File No: LTD/1743

May 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Irganox 2000

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:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1743	BASF Australia Ltd	Irganox 2000	Yes	≤ 1 tonne per annum	Antioxidant/stabiliser for thermoplastic polymers

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is 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. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Acute Toxicity Category 4 (by the inhalation route)	H332 – Harmful if inhaled

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R20: Harmful by inhalation

Human health risk assessment
Provided that the recommended control measures are implemented, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
Based on the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Acute Toxicity Category 4 (by the inhalation route): H332 – Harmful if inhaled

The above should be used for products/mixtures containing the notified polymer, if applicable, based on the concentration of the notified polymer present and the intended use/exposure scenario.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during extrusion and injection moulding processes:
  - Enclosed, automated systems where possible

- Local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified polymer during extrusion and injection moulding processes:
  - Avoid inhalation of vapours

  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.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment, physical 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 polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer 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 importation volume exceeds one tonne per annum notified polymer;
  - the polymer is intended to be used in plastics for food-contact applications;
  - additional information becomes available on the repeat dose toxicity of the notified chemical;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from an antioxidant/stabiliser for thermoplastic polymers, or is likely to change significantly;
  - the amount of polymer being introduced has increased, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer 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 (M)SDS of the products containing the notified polymer provided by the notifier were 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)
BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1,000 Da (1 tonne or less per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, use details, import volume, and identity of recipients.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2010)
China (2013)
Korea (2013)
USA (2014)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Irganox 2000 (notified polymer)

The following marketing names are for the thermoplastic products containing the notified polymer at < 1% concentration.

Injection moulding
Elastollan 1164 D53U
Elastollan 1175 A10 W
Elastollan 1195 A55U
Elastollan 1185 A 10 FHF

Extrusion
Elastollan 1180 A10 U
Elastollan 1185 A 10U
Elastollan 1185 A 10W
Elastollan 1185 A 12WM

MOLECULAR WEIGHT
> 500 Da

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

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Freezing Point	Not determined. Solid at -20 °C	Measured
Boiling Point	308 °C at 101.3 kPa	Measured
Density	1,068 kg/m^3 at 20 °C	Measured
Viscosity (Dynamic)	6,550 mPa.s at 40 °C	Measured
Vapour Pressure	< 1.33 × 10^{-11} kPa at 20 °C	Measured
Water Solubility	< 4 × 10^{-5} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	t½ = 42.2 hours at 50 °C at pH 7 t½ = 152.3 hours at 50 °C at pH 4 t½ = 43.3 hours at 50 °C at pH 9	Measured
Partition Coefficient (n-octanol/water)	log Pow = 3.4 at 25 °C	Measured
Adsorption/Desorption	log K_{oc} = 2.73	Calculated (KOCWIN v2.00; US EPA 2009).
Dissociation Constant	Not determined	The notified polymer contains functionalities with typical pKa of ~9. It is expected to be ionised in the environmental pH range (4 – 9).
Flash Point	Not detected up to boiling point	Measured
Flammability	Not determined	Not expected to be flammable/combustible based on measured flash point
Autoignition Temperature	390 °C	Measured
Explosive Properties	Not explosive	Measured
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

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

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer 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 polymer will be imported as a component of thermoplastic polymer base pellets at a concentration up to 1%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 0.2	< 0.2	< 0.6	< 0.6	1

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The thermoplastic polymer base pellets containing the notified polymer at up to 1% concentration will be packed in heavy duty 25 kg multilayer polyethylene bags and distributed by road to recipient sites where the polymer will be moulded into articles or manufactured into masterbatches. The articles and masterbatches will be distributed to customer sites by road.

USE
The notified polymer will be used as an antioxidant/stabiliser for thermoplastic polymers. The finished plastic articles will not be used for food contact applications.

OPERATION DESCRIPTION

Masterbatch production
The base pellets containing the notified polymer at < 1% concentration will be compounded with other raw materials to form coloured plastic pellets known as masterbatch, an intermediate material for producing plastic articles.

The plant operators will manually weigh out and transfer the base pellets containing the notified polymer into sealed mixers together with other ingredients including concentrated dyes. After mixing, extruder operators will release the mixture from the sealed tubes into extruders where the mixture will be melted and extruded through die holes to form spaghetti-like strings. The strings will pass through cooling water baths into pelletisers and classifiers that will cut the solidified strings into pellets. The resulting pellets will be graded and conveyed to hoppers for storage. Quality control technicians will scoop samples of the masterbatches for testing. Packaging operators will then fill the masterbatches into 25 kg drums for distribution.

Manufacture of plastic articles
In an extrusion process, the base pellets containing the notified polymer will be manually transferred into dispensers and extruded using similar processes as in manufacturing masterbatches (see above) to form colourless plastic articles. To form coloured articles, the base pellets will be mixed with the masterbatch before being manually transferred into the extruders. The plastic articles produced will be trimmed as required.

In an injection moulding process, the base pellets and masterbatch will be either vacuum-transferred or manually tipped into the feeding hopper on the injection-moulding machine. The mixed pellets will then be fed into the barrel of the machine by gravity. Once heated, the melted pellets will be moulded to form the shape of the articles and then cooled within the closed system. The resulting articles will be ejected into a suitable receptacle.

In both extrusion and injection moulding, the produced plastic articles will contain < 1% notified polymer.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration*	*Exposure Frequency*
Process worker	8 hours/day	30 – 50 days/year
Warehouse workers	8 hours/year	Various

EXPOSURE DETAILS
When the base pellets or masterbatches are in solid phase, the notified polymer will be encapsulated within the polymer matrix and will not be available for exposure.

Vapours of the notified polymer may be generated when the pellets or masterbatches containing the notified polymer at < 1% concentration are melted during extrusion and injection moulding processes. The notifier stated that the moulding machines are enclosed and automated, and the process areas are fitted with local exhaust ventilation to capture fugitive vapours from the heated plastic pellets. These engineering controls would minimise the potential for inhalation exposure to the notified polymer.

6.1.2. Public Exposure
Members of the public may come into contact with plastic articles containing the notified polymer at < 1% concentration; however, significant exposure as a result of casual contact during handling is not expected as the notified polymer is expected to be incorporated in the plastic matrix. However as the notified polymer will not be chemically bound, it may be released from products in low levels over time.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer 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 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	1.03 < LC50 < 5.01 mg/L/4 hour; harmful
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL not established
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution

No information on the toxicokinetics, metabolism and distribution for the notified polymer was provided. Based on the relatively high molecular weight (> 500 Da) and low water solubility (< 4×10^{-5} g/L at 20°C), dermal absorption is expected to be limited. However, given the signs of toxicity in the acute inhalation toxicity study and repeated dose oral toxicity study the notified polymer is absorbed via the oral and inhalation routes.

Acute toxicity

As no mortality was recorded in the acute oral and dermal toxicity studies, the notified polymer was considered to be of low toxicity via these routes in rat. However, oral application of the notified polymer to female rats at a dose level of 2,000 mg/kg bw resulted in treatment-related clinical signs of toxicity including reduced spontaneous activity, apathy, piloerection, half eyelid-closure, ataxy, bloody snout and sunken flanks.

An acute inhalation toxicity study conducted on the notified polymer showed that the polymer is harmful via inhalation. Eight of the ten test animals exposed at 5.01 mg/L for 4 hours died within one day. Gross necropsy of the animals that died before the end of the 14-day observation period revealed discoloration of the lungs and/or livers, oedema of the lungs or rigor mortis. No mortalities were observed in animals exposed at 1.03 mg/L for 4 hours. No gross abnormalities at necroscopy were observed in any of the animals that survived the exposure periods.

Irritation and sensitisation

Base on the studies provided for the notified polymer, the polymer is considered to be slightly irritating to the eye and skin. Very slight and recoverable skin erythema was noted in one of the three animals tested for dermal irritation. Slight and recoverable conjunctival redness was also observed in all three animals tested for eye irritation.

A LLNA conducted on the notified polymer did not reveal evidence of skin sensitisation.

Repeated dose toxicity

In a 28-day repeated dose oral toxicity study conducted on the notified polymer, 3 female rats treated at the dose level of 1,000 mg/kg bw/day died. Clinical signs including kyphosis, ataxia, tiptoeing and piloerection were noted for all rats treated at this level during the first 2 weeks of study. Severe body weight loss was also recorded in females in the group. The dose level was then reduced from 500 mg/kg bw/day and the observed symptoms alleviated. For the male rats, the mean body weight gain was reduced when treated at 1,000/500 and 250 mg/kg bw/day.

At terminal sacrifice, histopathological findings considered to be test substance-related were seen in the eye, liver and thyroid gland. Dose-dependent increase of the liver and thyroid weights was noted in the study. In the eye, a mostly minimal diffuse bilateral retinal atrophy with thinning of the outer nuclear layer was observed in animals treated at 1000/500 and 250 mg/kg bw/day. It was not reversible after 14 days of recovery. In the liver, a centrilobular hepatocellular hypertrophy was seen in all rats in all treated groups. This was accompanied by multifocal minimal anisokaryosis of hepatocytes in one of the males treated at 1,000/500 mg/kg bw/day. Hepatocellular hypertrophy was partially, and anisokaryosis was fully reversible after 14 days. In the thyroid gland, a diffuse follicular cell hypertrophy was noted in all rats in all treated groups and was considered to be related to the observed liver change. It was partially reversible.

In male rats, minimal multifocal epithelial degeneration of the seminiferous tubules in the testis, accompanied by intraluminal cellular debris in the epididymis, occurred in 2 of animals treated at 1000/500 mg/kg bw/day. It was also seen in some of the males treated at this level after 14 days recovery. Significant decrease of testes and epididymides weights was noted for the animals in the group.

As test substance-related effects were found at all dose levels, a NOEL could not be established for the study.

Mutagenicity/Genotoxicity
A bacterial reverse mutation test on the notified polymer did not reveal evidence of mutagenicity for the polymer.

Health hazard classification
Based on the available information, the notified polymer is 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. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Acute Toxicity Category 4 (by the inhalation route)	H332 – Harmful if inhaled

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R20: Harmful by inhalation

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer is harmful if inhaled. Based on limited data, the potential for systemic toxicity from repeated exposure cannot be ruled out. However, when the base pellets or masterbatches containing the notified polymer at < 1% concentration are in solid phase, the notified polymer will be encapsulated within the plastic matrix and will not be available for exposure. Therefore, the risk of the notified polymer to workers handling the solid form of the pellets or masterbatches containing the notified polymer is not considered to be unreasonable.

As vapours of the notified polymer may be generated when the pellets or masterbatches containing the notified polymer are heated to melt during extrusion and injection moulding processes, potential for inhalation exposure of the notified polymer for workers cannot be ruled out. The notifier stated that the moulding machines are enclosed and automated, and the process areas are fitted with local exhaust ventilation to capture fugitive vapours from the heated plastic pellets. Therefore, under the proposed use scenario, provided the engineering controls are in place to limit inhalation exposure, the risk of the notified polymer to the processing workers is not considered to be unreasonable.

6.3.2. Public Health
Members of the public may come into dermal contact with plastic articles containing the notified polymer at < 1% concentration. However, as the notified polymer will be encapsulated in the plastic matrix with relatively low concentration, significant exposure as a result of casual contact with the plastic articles is not expected. The notifier stated in the submission that the finished plastic articles containing the notified polymer will not be used for food contact applications. Therefore, when used in the proposed manner, the risk of the notified polymer to the public health is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported as a component of formulated thermoplastic polyurethane (TPU) pellets. The manufacture of plastic articles involves a highly automated process and moulding machines are fully enclosed in a bund. Any spillage of the notified polymer will be contained within the bunded areas. Any spilled

or rejected TPU during the manufacture of moulded articles is expected to be reused. The waste from the moulding process is expected to be < 20 kg per annum and is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
Majority of the notified polymer will be incorporated into moulded or extruded plastic articles. These are expected to be disposed of to landfill at the end of their useful life.

RELEASE OF CHEMICAL FROM DISPOSAL
Up to 0.2% (up to 10 kg) of the imported TPU pellets are expected to be released as waste from import containers and spills during the production of master-batch and moulded or extruded plastic articles which are expected to be disposed of to landfill. Plastic scrap containing up to 2 kg of the notified polymer may be disposed of to landfill.

7.1.2. Environmental Fate
No environmental fate data were submitted. Due to the low water solubility and low molecular weight (< 1,000 Da), the notified polymer may have a potential to bioaccumulate in aquatic organisms. However, this is not considered to be a concern given the low release to the aquatic environment expected based on the proposed use pattern. Most of the notified polymer will be incorporated into moulded articles which are expected to be disposed of to landfill at the end of their useful lives. A small amount of the notified polymer is expected to be sent to landfill as collected releases from TPU articles made from moulding and extrusion manufacturing facilities. In landfill, the notified polymer will undergo slow degradation processes via biotic and abiotic pathways eventually forming water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)
No significant concentrations of the notified polymer are expected in the aquatic environment based on proposed use pattern of the notified polymer. The Predicted Environmental Concentration for the notified polymer has therefore not been calculated.

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

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity (48 hours)	LL50 > 100 mg/L[a]	Not harmful
Daphnia Toxicity (21 days)	NOEL = 25 µg/L[a]	Not harmful

[a]All concentrations refer to nominal WAF (Water Accommodated Fraction) loading levels.

The ecotoxicological data indicates that the notified polymer has no toxicological effects at the limit of its water solubility. Therefore, the notified polymer is not expected to be harmful at the limit of its water solubility, and is not be formally classified under the Globally Harmonised System of Classification of Chemicals (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration
The notified polymer is not expected to be harmful to aquatic organism up to the limit of its water solubility. Hence, a Predicted No- Effect Concentration (PNEC) was not calculated.

7.3. Environmental Risk Assessment
Based on the reported use pattern and the expected low toxicity to the aquatic organisms, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Freezing Point Not determined. Solid at -20 °C

Method OECD TG 102 Melting Point/Melting Range.
EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks The test substance (96.5% purity) was a liquid at 20 °C. No typical phase transition was observed between 20 °C and -40 °C. The test substance was solid at -20 °C. A freezing point according to the criteria could not be determined.
Test Facility IBACON (2010a)

Boiling Point 308 °C at 101.3 kPa

Method OECD TG 103 Boiling Point.
EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks The boiling point was determined by visual judgement using capillary method. The samples were heated at a rate of 1 °C/min following a quick heating up to 288 °C. The purity of the test substance was 96.5%.
Test Facility IBACON (2009a)

Density 1,068 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks Gas comparison pycnometer method was used.
Test Facility IBACON (2009b)

Viscosity 6,550 mPa.s at 40 °C (Dynamic)

Method Viscosity meter Haake VT 500 (Rotative element MV3)
Remarks No test details were provided.
Results

Temperature (°C)	25	35	40	50	60	80	100	120	145
Viscosity (mPa.s)	78,000	12,000	6,550	2,000	700	170	65	35	19

Test Facility Ciba (2008)

Vapour Pressure < 1.33 × 10^{-11} kPa at 20 °C

Method OECD TG 104 Vapour Pressure.
EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks The vapour pressure was determined using the isothermal thermogravimetric effusion method. The purity of the test substance was 96.5%.
Test Facility NOTOX (2009)

Water Solubility < 4 × 10^{-5} g/L at 20 °C

Method OECD TG 105 Water Solubility.
EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks Column Elution Method. The quantification was achieved by measuring the UV signal of the test substance after HPLC separation.
Test Facility IBACON(2009d)

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH.
EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ hours*
4	50	42.2

pH	*T (°C)*	*$t_{½}$ hours*
7	50	152.3
9	50	43.3

Remarks The overall hydrolysis of the test substance was investigated using the total peak area. As per the sponsor's demand, further investigations were not conducted on the hydrolysis of the test substance at different temperatures. Therefore, the hydrolysis constant and half lives at 25°C were not calculated.
Test Facility CURRENTA (2009)

Partition Coefficient (n-octanol/water) log Pow = 3.4.at 25 °C

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks HPLC Method
Test Facility IBACON (2010b)

Flash Point Not detected up to boiling point

Method EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks No flash point was detected up to 308 °C. At 308 °C, the test substance was boiling.
Test Facility IBACON (2009c)

Autoignition Temperature 390 °C

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks The lowest autoignition temperature detected in the preliminary test was 412 °C. In three principal tests, the lowest autoignition temperatures detected were 397, 397 and 392 °C respectively. The autoignition temperature of the test substance was determined to be 390 °C.
Test Facility Siemens (2009a)

Explosive Properties Not explosive

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks The thermal stability test showed an endothermic effect in the temperature range of 270 – 380 °C directly followed by an exothermal decomposition in the temperature range of 380 – 495 °C with energy of 238 J/g or 456 J/g respectively. The heat of decomposition was detected below 500 J/g therefore a test on explosion was not necessary.
Test Facility Siemens (2009b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Council Regulation No 440/2008 B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/WISTAR RjHan:WI(SPF)
Vehicle	Cottonseed oil
Remarks - Method	No significant deviation of protocol was noted.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	3 F	2,000	0/3
2	3 F	2,000	0/3

LD50	> 2,000 mg/kg bw
Signs of Toxicity	Clinical signs of toxicity observed in all animals included reduced spontaneous activity, apathy, piloerection, half eyelid-closure, ataxy, bloody snout and sunken flanks were observed. These signs persisted for 4 days in one rat and for 1 day in the other five animals.
Effects in Organs	No treatment-related effects were recorded.
Remarks - Results	Single oral application of the notified polymer to six female rats at a dose level of 2,000 mg/kg bw resulted in treatment-related clinical signs of toxicity but no mortalities.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	BSL (2009a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Council Regulation No 440/2008 B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/WISTAR RjHan:WI
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	No significant deviations of the protocol were noted. Exposure period was 24 hours and residual test substance was removed using warm water.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5 M	2,000	0/5
2	5 F	2,000	0/5

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	No treatment-related effects were observed.
Signs of Toxicity - Systemic	No treatment-related effects were observed.
Effects in Organs	No treatment-related effects were observed.
Remarks - Results	

CONCLUSION	The notified polymer is of low toxicity via the dermal route.

TEST FACILITY BSL (2009b)

B.3. Acute toxicity – inhalation

TEST SUBSTANCE Notified polymer

METHOD OECD TG 403 Acute Inhalation Toxicity.
EC Council Regulation No 440/2008, 93/21/EEC B.2 Acute Toxicity (Inhalation).

Species/Strain	Rat/Sprague-Dawley derived, albino
Vehicle	Corn oil
Method of Exposure	Oro-nasal exposure.
Exposure Period	4 hours
Physical Form	Liquid aerosol.
Particle Size	MMAD = 2.1 μm for 1.03 mg/L dose group MMDA = 2.45 μm for 5.01 mg/L dose group
Remarks - Method	The test substance was heated to 50 °C in a water bath, diluted to a 50% w/w solution in corn oil, then heated again to 50 °C and allowed to cool to 35 °C prior to aerosolisation.

RESULTS

Group	*Number and Sex of Animals*	*Concentration <mg/L>*		*Mortality*
		Nominal	*Actual*	
1	10 (5 M/5 F)	10.91	1.03	0/10
2	10 (5 M/5 F)	410.64	5.01	8/10

LC50	1.03 < LC50 < 5.01 mg/L/4 hour
Signs of Toxicity	In 1.03 mg/L dose group, 2 males and 2 females appeared hypoactive but recovered by Day 2. In 5.01 mg/L dose group, 8 of 10 test animals (4 males and 4 females) died within one day after the exposure. All test rats appeared hypoactive and 3 exhibited irregular respiration immediately following the exposure. A prone posture was evident in six of the rats on Day 1. Two surviving animals recovered from the toxicity effects by Day 5.
Effects in Organs	Gross necropsy of the animals that died before the end of the study period revealed discoloration of the lungs and/or livers, oedema of the lungs or rigor mortis.
Remarks - Results	No gross abnormalities were noted for the animals that survived the exposure at the conclusion of the study on Day 14.

CONCLUSION The notified polymer is harmful via inhalation.

TEST FACILITY Eurofins (2009)

B.4. Irritation – skin

TEST SUBSTANCE Notified polymer

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Council Regulation No 440/2008 B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (Females)
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No signification deviation of protocol was noted. 0.5 g of the test

substance was administered on each treatment site and the exposure period was 4 hours.

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	0.33	0	1	< 72 h	0
Oedema	0	0	0	0	N/A	0

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

Remarks - Results: Very slight erythema was observed in one of the three treated animals at the 48-hour observation period only. All signs of irritation were resolved at the 72-hour observation period.

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

TEST FACILITY: BSL (2009c)

B.5. Irritation – eye

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation).

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 (Females)
Observation Period: 72 hours
Remarks - Method: No significant deviation of protocol was noted. 0.1 ml of the test substance was administered for each treatment and

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	0	0.33	1	< 48 h	0
Conjunctiva: chemosis	0	0	0	0	N/A	0
Conjunctiva: discharge	0	0	0	0	N/A	0
Corneal opacity	0	0	0	0	N/A	0
Iridial inflammation	0	0	0	0	N/A	0

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

Remarks - Results: Slight conjunctival redness in all three treated animals was observed at 1 hour after the exposure. Two of them recovered within 24 hours and one recovered in 48 hours.

CONCLUSION: The notified polymer is slightly irritating to the eye.

TEST FACILITY: BSL (2009d)

B.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)

Species/Strain: Mouse/CBA/J Rj

Vehicle	Acetone/olive oil
Remarks - Method	No significant deviation of protocol was noted. 3 mice (2 for treatment and 1 for negative control) were tested in preliminary test and 20 mice (5 for each group) were tested in the main test. 1% of *p*-phenylenediamine in the vehicle was used as positive control to confirm the reliability of the system and was conducted separately from this study (historical data).

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	352.8	1.0
12.5	148.9	0.4
25	185.0	0.5
1.0	335.5	1.0
Positive Control		
1% *p*-phenylenediamine	3585.6	9.6

Remarks - Results	The means of the lymph node weights per group showed no significant difference compared to the negative control.

CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.
TEST FACILITY	BSL (2009e)

B.7. Repeat dose toxicity

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/HsdRccHan: WIST
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Cotton seed oil
Remarks - Method	No significant deviation of protocol was noted. Due to signs of severe toxicity and mortality in the rats, the high dose level was reduced to 500 mg/kg bw/day on Day 14 for females and on Day 15 for males.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw/day)*	*Mortality*
Control	10 (5 M/5 F)	0	0/10
Low dose	10 (5 M/5 F)	50	0/10
Mid dose	10 (5 M/5 F)	250	0/10
High dose	10 (5 M/5 F)	1,000 (Day 1 to Day 13/14) → 500 (Day 14/15 to Day 28)	3/10
Control recovery	10 (5 M/5 F)	0	0/10
High dose recovery	10 (5 M/5 F)	1,000 (Day 1 to Day 13/14) → 500 (Day 14/15 to Day 28)	0/10

Mortality and Time to Death

Treatment led to premature mortality in 3 females at the dose level of 1,000 mg/kg bw/day. Two of them were found dead on Day 4 and Day 13, and one was euthanized on Day 17 due to severe toxicity effects.

Clinical Observations

Kyphosis, ataxia, tiptoeing and piloerection were noted for all rats treated at 1,000 mg/kg bw/day during the first 2 weeks of study. Severe body weight loss was also recorded in 4/5 females in the high dose group. After the dose level was reduced from 1,000 to 500 mg/kg bw/day, the observed symptoms alleviated. Reduced food consumption was also observed in the first 2 weeks for the high dose group.

For the male rats, the mean body weight gain was reduced when treated at 1,000/500 and 250 mg/kg bw/day.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

In the haematology assessment, no severe deviations were found. Toxicological relevance for single deviations could not be concluded and were considered to be incidental.

In determination of clinical chemical parameters, statistically significant differences were found between some dose groups and the corresponding control groups. As none of the mean and individual values showed marked pathological deviations, these differences in general were not considered to be of toxicological relevance.

In the determination of the urine-values, no relevant differences between test and control groups were found.

Effects in Organs

At terminal sacrifice, histopathological findings considered to be test substance-related were seen in the eye, liver and thyroid gland.

In the eye, a mostly minimal diffuse bilateral retinal atrophy with thinning of the outer nuclear layer was observed in animals treated at 1000/500 and 250 mg/kg bw/day. It was not reversible after the recovery period.

A centrilobular hepatocellular hypertrophy of the liver was seen in all rats in all treated groups and was accompanied by multifocal minimal anisokaryosis of hepatocytes in one of the males treated at 1,000/500 mg/kg bw/day. Hepatocellular hypertrophy was partially, and anisokaryosis was fully reversible after the recovery period. Hepatocellular hypertrophy of the liver is commonly seen as an adaptive response to a xenobiotic. Anisokaryosis was considered to be associated to the liver cell hypertrophy.

A diffuse follicular cell hypertrophy of the thyroid gland was noted in all rats in all treated groups which is generally considered to be an adaptive change in the rat related to the observed liver changes. It was partially reversible during the recovery period.

In the testis, minimal multifocal epithelial degeneration of the seminiferous tubules, accompanied by intraluminal cellular debris in the epididymis, occurred in 2 of the males treated at 1000/500 mg/kg bw/day. It was also seen in some of the males treated at this level after the recovery period. Significant decrease of testes and epididymides weights was noted for the animals in the group.

Upon the assessment of organ weights, the most relevant finding was the dose-dependent increase of the liver and thyroid weights.

Remarks – Results

Test substance-related effects were found at all dose levels including the low dose level of 50 mg/kg bw/day.

CONCLUSION

The No Observed Effect Level (NOEL) could not be established as test substance-related effects were found at all dose levels.

TEST FACILITY BSL (2010)

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified polymer

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.

	Plate incorporation procedure and Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98 and TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Phenobarbital and β-naphthoflavone induced rat liver microsomal fraction (S9)
Concentration Range in Main Test	a) With metabolic activation: 31.6 – 5,000 µg/plate b) Without metabolic activation: 31.6 – 5,000 µg/plate
Vehicle	DMSO
Remarks - Method	Main Test 1 and Test 2 used plate incorporation procedure and pre incubation procedure, respectively. Positive controls: • 10 µg/plate sodium azide (NaN_3) for TA100 and TA1535 • 10 µg/plate 4-nitro-o-phenylene-diamine (4-NOPD) for TA98 • 40 µg/plate 4-nitro-o-phenylene-diamine (4-NOPD) for TA1537 • 1 µL/plate methyl methane sulfonate (MMS) for WP2uvrA

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 5,000	> 5,000	Negative
Test 2	-	> 5,000	> 5,000	Negative
Present				
Test 1	> 5,000	> 5,000	> 5,000	Negative
Test 2	-	> 5,000	> 5,000	Negative

Remarks - Results	No precipitation and cytotoxicity of the test substance were observed up to the highest concentration tested (5,000 µg/plate) in both the absence and the presence of the metabolic activation. The positive controls produced distinct increase of revertants indicative of effectiveness of the assay.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BSL (2009f)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	214.18 mg $CaCO_3$/L
Analytical Monitoring	HPLC-MS/MS
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. Due to the limited water solubility of the test substance, a water accommodated fraction (WAF) was used in the test. Test substance (100 and 10 mg) was transferred to 1 litre beakers. Test medium (1 L) was added to each of the beakers and the mixture was stirred for 96 hours. After stirring the mixture was filtered through a 0.45 µm filter. The test solution of 1mg/L was prepared by dilution of the filtered 10 mg/L solution.

RESULTS

Nominal Concentration mg/L (WAF)	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
Control	20	0	0
1	20	0	0
10	20	0	0
100	20	0	0

LLC50	> 100 mg/L at 48 hours (WAF)
NOEL	100 mg/L at 48 hours (WAF)
Remarks - Results	All validity criteria for the test were satisfied. The test solutions were clear and colourless with no visible undissolved test substance. The notified polymer is considered, based on the test result, not harmful to aquatic invertebrates up to its limit of water solubility.
CONCLUSION	The notified polymer is not harmful to aquatic invertebrates up to its limit of water solubility.
TEST FACILITY	Eurofins (2009)

C.2.2. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OPPTS 850.1300 Daphnid Chronic Toxicity Test – Semi Static.
Species	*Daphnia magna*
Exposure Period	21 d
Auxiliary Solvent	N,N-Dimethylformamide (DMF)
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC-MS/MS
Remarks – Method	Due to low solubility of the test substance in test water, the organic solvent DMF was used to dose the test substance. A concentrated nominal solution (5,000 mg/L) was prepared by dissolving 200 mg of the test substance in

40 mL of DMF. Nominal concentrations of 1.6, 3.1, 6.3, 12.5 and 25 µg/L were prepared from this stock solution. The highest test concentration of 25 µg/L was slightly above the water solubility limit of the test substance which was determined to be approximately 15 µg/L.

Nominal loading tested, cumulative mean number of offspring released, number of offspring released per female daphnid (*Daphnia magna*), mean length and standard deviations and survival of parental daphnids.

Test Day 21	*Control*	*Solvent*	*Nominal loading Rate (mg/L)*				
			1.60	*3.1*	*6.3*	*12.5*	*25*
Total no. of offspring released by survived daphnid	965	1080	927	898	744	885	879
Total no. of offspring released per survived daphnid	107	108	92.7	89.8	93	98.3	87.98
Mean length (standard deviation) of survival parent daphnids (mm)	4.184 (0.06)	4.15 (0.15)	4.05 (0.1)	4.05 (0.08)	4.03 (0.09)	4.05 (0.17)	3.98 (0.14)
No. of adult daphnids immobilised	1	01	0	0	2	1	0
% Survival	90	100	100	100	80	90	100

21 day EL 50 (Immobilization) > 25 µg/L (WAF)
21 day EL 50 (Reproduction) > 25 µg/L (WAF)
21 day NOEL = 25 µg/L (WAF)

Remarks – Results

The survival of the test animals at the end of the test was in the range of 80 to 100% in the controls. This was observed at all test concentrations including the highest test concentration of 11 µg/L (nominal 25 µg/L). Thus, the survival of *Daphnia magna* was not affected by the test substance up to and including the highest test concentration.

The first young offspring released from their parent animals were recorded in the control, solvent control and at all test concentrations at day 8. Thus, the time of first brood was not affected by the test substance up to and including the highest test concentration.

The 21 day EL50s for immobilization and reproduction were determined to be > 11 µg/L as the mean measured concentration (nominal concentration 25 µg/L WAF). The NOEL was determined to be = 11 µg/L as a mean measured concentration (nominal concentration25 µg/L WAF). All the endpoints were determined by the study author and are considered acceptable. Since no effect was observed at the top nominal concentration of 25 µg/L which is above the water solubility, the notified polymer is considered not harmful to *Daphnia* up to the limit of water solubility.

CONCLUSION

The notified polymer is considered not harmful to daphnids on a chronic basis.

TEST FACILITY

Harlan (2011)

BIBLIOGRAPHY

BSL (2009a) Acute Oral Toxicity Acute Toxic Class Method with TKA 40385 (IRGANOX 2000) Final Report (Project No.: 084411, February, 2009) Planegg, Germany, BSL Bioservice Scientific Laboratories GmbH (Unpublished report submitted by the notifier).

BSL (2009b) Acute Dermal Toxicity (Limit Test) with TKA 40385 (IRGANOX 2000) Report (Project No.: 084409, February, 2009) Planegg, Germany, BSL Bioservice Scientific Laboratories GmbH (Unpublished report submitted by the notifier).

BSL (2009c) Acute Dermal Irritation/Corrosion with TKA 40385 (IRGANOX 2000) Final Report (Project No.: 084413, February, 2009) Planegg, Germany, BSL Bioservice Scientific Laboratories GmbH (Unpublished report submitted by the notifier).

BSL (2009d) Acute Eye Irritation/Corrosion with TKA 40385 (IRGANOX 2000) Final Report (Project No.: 084412, February, 2009) Planegg, Germany, BSL Bioservice Scientific Laboratories GmbH (Unpublished report submitted by the notifier).

BSL (2009e) Test of Sensitisation (Local Lymph Node Assay – LLNA) with TKA 40385 (IRGANOX 2000) Final Report (Project No.: 084414, February, 2009) Planegg, Germany, BSL Bioservice Scientific Laboratories GmbH (Unpublished report submitted by the notifier).

BSL (2009f) Reverse Mutation Assay Using Bacteria (*Salmonella typhimurium* and *Escherichia coli*) with TKA 40385 (IRGANOX 2000) Report (Project No.: 084404, February, 2009) Planegg, Germany, BSL Bioservice Scientific Laboratories GmbH (Unpublished report submitted by the notifier).

BSL (2010) 28-Day Repeated Dose Oral Toxicity Study with 14-Day Recovery Period in Rats with TKA 40385 (IRGANOX 2000) Report (Project No.: 084407, February, 2010) Planegg, Germany, BSL Bioservice Scientific Laboratories GmbH (Unpublished report submitted by the notifier).

Ciba (2008) Irganox 2000 Basic Data for Product Manager (Project No.: PA.WK 05 1468, January, 2008). Switzerland, Ciba Specialty Chemicals (Unpublished report submitted by the notifier).

CURRENTA (2009) Determination of the Hydrolysis of Irganox 2000 (TKA 40385) (Project 2008/147/01, June 2009). CURRENTA GmbH & Co.OHG, Services Analytik, D-51368 Leverkusen, Federal Republic of Germany (Unpublished report submitted by the notifier).

Eurofins (2009) Acute Inhalation Toxicity Study in Rats (Study Number: 26652, September, 2009). New Jersey, USA, Eurofins, Product Safety Laboratories (Unpublished report submitted by the notifier).

Harlan (2011) Irganox 2000 (TKA 40385): Effect on Survival, Growth and Reproduction of *Daphnia magna* in a Semi-Static Test over Three weeks (Project No.: C53161, April, 2011) Zelgiweg1 4452 Itingen, Switzerland, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

IBACON (2009a) Determination of the Boiling point of TKA 40385 (IRGANOX 2000) (Project 47232181, February, 2009). Rossdorf, Germany, Istitut für Biologische Analytik und Consulting IBACON GmbH (Unpublished report submitted by the notifier).

IBACON (2009b) Determination of the Relative Density of TKA 40385 (IRGANOX 2000) (Project 47233182, March, 2009). Rossdorf, Germany, Istitut für Biologische Analytik und Consulting IBACON GmbH (Unpublished report submitted by the notifier).

IBACON (2009c) Determination of the Flash Point of TKA 40385 (IRGANOX 2000) (Project 47238189, February, 2009). Rossdorf, Germany, Istitut für Biologische Analytik und Consulting IBACON GmbH (Unpublished report submitted by the notifier).

IBACON (2009d) Determination of the Water Solubility of TKA 40385 (IRGANOX 2000) (Project 47238185, June, 2009). Rossdorf, Germany, Istitut für Biologische Analytik und Consulting IBACON GmbH (Unpublished report submitted by the notifier).

IBACON (2010a) Determination of the Melting / Freezing Temperature of TKA 40385 (IRGANOX 2000) (Project 47231180, October, 2010). Rossdorf, Germany, Istitut für Biologische Analytik und Consulting IBACON GmbH (Unpublished report submitted by the notifier).

IBACON (2010b) Determination of the Partition Coefficient (n-Octanol/Water) of TKA 40385 (IRGANOX 2000) by High Performance Liquid Chromatography (HPLC) (Project 47237186, March, 2010). Rossdorf, Germany, Istitut für Biologische Analytik und Consulting IBACON GmbH (Unpublished report submitted by the notifier).

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOTOX (2009) Determination of the Vapour Pressure of Irganox 2000 (TKA 40385) by Isothermal Thermogravimetry (NOTOX Project 490148, February, 2009) 's-Hertogenbosch, the Netherlands, NOTOX B.V. (Unpublished report submitted by the notifier)

Siemens (2009a) Irganox 2000 (TKA 40385) Batch No.: 01940HP8 Auto-Flammability (Determination of the Temperature of Self-Ignition of Volatile Liquids and of Gases) A.15. (Report No.: 20081108.02, March, 2009). Frankfurt am Main, Germany, Siemens AG (Unpublished report submitted by the notifier).

Siemens (2009b) Irganox 2000 (TKA 40385) Batch No.: 01940HP8 Explosive Properties A.14. (OPPTS 830.6316) (Report No.: 20081108.01, March, 2009). Frankfurt am Main, Germany, Siemens AG (Unpublished report submitted by the notifier).

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.

US EPA (2009) Estimations Programs Interface Suite™ for Microsoft® Windows, v 4.00. United States Environmental Protection Agency. Washington, DC, USA. Accessed on 19 March 2014.