposure associated with this process in Australia. Environmental release of the notified chemical is unlikely during importation, storage and transportation, and an accidental spill or leak is the most likely reason for environmental release. The size of the container (20 kg plastic canister) will limit the impact on the environment of such incidents. Any significant spillage either will be salvaged for use or collected using dry absorbent material and disposed of to landfill.

Release of the notified chemical to the environment during blending of home and personal care products is expected to be minimal due to the use of mostly automated and closed systems. Water used for cleaning the blending equipment will be re-used in the first batch of the next campaign or sent to the on-site wastewater treatment plant if not permitted for quality control reasons. Some of the notified chemical is expected to be adsorbed to sludge during on-site treatment, which would be disposed of in landfill. It is anticipated that up to 0.3% of the notified chemical will be released to water from the formulation process. The amount expected to be disposed to landfill is not known, but expected to be small.

It can be reasonably assumed that up to 1% of the notified chemical remains in the empty containers. These will be rinsed and the rinsate containing the notified chemical will either be re-used or disposed of to the on-site treatment plant.

RELEASE OF CHEMICAL FROM USE

Since the notified chemical will be used in home and personal care products, almost all of the imported

volume will enter the sewer when the products are washed off the hair and skin and disposed of following household washing and bathing activities.

The percentage of notified chemical remaining in emptied consumer product containers is not known but will vary depending on the size and type of the containers and the type of consumer product. Generally this amount will be less than 5% of the container content. The end product containers will be sent primarily to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Spilled or leaked material should be collected using absorbent material into properly labelled containers and disposed of by a licensed waste disposal company. Rinsed empty import containers will be sent to a recycler. Canister rinsate may be discharged to an on-site wastewater treatment plant if not reused. Following use, emptied consumer product containers are expected to be collected through domestic garbage disposal and then disposed of to landfill. Alternatively, residual contents may be washed to sewer when containers are rinsed by consumers before recycling

7.1.2 Environmental fate

As the notified chemical has low volatility, very low water solubility, and high partition coefficients, it is expected to largely partition to sludge during sewage treatment. Minimal degradation is expected during sewage treatment as the notified chemical is not readily biodegradable. Residues reaching terrestrial environments, such as sludge-amended soils or landfills, are expected to associate with soil and slowly degrade. Residues entering aquatic environments are expected to show some bioconcentration in fish, but measured bioconcentration factors were well below the threshold value of 1000 that identifies chemicals as bioaccumulative. For details of the environmental fate studies, please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC can be estimated as outlined below, based on the hypothetical worst case assumption that all will be released to sewer, and subsequently to receiving waters. Note that actual concentrations are not expected to approach these values, as substantial removal is expected during sewage treatment through hydrophobic partitioning. The estimated upper limit of 1.3 µg/L for treated effluent exceeds the water solubility by a factor of ten.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	< 2000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	< 2000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	< 5.5	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.374	million
Removal within STP	0%	
Daily effluent production:	4,275	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	< 1.3	µg/L
PEC - Ocean:	< 0.13	µg/L

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 > 100 mg/L	Not harmful
Daphnia Toxicity	EL50 > 100 mg/L	Not toxic, to limit of water solubility
Algal Toxicity	EC50 > 5 mg/L	Not toxic, to limit of water solubility

Aquatic toxicity testing was complicated by the poor solubility of the test substance, but the test results indicate that the notified chemical is unlikely to be harmful to aquatic life in receiving waters. Dispensation from a stock solution in THF allowed the notified chemical to be maintained as a homogeneous dispersion for the fish test, but the solvent approached a concentration of 0.9 g/L at the highest test concentration of 100 mg/L, and immediate precipitation occurred at higher concentrations. No solvents were used for the daphnid test, but the notified chemical was below the quantifiable limit (5 µg/L) in the water accommodated fraction used for testing. The maximum solubility possible for the algal test was 5 mg/L, using a stock solution in THF containing 1% Tween 80, and could not be maintained in the presence of algae because of presumed sorptive interactions.

7.2.1 Predicted No-Effect Concentration

A lower limit to the PNEC can be determined by dividing the most sensitive test result (5 mg/L in algae) by an assessment factor of 100, as acute data are available for three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Algal toxicity	> 5	mg/L
Assessment Factor	100	
PNEC:	> 50	µg/L

7.3. Environmental risk assessment

The risk quotients (Q = PEC/PNEC) are tabulated below.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	< 1.3	> 50	**< 0.026**
Q – Ocean	< 0.13	> 50	**< 0.0026**

The notified chemical is not expected to pose a risk to the environment when it is used as proposed in home and personal care products, as estimated risk quotients remain well below one even under unrealistically conservative exposure assumptions.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Aquatic toxicity	Acute 2	Toxic to aquatic life

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS

- The notified chemical should be classified as follows under the ADG Code:
  - Class 9: Environmentally Hazardous Substance (aquatic environment), Packing Group III

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation controls to minimise occupational exposure to the notified chemical as introduced in the product TINOGARD TL (Benzotriazole Dodecyl p-Cresol):
  - Avoid contact with skin

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the product TINOGARD TL (Benzotriazole Dodecyl p-Cresol):
  - Use protective gloves

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

Storage

- The following precautions should be taken by Ciba (Australia) Pty Ltd regarding storage of the notified chemical:
  - Avoid vapour formation and ignition sources.
  - Keep only in the original container.
  - Ensure good exhaust ventilation.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, collection and subsequent safe disposal.

Transport and Packaging

- Avoid release to the environment. Refer to special instructions/safety data sheets.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the function or use of the chemical has changed from an ingredient in cosmetics and domestic products at ≤ 0.05%.

(2) Under Section 64(2) of the Act; if
- the amount of chemical being introduced has increased from 2 tonnes, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet
The MSDS of the notified chemical (provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point -54°C

Method EC guideline NO L 251/A.1
Test Facility Ciba-Geigy Ltd (1986b)

Boiling Point 415°C at 101.3 kPa

Method OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks OECD TG 103/ EC Directive 92/69/EEC A.2 Boiling Point method was not used as it is only applicable in the temperature range up to 573°K.
Test Facility Ciba-Geigy Ltd (1986c)

Density 1003 kg/m^3 at 20°C

Method OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Pycnometer method
Test Facility Ciba-Geigy Ltd (1986d)

Vapour Pressure $2.4x10^{-8}$ kPa at 25°C

Method OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Test Facility Ciba-Geigy Ltd (1986c)

Water Solubility 0.13 µg/L at 20°C

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Column Elution Method. The radiolabelled test substance was used without radiodilution and analysed by liquid scintillation counting.
Test Facility Huntingdon Life Sciences Ltd (2006).

Hydrolysis as a Function of pH

Method The test could not be conducted because of the lack of a sufficiently sensitive analytical method (Ciba-Geigy Ltd, 1986e). Examination of the chemical structure indicates that the notified chemical is unlikely to hydrolyse in the environmental pH range of 4–9.

Partition Coefficient (n-octanol/water) log Pow = 8.9 at 20°C

Method Calculation by fragment method, using CLOGP3.2.
Remarks Experimental determination was impractical as the calculated partition coefficient falls outside the recommended ranges for the HPLC Method (0 to 6) and the Flask Method (-2 to 4).
Test Facility Ciba-Geigy Ltd (1986f)

Adsorption/Desorption – screening test log K_{oc} > 5.6 at 40°C

Method OECD TG 121 Estimation of the Adsorption Coefficient (K*oc*) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).
Remarks The retention time and capacity factor of the test substance were outside the calibration range. The notified chemical is expected to sorb very strongly to soil, with a much higher

adsorption coefficient than the reference substance DDT.
Test Facility Fraunhofer IUCT (1995)

Dissociation Constant pKa = 8.9

Method Calculated for phenolic group.
Remarks Reliable measurement is precluded by the very low water solubility.
Test Facility Ciba-Geigy Ltd (1995)

Flash Point > 200ºC at 97.8 kPa

Method EC Directive 92/69/EEC A.9 Flash Point.
Test Facility Ciba-Geigy Ltd (1986g)

Autoignition Temperature 410ºC

Method EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Test Facility Ciba-Geigy Ltd (1986h)

Explosive Properties Not explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Test Facility Ciba-Geigy Ltd (1986i)

Surface Tension 71.5 mN/m at 20ºC

Method OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Ring method. The notified chemical is not considered to be surface active.
Test Facility Ciba-Geigy Ltd (1986j)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – skin

TEST SUBSTANCE: Notified chemical (> 90%)

METHOD: OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Administered as supplied
Observation Period	7 days
Type of Dressing	Occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.66	1	0.33	1	< 7 days	0
Oedema	0	0	0	1	< 24 hours	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results: Slight erythema was observed in all 3 animals; resolving by 48 hours in one, 72 hours in another and 7 days in the third. Slight oedema was observed 1 hour after treatment in 1 animal only but this had disappeared by 24 hours.

In addition to the effects seen on the treated site, severe weight loss was observed in one individual caused by the rejection of food.

CONCLUSION: The notified chemical is slightly irritating to the skin.

TEST FACILITY: Ciba-Geigy Ltd (1986l)

B.2. Irritation – eye

TEST SUBSTANCE: Notified chemical (> 90%)

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	7 days
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.33	0	1	1	< 7 days	0
Conjunctiva: chemosis	0	0	0	1	< 24 hours	0
Conjunctiva: discharge	0	0	0	0	-	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	The notified chemical produced slight redness in the eyes of all 3 animals 1 hour after treatment. This had cleared by 48 hours in one animal and 7 days in another. Slight oedema was observed in 1 animal 1 hour after treatment but had cleared by 24 hours. There were no abnormal observations at the end of the observation period.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Ciba-Geigy Ltd (1986m)

B.3. Skin sensitisation

TEST SUBSTANCE	Notified chemical (> 90%)
METHOD	OECD TG 406 Skin Sensitisation – Guinea Pig Maximisation Test. EC Directive 96/54/EC B.6 Skin Sensitisation – Guinea Pig Maximisation Test.
Species/Strain	Guinea pig/Pirbright White
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 1% topical: 10%
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 20
INDUCTION PHASE	Induction Concentration: intradermal: 1% topical: 10%
Signs of Irritation	Not reported
CHALLENGE PHASE	
1st challenge	topical: 10%
Remarks - Method	The preliminary irritation test was not conducted and therefore a maximum non-irritating concentration was not determined. Therefore, it is not clear whether the concentrations used in the test are appropriate for determination of the skin sensitisation potential of the notified chemical. The test did not include a report on the irritant effects observed after the induction phase.
RESULTS	
Remarks - Results	No indication of irritation or sensitisation was observed at either 24 hours or 48 hours following topical challenge with the notified chemical at a concentration of 10%.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test. The notified chemical may have skin sensitising ability but the test conditions employed are inadequate or not sufficiently documented. Therefore, on the basis of inadequate evidence, no conclusion is made.
TEST FACILITY	Ciba-Geigy Ltd (1986n)

B.4. Repeat dose toxicity

TEST SUBSTANCE	Notified Chemical (> 90%)
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Crl:CD (SD) BR
Route of Administration	Oral – gavage

Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: None
Vehicle	Olive oil
Remarks - Method	No recovery groups were observed following the 28 days of treatment with the notified chemical. No other significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration mg/kg bw/day*	*Mortality*
control	5 per sex	0	0
low dose	5 per sex	50	0
mid dose	5 per sex	250	0
high dose	5 per sex	1000	0

Mortality and Time to Death

No mortalities occurred during the study.

Clinical Observations

Slight body weight increases (up to 6.8%) were observed in all treated males compared to control animals. Slight body weight decreases (up to 8.2%) were observed in females treated with 50 and 250 mg/kg bw/day.

Laboratory Findings

Haematology

Slight, statistically significant increases in mean cell volume in high dose females; and platelet count in low dose females were observed but the values remained within the normal historical range. A slight, statistically significant decrease in mean cell haemoglobin concentration was observed in males in the mid dose group but the value remained within the normal historical range.

In males in the low and mid dose groups a statistically significant reduction in thromboplastin time was observed. A statistically significant increase in thromboplastin time was observed in high dose males but all values were within the normal historical range.

In male rats, a dose-related increase in partial thromboplastin time was observed. However, this was considered equivocal as all values remained within the normal historical range.

Clinical Chemistry

The findings of the blood chemistry analysis are summarised in the table below:

	Females			Males		
Parameter	Low dose	Mid dose	High dose	Low dose	Mid dose	High dose
Urea					-	
Creatinine	+					
Total bilirubin				+		
Triglycerides	-				+	
Aspartate-aminotransferase	+					
γ-glutyl-transpeptidase						+
Alkaline phosphatase	+					
Inorganic phosphorus	+				-	
Sodium	+					
Potassium			+			
Calcium		-				
γ-globulin				+	+	+

+ = statistically significant increase but within normal historical range.
- = statistically significant decrease but within normal historical range.

In the analysis on protein levels, a dose-related increase in β-globulin levels was apparent in treated males. A statistically significant increase in γ-globulin levels was observed in all treated males but there was no apparent dose response.

Effects in Organs

Macroscopic examination at necropsy revealed a number of abnormalities in the livers of animals of both sexes:
Clay-coloured livers were observed in 2 females in the mid dose group, 4 females in the high dose group as well as 1 male in the control group, 3 males in the low dose group, 1 male in the mid dose group and 4 males in the high dose group.
Mottled liver were observed in the high dose groups only (2 females and 1 male).

However, there were no significant differences in liver weights between treated and control animals and histopathological examination of the liver failed to find any further evidence of adverse effects related to treatment.

Dilated kidneys (bilateral) were observed in 1 female from the mid dose group and 1 male from the control group.

Discolouration of the thymus (either red spots or dark red markings) were observed in 1 female from the mid dose group as well as 1 male from the control group, 2 males from the low dose group and 1 male from the high dose group.

A soft heart was observed in 1 female from the high dose group and yellow material in the pericardium was found in 1 male from the high dose group.

Clear red fluid in the thoracic cavity was found in 1 male in the high dose group.

Statistically significant increases were observed in the absolute weight of hearts of the males in the low dose group. A statistically significant decrease in absolute and relative spleen weights was also noted in low dose males.

Males in the high dose group displayed a statistically significant decrease in relative thyroid gland weights.

Remarks – Results

Variations between treated and control animals in body weight, haematological and clinical chemistry values was observed but there was no evidence of a dose relationship and therefore, were not considered treatment-related. (The exception was β-globulin levels, which, in the absence of organ-related adverse effects were not considered treatment-related). Macroscopic lesions were observed in the liver, kidneys and thymus with similar frequency in treated and control animals of both sexes without any apparent relationship to treatment. Histopathological examination revealed minor adverse effects in both treated and control animals without any apparent relationship to treatment.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as > 1000 mg/kg bw/day in this study, based on the lack of adverse findings at the highest dose level.

TEST FACILITY	Biomedizinische Forschungsgesellschaft mbH (1987)

B.5. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical (98.4%)
METHOD	Method prescribed by "Guideline on toxicity study data for application of new chemical standards (Notice 237 of Kanpogyo, notice 306 of Yaku and notice 303 of 62 Kikyoku) (Japan).
Species/Strain	Chinese Hamster
Cell Type/Cell Line	Lung fibroblasts

Metabolic Activation System	Phenobarbital-, 5,6-benzoflavone-induced rat liver S9 fraction
Vehicle	1% carboxymethyl cellulose sodium salt solution
Remarks - Method	The method was considered analogous to OECD TG 473.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1250*, 2500*, 5000*	24	24
Test 2	1250*, 2500*, 5000*	48	48
Test 3	1250*, 2500*, 5000*	6	24
Present			
Test 3	1250*, 2500*, 5000*	6	24

* cultures selected for metaphase analysis.

RESULTS

Remarks - Results	The percentage of cells with numerical or structural aberrations did not exceed 2% in any of the cultures treated with the notified chemical. The percentage of numerical and structural aberrations observed in the negative control were within normal limits and the positive control used in the direct method test ((N-methyl-N'-nitro-N-nitrosoguanidine demonstrated the sensitivity of the assay. However, the positive control used in the activation method (1,2-benzo(α)pyrene) failed to induce an increase in chromosomal aberrations in the absence of metabolic activation. Therefore, the results of that assay were not considered when determining the potential of the notified chemical to induce an increase in chromosomal aberrations. In Test 3, precipitate was observed on the surface of the cultures. However, this did not impede scoring.
CONCLUSION	The notified chemical was not clastogenic to Chinese hamster lung fibroblasts treated *in vitro* under the conditions of the test.
TEST FACILITY	Biosafety Research Center (Japan) (1987)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Bacteria from sewage treatment plant, Reinach, Switzerland.
Exposure Period	28 days
Auxiliary Solvent	None reported: the test substance was not dissolved in the medium.
Analytical Monitoring	Evolution of carbon dioxide, by precipitation of barium carbonate.
Remarks - Method	Aniline was used as reference substance.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
4	0/2	4	38
10	0/5	10	72
13	3/6	13	79
28	19/13	28	91

Remarks - Results	The two sets of values for the test substance represent degradation at loading levels of 10 and 20 mg/L.
CONCLUSION	Not readily biodegradable.
TEST FACILITY	Ciba-Geigy Ltd (1986p)

C.1.2. Bioaccumulation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 305 Bioconcentration: Flow-through Fish Test. EC Directive 98/73/EC C.13 Bioconcentration: Flow-Through Fish Test.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	Exposure: 29 days Depuration: 42 days
Auxiliary Solvent	None
Concentration Range	Nominal: 0.05 µg/L Actual: 0.051 µg/L
Analytical Monitoring	Combustion/liquid scintillation counting.
RESULTS	
Bioconcentration Factor	135
CT50	6 days
Remarks - Results	Concentrations in fish were at steady state from days 14 to 29. The notified chemical accounted for 42-48% of radioactivity in edible fish portions, and 24-27% in non-edible portions.
CONCLUSION	Bioconcentration factors are well below the threshold value of 1000 that identifies chemicals as bioaccumulative.
TEST FACILITY	Huntingdon Life Sciences Ltd (2007)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static
Species	Zebra fish (*Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	Tetrahydrofuran
Water Hardness	194 mg $CaCO_3$/L
Analytical Monitoring	Undisclosed method
Remarks – Method	The auxiliary solvent was present at 887 mg/L at the highest test concentration. Immediate precipitation was observed at higher concentrations.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	10	0	0	0	0	0
10	9.0	10	0	0	0	0	0
18	14.5	10	0	0	0	0	0
32	23.6	10	0	0	0	0	0
58	49.2	10	0	0	0	0	0
100	79	10	0	0	0	0	0

LC50	> 100 mg/L at 96 hours.
NOEC	32 mg/L at 96 hours.
Remarks – Results	Results are expressed as nominal concentrations. Swimming behaviour was slightly affected in single fish at the two highest exposures.
CONCLUSION	Not harmful to fish.
TEST FACILITY	Ciba-Geigy Ltd (1986q)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – limit test/static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	GC/FID detection
Remarks - Method	Daphnids were exposed to water accommodated fractions, obtained by filtration (0.45 µm membrane filter) of a sonicated and stirred supersaturated dispersion.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
100	< 0.005	20	0	0

EL50	> 100 mg/L at 48 hours
NOEL	100 mg/L at 48 hours
Remarks - Results	The test medium remained clear throughout the test period.

CONCLUSION Not toxic to daphnids, up to the limit of water solubility.

TEST FACILITY RCC (2002)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 5.0 mg/L Actual: 4.56 mg/L (initial), 3.56 mg/L (final)
Auxiliary Solvent	The stock solution was prepared in 1% Tween 80 in tetrahydrofuran.
Water Hardness	Typical algal culture medium (soft water) containing various salts including 18 mg/L calcium chloride dihydrate.
Analytical Monitoring	HPLC of dichloromethane extracts (LOQ 0.026 mg/L).
Remarks - Method	The measured concentration of the test substance remained constant in the absence of algae (and with prior rinsing of the recovery vessels with extraction solvent) at a nominal concentration of 5 mg/L. The test substance precipitated or formed a dispersion at higher concentrations.

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOEC mg/L*	*E_rC50 mg/L at 24-48 h*	*NOEC mg/L*
> 5	5	> 5	5

RESULTS

Remarks - Results	Microscopic examination revealed no abnormalities in any of the control and test cultures. An increase in pH from 8.0 to 10.2 in test and control cultures indicates good algal growth. Cell densities increased by a factor of 62 in controls, 47 in the solvent control and 68 in the test cultures.

CONCLUSION Not toxic to algae, up to the limit of water solubility.

TEST FACILITY Safepharm (1995)

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