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March 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Phenol, 2-(1,1-dimethylethyl)-6-methyl-4-[3-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]propyl]-

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 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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESS-MENT REFERENCE	APPLICANT	CHEMICAL OR TRADE NAME	HAZARD-OUS CHEMICAL	INTRODUC-TION VOLUME	USE
STD/1484	Mitsui & Co (Australia) Ltd	Phenol, 2-(1,1-dimethylethyl)-6-methyl-4-[3-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]propyl]-	No	≤ 10 tonnes per annum	Antioxidant and stabiliser for plastics

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

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

Environmental risk assessment
On the basis of the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical during reformulation processes:
  - Enclosed, automated processes, where possible
  - Ventilation system including local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation processes:
  - Avoid inhalation of powder

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during reformulation processes:
  - Respiratory protection when powder form is present
  - Gloves, protective clothing

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the (M)SDS should be easily accessible to employees.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

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 food contact regulations in the EU or the US regarding the use of the notified chemical have changed;
- The notified chemical is proposed to be used in food contact materials (containers and contact films) other than as follows:
  - ≤0.2% concentration in polypropylene, low density polyethylene and linear low density polyethylene, including homopolymers and copolymers, in contact with all food types; or
  - ≤0.2% concentration in high density polyethylene, including homopolymers and copolymers, in contact with alcoholic food; or
  - ≤0.12% concentration in high density polyethylene, including homopolymers and copolymers, in contact with aqueous, acidic and fatty food.
-

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from an antioxidant and stabiliser for plastics, or is likely to change significantly;
- the amount of chemical being introduced has increased, 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.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet
The (M)SDS of the notified chemical (and products containing the notified chemical) provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Mitsui & Co (Australia) Ltd (ABN: 64 004 349 795)
Level 46 Gateway
1 Macquarie Place
Sydney NSW 2000

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: analytical data, degree of purity, manufacture/import volume and site of manufacture/reformulation.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: water solubility, hydrolysis as a function of pH, absorption/desorption, dissociation constant, flash point, autoignition temperature, explosive properties, acute inhalation toxicity and genotoxic damage *in vivo*.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
EU (EFSA) – 2009
Canada (NDSL) - 2005
USA (TSCA) – 2013
US (FDA) – 2001
Korea (ESL) - 2001

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sumilizer GP

CAS NUMBER
203255-81-6

CHEMICAL NAME
Phenol, 2-(1,1-dimethylethyl)-6-methyl-4-[3-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]propyl]-

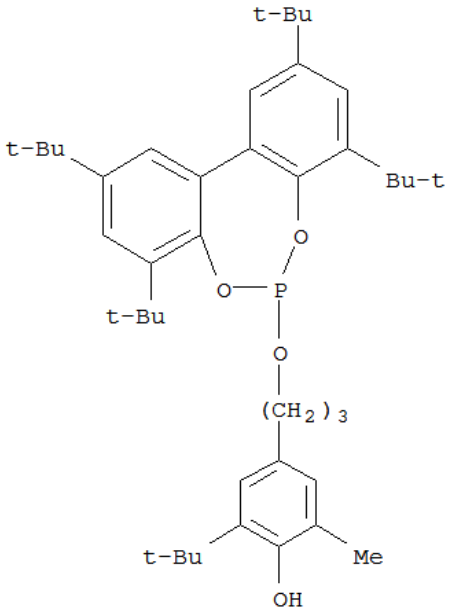
OTHER NAME(S)
2,4,8,10-Tetra-tert-butyl-6-[3-(3-methyl-4-hydroxy-5-tert-butylphenyl)propoxy]dibenzo[d,f][1,3,2]dioxaphosphepin

6-[3-(3-Methyl-4-hydroxy-5-tert-butylphenyl)propoxy]-2,4,8,10-tetra-tert-butyldibenzo[d,f][1,3,2]dioxaphosphepin

6-[3-(3-tert-Butyl-4-hydroxy-5-methylphenyl)propoxy]-2,4,8,10-tetra-tert-butyldibenzo[d,f][1,3,2]dioxaphosphepin

MOLECULAR FORMULA
$C_{42}H_{61}O_4P$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
660.91 Da

ANALYTICAL DATA
IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
>95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None identified.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)
None identified.

ADDITIVES/ADJUVANTS
None.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White powder

Property	Value	Data Source/Justification
Melting Point/Freezing Point	119.2 °C	Measured
Boiling Point	355.1 °C at 98.7 kPa	Measured
Density	1102 kg/m^3 at 20.1 °C	Measured
Vapour Pressure	6.4 x 10^{-21} kPa at 25 °C	Calculated
Water Solubility	<1.5 x 10^{-4} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical contains hydrolysable functionality, however, is not expected to be significantly hydrolysed due to its low water solubility.

Partition Coefficient (n-octanol/water)	log Pow >5.7 at 20 °C	Measured
Adsorption/Desorption	Not determined	The notified chemical is expected to sorb to soil, sediment and sludge based on its low water solubility.
Dissociation Constant	Not determined	The notified chemical contains dissociable functionality, however, is not expected to be significantly ionised in the environmental pH range of 4 – 9.
Particle Size	Inhalable fraction (< 100 μm): 66.7% Respirable fraction (< 10 μm): 2.25% MMAD= 78.0 μm	Measured
Flash Point	120 °C	(M)SDS
Solid flammability	Not highly flammable	Measured
Autoignition Temperature	437 °C	(M)SDS
Explosive Properties	Not determined	Not expected to have explosive properties
Oxidising Properties	No oxidising properties	Measured

* MMAD = Mass Median Aerodynamic Diameter

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The notified chemical is expected to be stable under normal conditions of use. Powders may form explosive dust cloud with air. The notified chemical may react with strong oxidants causing fire hazard (Sumitomo, 2011).

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported at up to 100% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 10	≤ 10	≤ 10	≤ 10	≤ 10

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Mitsui & Co (Australia) Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a neat chemical and as a master batch (containing up to 10% notified chemical) in either a 20 kg lined paper bag or 500 kg flexible bags.

USE
The notified chemical will be used as an antioxidant/stabiliser for plastics, including plastic material (containers and contact films) for food contact applications. It will be used at a concentration up to 0.2% in non-food contact plastic materials. When used in food contact applications, the notified chemical will be present in the following polyolefins: ≤0.2% in polypropylene, low density polyethylene and linear low density polyethylene, including

homopolymers and copolymers, in contact with all food types; ≤0.2% in high density polyethylene, including homopolymers and copolymers, in contact with alcoholic food; and ≤0.12% in high density polyethylene, including homopolymers and copolymers, in contact with aqueous, acidic and fatty food.

OPERATION DESCRIPTION

Master-batch production

The notified chemical (>95% concentration) will be emptied into a blending machine under either local exhaust ventilation and/or a closed system and kneaded by an extruder or mixer to yield the master batch pellet (containing up to 10% of the notified chemical). The master-batch pellets are packaged, stored and transported by road to customers.

Moulding of plastic articles

The notified chemical or the master batch pellet (containing up to 10% of the notified chemical) will be blended with a polymer to yield a polymer pellet containing up to 0.2% of the notified chemical. The blending procedure is performed under local exhaust ventilation and/or in a closed system. The polymer blend is kneaded using an extruder or mixer. The notified chemical is encapsulated into the polymer pellets or into the moulded plastic articles. The polymer pellets and plastic articles are packaged, stored and transported to customers.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	2-4	24
Production operators (master-batch)	8	50
Production operators (pellet)	8	200
Production operators (plastic articles)	8	300
Laboratory technicians	8	50
Equipment cleaning	8	50

EXPOSURE DETAILS

Transport and storage workers may come in contact with the notified chemical (at >95% or at 10% concentration) only in the event of accidental rupture of containers.

During master batch production of the notified chemical (>95% concentration), dermal, ocular and inhalation exposure may occur during emptying/weighing into a blending reactor, mixing and extrusion, blend discharge, quality control operations and maintenance, and cleaning of equipment. Exposure is expected to be minimised through the use of mechanical ventilation and/or enclosed systems as well as through the use of personal protective equipment (PPE) such as coveralls, safety glasses and impervious gloves. The notified chemical contains only a small proportion of particles of respirable size; however, inhaled particles may be ingested.

Once incorporated into the master batch, the notified chemical would be encapsulated in the polymer matrix; therefore exposure to workers during plastic moulding is expected to be low.

6.1.2. Public Exposure

Dermal exposure

Members of the public are likely to make contact with plastic materials containing the notified chemical; however, significant exposure as a result of casual contact during handling is not expected as the notified chemical is expected to be incorporated in the plastic matrix. However as the notified chemical will not be chemically bound, it may be released from products in low levels over time. The notified chemical is known to degrade into oxidation and hydrolysis products.

Exposure via foods

Members of the public are expected to come into contact with a diverse range of plastic products containing the notified chemical (at ≤0.2% concentration) including those that come in contact with food (containers and contact films). A migration study was performed on food contact materials containing the notified chemical (Covance, 2000) to determine the potential migration of the notified chemical and its oxidation and hydrolysis products from low density polyethylene (LDPE), polypropylene (PP) and high density polyethylene (HDPE) into food-simulating solvents under exaggerated conditions of use. The highest migration concentration of the notified chemical and its by-products were found in PP containing 95% ethanol (simulating fatty foods), tested with an initial concentration of the notified chemical of 0.1%. The details of this study are in Appendix B.

The notified chemical has undergone assessment by the US Food and Drug Administration (US FDA) and the European Food Safety Authority (EFSA).

The US FDA (2001b) provides a limit of the notified chemical that comes in contact with food, using various food contact materials:

- for HDPE, including homopolymers and copolymers, − ≤0.2% by weight, in contact with alcoholic foods, and ≤0.12% by weight, in contact with aqueous, acidic and fatty foods;
- for LDPE, linear LDPE and PP, including homopolymers and copolymers, − ≤0.2% by weight, in contact with all food types.

An earlier notification (US FDA 2001a) reported slightly more conservative limits for PP, LDPE and linear LDPE (≤0.10%).

EFSA assessed the notified chemical in 2007 and 2009 (EFSA, 2007 and EFSA, 2009) and established a specific migration limit (SML) for the notified chemical to be 0.05 mg/kg in 2007 (expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products).The SML was revised to 5 mg/kg in 2009, due to the provision of additional data.

Dietary exposure estimation

Food Standards Australia New Zealand (FSANZ) estimated possible exposure of the Australian population to the notified chemical and its oxidation and hydrolysis products from the diet. This estimation was based on individual food consumption data from the 1995 Australian National Nutrition Survey (NNS), which sampled 13,858 respondents aged 2 years and older using a 24-hour recall methodology (ABS, 1998). The 1995 NNS is considered to be a representative sample of the Australian population and, as such, a diversity of food consumption patterns was reported.

Total food consumption for all food groups for all 1995 NNS respondents was summed and combined with the maximum migration levels derived from data for three different types of foods (fatty, alcoholic and other foods) to provide an estimate of potential maximum total dietary exposure to the notified chemical. The total dietary exposure was then divided by the number of respondents in the 1995 NNS to give a mean dietary exposure to the notified chemical on a milligrams per day basis. The total estimated dietary exposure value thus derived provides a worst-case scenario of potential dietary exposure to the notified chemical because it was based on (1) the maximum migration rates for any of the three plastics (LDPE, PP, HDPE), including migration from by-products (i.e. sum of the notified chemical, the oxidation product of the notified chemical and the hydrolysis product of the notified chemical); and (2) total food consumption values for all foods (in effect assuming that all food eaten is packaged).

The assumptions made in this dietary exposure estimation included:

- fatty foods included those food groups where the amount of total fat made up >10% of the amount of total food intake for that food group (of 345 food groups considered, 122 were considered to meet this criteria and this included high fat food groups such as fats, oils, butter, table spreads etc, but also other food groups such as sweet and savoury biscuits, pastries, meat and poultry products and dishes, dressings, potato crisps, cheeses, ice creams, chocolate etc);
- alcoholic foods included all beverage groups containing >1.15% alcohol (including low alcohol beers, beers, wines, spirits, liqueurs and ready-to-drink mixed alcoholic beverages);
- all other foods (including both acidic and aqueous) were assumed to be any food not identified as a fatty or alcoholic food, except domestic (tap) water and where water was added to tea and coffee beverages;
- where migration data for specific food types (fatty foods, alcoholic foods, other foods) were provided, the notified chemical and its degradation products (oxidation and hydrolysis products), were assumed to migrate into all products in that food type at the maximum rate;
- 1 L of a food is equal to 1 kg; and

- where a food was not included in the dietary exposure assessment, it was assumed to contain a zero migration of the notified chemical (i.e. tap water).

ESTIMATED DIETARY EXPOSURE TO THE NOTIFIED CHEMICAL FOR THE AUSTRALIAN POPULATION AGED 2 YEARS AND ABOVE

Food groups	*Maximum migration rate* (mg/kg food)*	*Mean Food Consumption (g/person/day)*	*Dietary exposure (mg/person/day)*	*Contribution%*
Fatty foods	5	248	1.24	96
Alcoholic foods	0.144	205	0.03	2
All other foods (excl. tap water)	0.01	2116^	0.02	1
Total dietary exposure			*1.29*	*100#*

* Highest migration rates based on the concentration data (US FDA, 2000). Standard food volume-to-surface area ratio of 10g/in^2 assumed.
fatty foods based on the maximum average total migration of the notified chemical and its oxidation and hydrolysis products from PP to 95% ethanol and under high temperature;
alcoholic foods based on the maximum average total migration of the notified chemical and its oxidation and hydrolysis products from PP to 50% ethanol; and
all other foods based on the maximum average total migration of the notified chemical and its oxidation and hydrolysis products from LDPE to 10% ethanol. In this case, the concentration was equivalent to the validated limit of detection.
^Mean food consumption for all other foods includes beverages.
Due to the effect of rounding, contributions do not add up to 100%.

Estimated dietary exposure to the notified chemical and its associated by-products, based on Australian food consumption data, was 1.29 mg/person/day, the primary source of estimated dietary exposure being fatty foods (96%).

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 90 days.	NOEL = 100 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic

Toxicokinetics, metabolism and distribution.
No information is available on the toxicokinetics of the notified chemical. However based on the molecular weight (>500), low water solubility (<1.5 x 10^{-4} g/L at 20°C) and high partition coefficient (log Pow >5.7), dermal, GI and respiratory tract absorption is expected to be limited. The respirable fraction is low (2.25%); however, clearance of inhaled material from the upper respiratory tract is expected to lead to some ingestion.

Acute toxicity.
The notified chemical was found to be of low acute dermal (LD_{50} >2000 mg/kg) and oral (LD_{50} >2000 mg/kg) toxicity in the rat. An acute inhalation toxicity study was not conducted.

Irritation and sensitisation.
The notified chemical was found to be non-irritating to the rabbit skin and eye. It was non-sensitising in the guinea pig.

Repeated dose toxicity.

A 90-day repeated dose oral gavage study, which included a 28-day recovery period, was conducted in the rat. Rats of the Crj:CD(SD) strain were treated at 0 (control), 100, 300 and 1000 mg/kg bw/day. Rats in the control and 1000 mg/kg bw/day groups were also observed for 28 days after treatment.

There were no observed treatment related deaths or clinical signs during administration and recovery periods.

No treatment related changes in body weights, food and water consumption, urinalysis, haematological examination, necropsy and histopathological examination were observed.

Glucose levels in male rats were significantly increased at various treatment groups at different days during administration, but changes were not seen in female rats. Female rats showed a statistically significant increase in total cholesterol at the high dose which was not seen in male rats.

An increase in the relative weight of the liver was observed in female rats at mid and high treatment groups. Male rats at the high dose displayed an increase in absolute and relative weights of the liver and absolute weight of the kidneys.

A NOEL of 100 mg/kg bw/day was derived based on liver weight changes seen in female rats at 300 mg/kg bw/day.

Mutagenicity/genotoxicity.
The notified chemical and its oxidation product were not mutagenic in bacterial reverse mutation studies and were not clastogenic in *in vitro* mammalian chromosome aberration tests.

Health hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The highest exposure (dermal, ocular and inhalation) of workers to the notified chemical (up to >95% concentration) may occur during emptying/weighing, blend discharge and quality control operations for powder blending and master batch production. Worker exposure is not likely to occur during the later stages of production since the notified chemical will be encapsulated into the polymer matrix and will not be bioavailable.

6.3.2. Public Health

Dermal exposure of the public to plastic article containing the notified chemical is expected to be low, due to it being incorporated within the plastic matrix.
The highest migration of the notified chemical and its oxidation and hydrolysis products is expected from contact with fatty foods (≥10% fat content) packaged in PP plastic materials. Based on the available data, absorption of the notified chemical following ingestion is expected to be limited.

In order to estimate the risk associated with ingestion, a comparison of the toxicological data with the worst-case exposure estimate gives:

NOEL for increased liver weight changes	=	100 mg/kg bw/day
Safety factor (for extrapolation from a single repeated dose animal study) (US FDA, 2010)	=	2000
Typical weight of a person	=	60 kg bw
Tolerable Daily Intake (TDI)	=	3 mg/day[1]
Estimated worst-case, long-term dietary exposure	=	1.29 mg/person/day
Estimated exposure as a percentage of TDI	=	43 %

[1]100 mg/kg bw/day * 60 kg bw/2000 = 3 mg/day
The estimated dietary exposure to the notified chemical and its associated by-products was 1.29 mg/day. Using a worst-case public exposure assumption, the maximum estimated dietary exposure is 43% of the derived TDI of 3 mg/day (US FDA, 2000).

Therefore, despite numerous conservative assumptions (both in the exposure estimation and in the use of the safety factor from the NOEL), the notified chemical is not considered to pose an unacceptable risk to public health at the levels of exposure that are estimated to result from its proposed use.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical is not manufactured in Australia, however, reformulation of the notified chemical into master batch pellets will take place in Australia. Addition of the notified chemical to the mixing chamber will be achieved by contained automatic procedures, thus reducing the potential for spills to occur. Engineering controls in the form of local exhaust ventilation and/or closed system charging will be used at the mixing chamber. Waste material from spills, cleaning of equipment and residues in empty containers are estimated at 2% of the total import volume of the notified chemical. Wastes of the notified chemical in raw materials and manufactured master batch are solid, therefore they are expected to be physically contained and disposed of to landfill. No release to sewer is expected.

RELEASE OF CHEMICAL FROM USE

Master batch pellets will be mixed with polymer and will be moulded into plastic articles. Wastes from this process will be in the form of master batch pellets or as manufactured plastic. In total, approximately 0.5% (of the total import volume) of the notified chemical is expected to be released as waste material from spills, cleaning of equipment and residues in empty containers. Wastes are expected to be recycled into the moulding process where suitable or they are expected to be collected and disposed of to landfill. No release to sewer is expected.

RELEASE OF CHEMICAL FROM DISPOSAL

At the end of their useful lives, articles containing the notified chemical are expected to be recycled or disposed of to landfill.

7.1.2. Environmental Fate

For the details of the environmental fate studies please refer to Appendix C.

The vast majority of the notified chemical will be incorporated into plastic articles. The notified chemical will be physically bound into the inert polymer matrix and in this form it is not expected to be mobile or bioavailable. The notified chemical has low solubility in water ($<1.5 \times 10^{-4}$ g/L) and a high n-octanol partition coefficient (log Pow >5.7) which indicate that it has low mobility. Hence, notified chemical disposed of to landfill as wastes and residues from reformulation are expected to be immobile. The notified chemical is not readily biodegradable according to the biodegradation study. In landfill, the notified chemical in plastics and residues is expected to eventually undergo biotic and abiotic degradation to form water and oxides of carbon and phosphorus. The notified chemical is not expected to be bioaccumulative in fish according to the bioaccumulation study. The notified chemical is expected to be relatively immobile within the plastic matrix, but may be slowly released as the polymer matrix degrades within the landfill.

7.1.3. Predicted Environmental Concentration (PEC)

The notified chemical is not expected to be discharged to the aquatic compartment based on the intended use and likely disposal pathway. Therefore, the predicted environmental concentration (PEC) was not calculated.

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	LL50 (96 h) > 10 mg/L (WAF)*	Not harmful to fish up to the limit of solubility
Daphnia Toxicity	EL50 (48 h) > 10 mg/L (WAF)*	Not harmful to aquatic invertebrates up to the limit of solubility
Algal Toxicity	E_rL50 (72 h) > 10 mg/L (WAF)*	Not harmful to algae up to the limit of solubility

*WAF: Water Accommodated Fractions

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified chemical is not harmful to fish, aquatic invertebrates and algae. The reported endpoints are based on nominal loading rates of the water accommodated fraction (WAF) used for testing, consistent with international best practice (OECD, 2000).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) was not calculated as low potential for aquatic exposure is expected based on the reported use pattern.

7.3. Environmental Risk Assessment

The Risk Quotient, Q (= PEC/PNEC), has not been calculated since a PEC is not available.

The notified chemical will be used in the manufacture of plastic polymer articles. The majority of the notified chemical will be incorporated within the inert polymer matrix and will not be mobile or bioavailable. On the basis of the low toxicity to aquatic organisms and low potential for exposure to the aquatic environment, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point 119.2 °C

Method	OECD TG 102 Melting Point/Melting Range. EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	The endothermic heat effect (melting) was observed at 123 °C and a second endothermic effect was seen at about 280 °C.
Test Facility	RCC (2002d)

Boiling Point 355.1 °C at 98.7 kPa

Method	OECD TG 103 Boiling Point. EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks	Endothermic effect was observed at 130 °C and 360 °C.
Test Facility	RCC (2002b)

Density 1102 kg/m^3 at 20.1 °C

Method	OECD TG 109 Density of Liquids and Solids. EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	Determined using a gas comparison pycnometer.
Test Facility	RCC (2003d)

Water Solubility <1.5 x 10^{-4} g/L at 20 °C

Method	OECD TG 105 Water Solubility. Column Elution Method.
Remarks	The test was conducted according to the guidelines above using good laboratory practice (GLP). The water solubility of the test substance (notified chemical) at 20 °C ± 0.5 °C was determined to be below the detection limit of HPLC - UV/VIS, which is <1.5 x 10^{-4} g/L.
Test Facility	RCC (2002f)

Partition Coefficient (n-octanol/water) log Pow = >5.7 at 20 °C

Method	OECD TG 107 and 117 Partition Coefficient (n-octanol/water). HPLC Method/Flask Method
Remarks	The test was conducted according to the guidelines above using good laboratory practice (GLP). A good solubility of the test substance (notified chemical) in n-octanol and a very poor solubility in water were observed during the preliminary test indicating a partition coefficient above 6. Hence, the partition coefficient of the test substance cannot be determined according to the OECD guidelines 107/117. Therefore, the partition coefficient of the test substance was estimated using the solubility of the test substance in n-octanol (72.9 g/L) and that of the test substance in water (reported value from water solubility test). Additionally, a log Pow value was also calculated using a model calculation based on the solubilities of theoretical fragmentation (KOWWIN v1.6, 1998). The log Pow value calculated using the respective solubility of the test substance in n-octanol and water to be >5.7; whereas, the log Pow value was predicted to be log Pow = 16.5.
Test Facility	RCC (2002e).

Particle Size Mass median diameter (MMD) 78 μm

Method	EC Document ECD/TM/February 1996: "Particle Size Distribution, Fibre Length and Diameter Distribution"

Range (μm)	*Mass (%)*
<250	99.81
<100	66.7
<10	2.25
<1	0.49

Remarks Determined using the laser diffraction method.
Test Facility RCC (2003c)

Solid Flammability Not highly flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks The notified chemical could not be ignited with a flame.
Test Facility RCC (2002c)

Oxidizing Properties Not oxidising

Method EC Council Regulation No 440/2008 A.17 Oxidizing Properties (Solids).
Remarks The burning zone of the mixtures of notified chemical/cellulose did not propagate over the 20 mm zone.
Test Facility RCC (2003b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	According to EC Official Journal of the European Communities No L 383 A/2. B.1.
Species/Strain	Rat/Crj:CD (SD) IGS (SPF)
Vehicle	Methylcellulose aqueous solution (5%)
Remarks - Method	After administration, observation of clinical signs and mortality were made at: 10 and 30 minutes; 1, 2 and 4 hours; and daily for 2 weeks thereafter. Each animal was weighed on days 0, 7 and 14 during the observation period.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
0	5M; 5F	0	0/10
2000	5M; 5F	2000	0/10

LD50	>2000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	There was no significant difference in body weight and body weight gain between treatment and control groups. Retention of a white substance in the urinary bladder was found in both control and treated male rats. Retention of fluid in the uterine horn in two females from the 2000 mg/kg bw group was not considered to be test substance related.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Sumitomo (1993)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rat/HanBrl: WIST (SPF)
Vehicle	Polyethylene glycol (PEG) 300
Type of dressing	Semi-occlusive.
Remarks - Method	Twenty-four hours after application, the dressing was removed and the skin was flushed with lukewarm water and dried with paper towels. Observations were conducted for 14 days after application.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
2000	5M; 5F	2000	0/10

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	None
Signs of Toxicity - Systemic	None
Effects in Organs	None
Remarks - Results	Two female animals showed body weight loss of 1.7% to 2.2% after 1

	week, which was regained and increased by the end of the observation period.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	RCC (2003e)

B.3. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	According to EEC Methods for the Determination of Toxicity B.4 Acute Toxicity (Skin Irritation) (1992).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3M
Vehicle	Corn oil
Observation Period	72 hr
Type of Dressing	Occlusive.
Remarks - Method	The shaved skin was exposed with 0.5g of the test substance moistened with the vehicle and spread on a 2.5 cm square lint patch and applied to intact skin for 4 hr. After exposure period and removal of patches, the treated areas were wiped with absorbent cotton dipped in acetone.
Remarks - Results	There were no signs of erythema and oedema observed in any animal during the observation period of 72 hr after patch removal. All scores were 0.
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	Sumitomo (1998b)

B.4. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	According to EEC Methods for the Determination of Toxicity B.5 Acute Toxicity (Eye Irritation) (1992).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3M
Observation Period	72 hr
Remarks - Method	A volume of 0.1 mL (0.029g) of the test substance was placed in the conjunctival sac of one eye of each animal, with the other untreated eye serving as the control. A hand slit-lamp was used to score the irritation and observations after 24 hr were made with the aid of fluorescein.
Remarks - Results	There were no signs of eye irritation observed in any animal during the observation period of 72 hr after patch removal. All scores were 0.
CONCLUSION	The notified chemical is non-irritating to the eye.
TEST FACILITY	Sumitomo (1998b)

B.5. Skin sensitisation

Test Substance	Notified chemical
METHOD	Maximisation Test according to EEC Methods for the Determination of Toxicity, B.6. (Skin Sensitization), (1996)
Species/Strain	Guinea pig/Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 5% test substance suspension in corn oil topical: 50% test substance in acetone

MAIN STUDY		
Number of Animals	Test Group: 20F	Control Group: test substance negative control: 10F 10% alpha-hexylcinnamaldehyde (HCA) positive control: 5F 10% HCA negative control: 5F
INDUCTION PHASE	Induction Concentration: intradermal: 5% test substance in corn oil 5% test substance in Freund's complete adjuvant in water topical: 50% test substance in acetone	
CHALLENGE PHASE		
1st challenge	topical: 5% test substance in acetone	
Remarks - Method	A dose finding study was carried out to select suitable concentrations for sensitisation and challenge.	
Remarks - Results	There were no signs of erythema and swelling observed in the test substance treated animals (sensitised) or the test substance negative control animals. A sensitising response was seen with the positive control HCA.	
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.	
TEST FACILITY	Sumitomo (1998d)	

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	90-Day Repeated Dose Toxicity Study in Rats (Oral).
Species/Strain	Rat/Crj:CD(SD)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 90 days Dose regimen: 7 days per week Post-exposure observation period: 28 days
Vehicle	Methylcellulose (0.5% w/v in distilled water)
Remarks - Method	The test was conducted in compliance with good laboratory practice (GLP). The test substance was tested after the completion of the study to confirm its stability during the period of use. Rats were quarantined and acclimatised for up to 14 days and 3 rats per sex were necropsied to confirm the absence of abnormalities.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	16M; 16F	0	0/32
low dose	16M; 16F	100	0/32
mid dose	16M; 16F	300	0/32
high dose	16M; 16F	1000	0/32
control recovery	10M; 10F		0/20
high dose recovery	10M; 10F		0/20

Mortality and Time to Death

There were no treatment related deaths.

Clinical Observations

There were no clinical signs related to treatment during administration and recovery periods. The hair loss observed in one male rat each from the control and the 1000 mg/kg group and in one female rat in the 100 mg/kg group during administration period or recovery period, was considered incidental.

Food and Water Consumption and Body Weight Gain

Transient non-dose related statistically significant increase in absolute food consumption was observed (male rats in the 1000 mg/kg group at day 15 and in the 100 and 1000 mg/kg groups at day 57). In females, absolute food consumption increased significantly in the 300 mg/kg group at day 64 of administration and decreased in the 1000 mg/kg group at recovery day 22.

Transient non-dose related statistically significant changes were seen in water consumption in female rats only (in the 100 mg/kg group during day 64 of the administration period and in 1000 mg/kg group at days 1, 15 and 22 of the recovery period).

A statistically significant increase in body weight gain was noted in the 1000 mg/kg group in males at day 57; while a decrease was noted during the recovery period. No such changes were seen in females.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Glucose levels in male rats were significantly increased at the 100 mg/kg group at day 42; dose related as well as statistically significant increases at all dose groups were also seen at day 90. Glucose level changes were not seen in female rats.

Female rats showed a statistically significant increase in total cholesterol levels at day 42 (300 mg/kg group) and at day 90 (1000 mg/kg). At day 42, inorganic phosphorus levels were significantly increased in the 100 mg/kg group and sodium levels were decreased in the 1000 mg/kg group. Total bilirubin levels were also increased significantly in the 1000 mg/kg group during the recovery period.

During the recovery period, a statistically significant increase in the levels of glutamic oxaloacetic transaminase (GOT), alkaline phosphatase (ALP), blood urea nitrogen (BUN) and creatinine were seen in males in the 1000 mg/kg group.

In female rats, non-dose related statistically significant decrease in haemoglobin levels (100 and 1000 mg/kg groups), decrease in haematocrit levels (1000 mg/kg group) and increase in platelet levels (1000 mg/kg group) were reported. There were no significant changes in males.

There were no statistically significant changes in urinalysis between the control and treatment groups.

Effects in Organs

No treatment-related macroscopic and microscopic findings were noted. Statistically significant dose-related increase in absolute liver weights was seen in females (300 and 1000 mg/kg groups) and in males (1000 mg/kg group). Significant changes in the weight of various organs were also seen during recovery period in females (decrease in relative heart weight and increase in absolute heart weight) and in males (increase in relative lung weight, decrease in relative liver weight, increase in absolute liver weight, increase in absolute and relative spleen weight and increase in absolute and relative weight of the kidneys).

CONCLUSION

The study authors established the No Observed Effect Level (NOEL) as 100 mg/kg bw/day in this study, based on liver weight changes seen in female rats in the 300 mg/kg and 1000 mg/kg groups.

TEST FACILITY	Panapharm Laboratories (1999)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 1992/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98 and TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Phenobarbital/benzoflavone-induced rat liver (S9 homogenate)
Concentration Range in	a) With metabolic activation: 19.5, 39.1, 78.1, 156 and 313µg/plate

Main Test	b) Without metabolic activation: 4.88, 9.77, 19.5, 39.1 and 78.1 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	A preliminary test was conducted to determine the dose levels for the main test. Because there was no observed bacterial cytotoxicity, the solubility limits (where precipitation occurred) determined the highest doses to be used in the main test.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>78.1	≥78.1	Negative
Present				
Test 1	>5000	>313	≥313	Negative

Remarks - Results	There were no significant increases observed in the frequency of revertant colonies in the preliminary or main test, for any of the bacterial strains up to and including the maximum doses, either with or without metabolic activation.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Sumitomo (1998c)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Oxidation product of the notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98 and TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Phenobarbital/benzoflavone-induced rat liver (S9 homogenate)
Concentration Range in Main Test	a) With metabolic activation: 15.6 - 500 µg/plate b) Without metabolic activation: 3.9 - 125 µg/plate
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	A preliminary assay was conducted (at 15 - 5000 µg/plate) to determine the dose levels for the main test. These were determined on the basis of solubility.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>125	≥31.3	Negative
Test 2		>125		Negative
Present				
Test 1	>5000	>500	≥500	Negative
Test 2		>500		Negative

Remarks - Results	There were no significant increases observed in the frequency of revertant colonies in the preliminary or main tests, for any of the bacterial strains up to and including the maximum doses, either with or without metabolic

activation. The positive controls performed as expected, confirming the validity of the test system.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY KOEI (2000)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain Chinese hamster
Cell Type/Cell Line Lung cells (CHL/IU)
Metabolic Activation System Phenobarbital/benzoflavone-induced rat liver (S9 homogenate)
Vehicle Dimethyl sulfoxide
Remarks - Method A cytotoxicity test was carried out for both Test 1 and Test 2, in order to determine the dose levels.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	3.13, 6.25, 12.5, 12, 50, 100, 200*, 400* and 800*	6 hr	24 hr
Test 2a)	3.13, 6.25, 12.5, 12, 50, 100, 200*, 400* and 800*	24 hr	24 hr
Test 2b)	3.13, 6.25, 12.5, 12, 50, 100*, 200*, 400* and 800	48 hr	48 hr
Present			
Test 1	3.13, 6.25, 12.5, 12, 50, 100, 200*, 400* and 800*	6 hr	24 hr
Test 2	3.13, 6.25, 12.5, 12, 50, 100, 200*, 400* and 600*	6 hr	30 hr

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 800	>800	≥100	Negative
Test 2a)	≥ 400	≥800	≥100	Negative
Test 2b)	≥ 400	≥400	≥100	Negative
Present				
Test 1	≥800	≥800	≥100	Negative
Test 2	≥800	≥600	≥100	Negative

Remarks - Results The vehicle and positive controls gave satisfactory responses, confirming the validity of the test system.

There was no observed increase in the incidence of chromosomally aberrant cells in any treatment conditions.

CONCLUSION The notified chemical was not clastogenic to Chinese hamster lung cells treated *in vitro* under the conditions of the test.

TEST FACILITY Sumitomo (1998a)

B.10. Genotoxicity – in vitro

TEST SUBSTANCE Oxidation product of the notified chemical

METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	Lund cells (CHL/IU)
Metabolic Activation System	Phenobarbital/benzoflavone-induced rat liver (S9 homogenate)
Vehicle	Dimethyl sulfoxide
Remarks - Method	A preliminary test for dose determination was conducted at 7, 21, 62, 185, 556, 1667 and 5000 µg/mL. Test 1b is assumed not to contain S9, although this was not stated clearly in the study.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1a	250*, 500*, 1000* and 2000*	4 hrs	24 hrs
Test 1b×	250*, 500*, 1000* and 2000*	24 hrs	24 hrs
Present			
Test 1a	250*, 500*, 1000* and 2000*	4 hrs	24 hrs
Test 2 (confirmation test)	250*, 500*, 1000* and 2000*	4 hrs	30 hrs

*Cultures selected for metaphase analysis.
×Presence/absence of S9 not clearly specified

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1a	>5000	>2000	≥1000	Negative
Test 1b		>2000	≥1000	Negative
Present				
Test 1a	>5000	>2000	≥1000	Negative
Test 2 (confirmation)		>2000	≥1000	Negative

Remarks - Results	Precipitation was observed at ≥556 µg/mL for the dose determination test. The positive controls performed as expected, confirming the validity of the test system.
CONCLUSION	The notified chemical was not clastogenic to Chinese hamster lung cells treated in vitro under the conditions of the test.
TEST FACILITY	Nippon (2000)

B.11. Migration Study

TEST SUBSTANCE	Notified chemical and its oxidation and hydrolysis products
METHOD	Determination of the Potential Migration from Polyolefins into Food-Stimulating Solvents – analytical methodology supplied by Sumitomo Chemical Co. Ltd. (Japan) and modified as deemed necessary by Covance
Remarks - Method	The test articles used in the migration study were the following: LDPE containing 0.1% of the notified chemical, PP containing 0.2% of the notified chemical, PP containing 0.1% of the notified chemical, and HDPE containing 0.1% of the notified chemical. The control test articles consisted of LDPE, PP and HDPE without the notified chemical. Analytical standards for the notified chemical and its oxidation and hydrolysis products were provided by Sumitomo. The limit of detection was 0.1µg/in^2. The food-simulating solvents consisted of 95% ethanol for fatty foods, 50% ethanol for high alcohol foods and 10% ethanol for aqueous and acidic foods and low alcohol beverages. The extracts were treated at up to 100°C for up to 240 hrs and analysed for the presence of the notified chemical and

its oxidation and hydrolysis products.
Validation was conducted by spiking the 240-hr extracts with a known concentration of the analyte. The percentage recovery ranged between 86-119%.

CONCENTRATION OF THE NOTIFIED CHEMICAL AND ITS BY-PRODUCTS IN FOOD-SIMULATING SOLVENTS

	Food Contact Material (containing 0.1% notified chemical except values indicated with)*	*Mean Concentration (µg/in^2) at 2 hrs and at 240 hrsextraction (2 hrs / 240 hrs)*		
		In 10% Ethanol – simulating aqueous/acidic foods & low-alcohol beverages	*In 50% Ethanol – simulating high-alcoholic foods*	*In 95% Ethanol – simulating fatty foods*
Notified Chemical	LDPE	<0.10 / <0.10		
	PP		0.68* / 0.50*	39.7 / 36.2
	HDPE		0.68 / 0.26	0.56 / 2.37
Oxidation Product	LDPE	<0.10 / <0.10		
	PP		0.11* / 0.26*	7.51 / 6.67
	HDPE		0.52 / 0.90	0.20 / 0.51
Hydrolysis Product	LDPE	<0.10 / <0.10		
	PP		<0.10* / 0.69*	2.79 / 4.64
	HDPE		2.22 / 7.34	1.43 / 3.86

*The notified chemical was present at 0.2% in the food contact material used (PP)

CONCLUSION

The notified chemical and its known degradation products migrate from polyolefin materials in the presence of food simulating solvents.

TEST FACILITY

Covance (2000)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	Measure of biochemical oxygen demand (BOD). The test substance was analysed by HPLC.
Remarks - Method	The test was conducted in Japan according to the "Biodegradation test of chemical substances by microorganisms etc." stipulated in the Order Prescribing the Item of Test Relating to the New Chemical Substances, 1974. The Test guideline used was equivalent to OECD TG 301 C, 1992. It was not reported in the study if the toxicity control was conducted.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
28	9	7	62

Remarks - Results	All validity criteria for the test were satisfied. The reference compound reached the 60% pass level by day 7 indicating the suitability of the inoculum. The test substance attained 9% degradation after 28 days and therefore is not considered to be readily biodegradable under the conditions of OECD Guideline 301C.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	KOEI (1998)

C.1.2. Bioaccumulation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 305C Bioconcentration: Flow-through Test - Continuous flow.
Species	Carp (*Cyprinus carpio*)
Exposure Period	8 weeks
Auxiliary Solvent	None reported
Concentration Range	Level 1: 1 mg/L Level 2: 0.1mg/L
Analytical Monitoring	HPLC
Remarks - Method	The test was conducted in Japan according to the "Method for Testing the Degree of Accumulation of Chemical Substances in Fish Body" Stipulated in the Testing Methods for New Chemical Substances, 1974. No significant deviations from the test guidelines were reported. The Test guideline used was equivalent to OECD TG 305C. The test was conducted according to good laboratory practice (GLP).
RESULTS	
Bioconcentration Factor	Level 1: ≤ 2.9 Level 2: ≤ 31
LC50 (48 h)	≥ 1000 mg/L
Remarks - Results	All validity criteria for the test were satisfied. BCFs of the test substance were found to have reached equilibrium after 8 weeks. Examination of

depuration was not reported, however, it is not required as the observed BCF values were low. No significant differences among the BCFs were observed at the two levels.

CONCLUSION The notified chemical is not expected to bioaccumulate in fish.

TEST FACILITY Kurume (1998)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test - Semi-static.

Species	Zebra fish (*Brachydanio rerio*)
Exposure Period	96 hour
Auxiliary Solvent	N, N-dimethylformamide (DMF)
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	The test was conducted according to the guidelines above using good laboratory practice (GLP). No significant deviations from the test guidelines were reported. Due to the very low water solubility of the test substance, an undiluted filtrate of a supersaturated dispersion with the maximum concentration of dissolved test substance (Water Accommodated Fractions, WAFs) at the loading rate of 10 mg/L was used as the only test concentration. The loading rate of 10 mg/L of the test item is above its solubility limit. DMF was used as a carrier solvent. The test item dispersion was stirred over 96 hours to dissolve a maximum amount of the test item in test solution. After stirring, the dispersion was filtered through a membrane filter (0.45 µm), and the undiluted filtrate was used as test solution. In the pre-experiment, the practically maximum achievable concentration of the test item was in DMF was about 100 mg/L (i.e. the maximum loading rate in the test solution was 10 mg/L with 100 µL/L of DMF). The test solutions were renewed at every 24 hours during the 96 hour exposure.

RESULTS

Nominal Concentration (mg/L)	*Number of Fish*	*Mortality (96 h)*
Control	7	0
Solvent control	7	0
10	7	0

LL50	>10 mg/L at 96 hours
NOEL	10 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. The test solution was clear throughout the test solution renewal periods. All biological results are related to the loading rate of 10mg/L of the test item. The NOEL was determined directly from the raw data. The LL50 could not be quantified due to the absence of a toxic effect of the test item at that test concentration. At the start of the test solution renewal periods, the measured concentrations of the test item were in the range of 2.3 µg/L to <LOD (limit of detection: 0.2 µg/L). At the end of the test solution renewal periods, the measured concentrations of the test item were in the range of 0.79 µg/L to <LOD.

CONCLUSION The notified chemical is not harmful to fish up to its solubility limit.

TEST FACILITY RCC (2003a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static
Species *Daphnia magna*
Exposure Period 48 hours
Auxiliary Solvent N, N-dimethylformamide (DMF)
Water Hardness 250 mg $CaCO_3$/L
Analytical Monitoring HPLC
Remarks - Method The test was conducted according to the guidelines above using good laboratory practice (GLP). No significant deviations from the test guidelines were reported. Due to the very low water solubility of the test substance, an undiluted filtrate of a supersaturated dispersion with the maximum concentration of dissolved test substance (Water Accommodated Fractions, WAFs) at the loading rate of 10 mg/L was used as the only test concentration. The loading rate of 10 mg/L of the test item is above its solubility limit. DMF was used as a carrier solvent. The test item dispersion was stirred over 96 hours to dissolve a maximum amount of the test item in test solution. After stirring, the dispersion was filtered through a membrane filter (0.45 µm), and the undiluted filtrate was used as test solution. In the pre-experiment, the practically maximum achievable concentration of the test item was in DMF was about 100 mg/L (i.e. the maximum loading rate in the test solution was 10 mg/L with 100 µL/L of DMF).

RESULTS

Concentration		*Number of D. magna*	*Number Immobilised (48 h)*
Nominal	*Mean measured*		
Control	-	20	0
Solvent control	-	20	0
10 mg/L	1.9 µg/L	20	0

LL50 >10 mg/L at 48 hours
NOEL 10 mg/L at 48 hours.
Remarks - Results All validity criteria for the test were satisfied. The test solution was clear throughout the whole test duration. All biological results are related to the loading rate of 10mg/L of the test item. The NOEL was determined directly from the raw data. The EL50 could not be quantified due to the absence of a toxic effect of the test item at the tested concentration. The measured concentration of the test item in the sample at the start and the end of the test was 1.9 and 1.8 µg/L, respectively. The test item was stable during the test period of 48 hours under the test conditions. The mean measured concentration of the test item (measurements of the test solutions at the start and end of the test) was 1.9 µg/L.

CONCLUSION The notified chemical is not harmful to aquatic invertebrates up to its solubility limit.

TEST FACILITY RCC (2002a)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test- Static.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Dilutions: 1:22, 1:10, 1:4.6, 1:2.2, undiluted filtrate (loading rate of 10 mg/L)
Auxiliary Solvent	N, N-dimethylformamide (DMF)
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. An undiluted filtrate of a supersaturated dispersion with the maximum concentration of dissolved test substance (Water Accommodated Fractions, WAFs) at the loading rate of 10 mg/L was used as the maximum test concentration. The undiluted filtrate (loading rate of 10mg/L) and four diluted samples (stated above at the concentration range) were tested. The loading rate of 10 mg/L of the test item is above its solubility limit. DMF was used as a carrier solvent. The test item dispersion was stirred over 96 hours to dissolve a maximum amount of the test item in test solution. After stirring, the dispersion was filtered through a membrane filter (0.45 µm), and the undiluted filtrate was used as test solution. In the pre-experiment, the practically maximum achievable concentration of the test item in DMF was about 100 mg/L (i.e. the maximum loading rate in the test solution was 10 mg/L with 100 µL/L of DMF).

RESULTS

Biomass (72 h)		*Growth (72 h)*	
E_yL_{50} (mg/L)	NOE_yL (mg/L)	E_rL_{50} (mg/L)	NOE_rL (mg/L)
> 10	10	> 10	> 10

Remarks - Results	All validity criteria for the test were satisfied. The test solution was clear throughout the entire test period. The NOEL was determined directly from the raw data. The EL_r50 could not be quantified due to the absence of a toxic effect of the test item at the tested concentration. At the beginning of the test, the measured concentration of the test item in the samples was 1.1 µg/L. At the end of the test, the concentration of the test item in the samples decreased below the limit of detection of the analytical method (0.2 µg/L).
CONCLUSION	The notified chemical is not harmful to algae up to its solubility limit.
TEST FACILITY	RCC (2003f)

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