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July 2014

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

Efka®-K-201

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/1699	BASF Australia Ltd	Efka®-K-201	ND*	≤ 15 tonnes per annum	Component of inks and coatings

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified polymer cannot be classified 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 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

On the basis of its limited aquatic exposure and assessed use pattern, the notified polymer is not expected 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 engineering controls to minimise occupational exposure to the notified polymer during reformulation:
 - Local exhaust ventilation
 - Enclosed, automated systems where possible
- 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 polymer during reformulation:
 - Avoid skin and eye contact
- 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 polymer during reformulation:
 - Chemical resistant gloves
 - Protective coveralls
 - Safety glasses

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.
- 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 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/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 polymer has a number-average molecular weight of less than 1000 Da;
- or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from component of inks and coatings, 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.

Safety Data Sheet

The SDSs of the notified polymer and product containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the SDSs 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: Synthetic polymer with $M_n \geq 1000$ Da.

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, polymer constituents, residual monomers, impurities, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Efka® PX 4701 (notified polymer)
Dispex Ultra PX 4585 (product containing notified polymer at < 60% concentration)
Efka® PX4310 (product containing notified polymer at < 60% concentration)

OTHER NAME(S)

Efka®-K-201

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: amber to brown viscous liquid.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid at room temperature.
Boiling Point	Not determined	Expected to decompose without boiling
Density	900 – 1,200 kg/m ³ at 20 °C	SDS
Vapour Pressure	< 1.3 × 10 ⁻⁹ kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2013)
Water Solubility	Fully miscible at 21 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional

Partition Coefficient (n-octanol/water)	Not determined	groups. However, significant hydrolysis is not expected in the environment pH range of 4 – 9. The notified polymer has a structure characteristic of a surfactant. Therefore, it may partition to the n-octanol/water phase boundary.
Adsorption/Desorption	Not determined	The notified polymer is expected to be immobile in soil based on its high molecular weight and presence of ionic functionality which will adsorb to soil and sediment.
Dissociation Constant	Not determined	It is expected to be ionised in the environment given the presence of dissociable functional groups.
Flash Point	Not determined	Expected to decompose
Autoignition Temperature	Not determined	Expected to decompose prior to ignition.
Explosive Properties	Not explosive	Contains no explosives that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that 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 not be manufactured within Australia. The notified polymer will be imported as the pure raw material or as a component in solvent or water based ink and coating formulations at < 5% concentration.

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

Year	1	2	3	4	5
Tonnes	5 – 15	5 – 15	5 – 15	5 – 15	5 – 15

PORT OF ENTRY

Throughout Australia

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as the raw material for reformulation in 200 kg open head steel drums or 25 kg open head steel pails. Ink formulations containing the notified polymer at < 5% concentration will be imported in sealed ink cartridges. Surface coatings containing the notified polymer at < 5% concentration will be imported in containers suitable for supply to both the industrial and domestic markets. The notified polymer and products containing it will be transported throughout Australia by road or rail.

USE

The notified polymer will be used in inks and surface coatings at concentrations of < 5%. The notified polymer will be used in solvent and water based ink formulations, inkjet inks, water based flexographic inks, overprint

varnishes, paints, renders, primers and sealers. Products containing the notified polymer will be used by both the industrial and domestic markets.

OPERATION DESCRIPTION

When not imported in finished products, the notified polymer (at up to 100% concentration) will be reformulated into surface coatings and printing inks. At the reformulation sites the contents of the imported drums and pails containing the notified polymer will be transferred to a mixing vessel, using a sparge, pail or jug, for blending with pigments and other ingredients to form the finished products. Following quality control analysis, the finished products (containing < 5% notified polymer) will be transferred (gravity feed or low-pressure pump) to 5 to 20 L cans and pails for distribution to end-users.

Surface coatings containing the notified polymer may be applied by brush, roller or spray on a wide range of substrates by both commercial and domestic users. The use of flexographic inks and overprint varnishes containing the notified polymer is expected to require manual transfer from the cans and pails they are packaged in to the printing equipment, with the printing process itself being largely enclosed and automated. Flexographic inks and overprint varnishes are only expected to be used by industry, while inkjet cartridges will be used by both industry and consumers.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	8	200
Service technicians	8	200
Office staff	0.17	10
Professional painters	8	200

EXPOSURE DETAILS

Transport and storage workers are unlikely to be exposed to the notified polymer (at up to 100% concentration) except in the unlikely event of an accident.

Reformulation

Reformulation will be largely enclosed and automated; however workers may be exposed (dermal and ocular) to the notified polymer at up to 100% concentration when transferring the contents of the imported drums and pails to the mixing equipment and during quality control testing. Dermal and ocular exposure to workers should be mitigated through the stated use by the notifier of personal protective equipment (PPE) including protective coveralls, impervious gloves and goggles. Inhalation exposure is not expected given the low vapour pressure of the notified polymer and enclosed processes.

Printing applications

Dermal or ocular exposure may occur to the inks or overprint varnishes containing the notified polymer at < 5% concentration during transfer processes, cleaning and maintenance. Inhalation exposure is not expected given the low vapour pressure of the notified polymer. Exposure at other times is expected to be limited by the automated and enclosed nature of the printing processes. The stated use by the notifier of PPE by workers, such as goggles, impervious gloves and coveralls should minimise exposure.

Coating applications

Exposure to the surface coatings containing the notified polymer (at < 5% concentration) may occur during transfer, application and cleaning processes. The potential for exposure should be minimised through the stated use by the notifier of PPE (goggles, impervious gloves, coveralls) by workers, including the use of respiratory protection during spray application. Inhalation exposure should be further mitigated through the use of exhaust ventilation and spray booths where possible.

Workers may come into contact with the inks and surface coatings containing the notified polymer after application to substrates. However, once the inks and surface coatings have dried, the notified polymer will be bound within a polymer matrix and will not be bioavailable.

6.1.2. Public Exposure

Ink-jet cartridges and surface coatings containing the notified polymer (at < 5% concentration) will be available for use by the public. Exposure (dermal, ocular and inhalation) to the notified polymer may occur during use of the surface coatings. Given the inks containing the notified polymer will be contained within sealed cartridges, significant exposure is not expected.

The public may come into contact with the inks and surface coatings containing the notified polymer after application to substrates. However, once the inks and surface coatings have dried, the notified polymer will be bound within a polymer matrix and will not be bioavailable.

6.2. Human Health Effects Assessment

The results from a toxicological investigation conducted on the notified polymer is summarised in the following table. For full details of the studies, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics

The notified polymer has a high molecular weight (> 1,000 Da) and a low percentage (< 10%) of low molecular weight species < 1000 Da; hence absorption across biological membranes is expected to be limited.

Irritation and sensitisation

The notified polymer contains a functional group which is a structural alert for skin irritation and sensitisation. However, the potential for causing these effects may be limited by the high molecular weight of the notified polymer and low percentage (< 10%) of low molecular weight species < 1000 Da. Furthermore, the functional group equivalent weight (FGEW) is > 3,500 Da.

Mutagenicity/Genotoxicity.

The notified polymer (< 60%) was not mutagenic in a bacterial reverse mutation study.

Health hazard classification

Based on the available information, the notified polymer cannot be classified 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 notified polymer has the potential to be an irritant and a sensitiser, due to the presence of a relevant structural alert. However, the risk of irritation and sensitisation effects from exposure to the notified polymer may be limited by the high molecular weight (> 1,000 Da) and low percentage (< 10%) of low molecular weight species < 1000 Da.

During reformulation, workers may be at risk of irritation and sensitisation effects when handling the notified polymer at concentrations of up to 100%; however exposure is expected to be low given the proposed use of PPE and the largely enclosed, automated processes.

During end use, workers will be exposed to inks or surface coatings containing the notified polymer at concentrations of < 5%. Given the low end use concentration, high molecular weight and low percentage of low molecular weight species, the potential risk of irritation and sensitisation effects is expected to be low. Furthermore, exposure to the notified polymer during end use is expected to be limited by the use of engineering controls and appropriate PPE.

Once the inks and surface coatings have dried, the notified polymer will be bound within an inert matrix and will not be bioavailable, thereby limiting any further potential for exposure.

Therefore, given the proposed use of PPE and engineering controls in place to limit exposure during reformulation, and low end use concentration, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer has the potential to be an irritant and a sensitiser. Ink-jet cartridges and surface coatings containing the notified polymer at < 5% concentration will be available for use by the public. Exposure to the notified polymer may occur during use of the surface coatings. Significant exposure is not expected from use of the ink-jet cartridges. Given the low end use concentration, high molecular weight and low percentage of low molecular weight species, the potential risk of irritation and sensitisation effects is expected to be low.

Once the inks and surface coatings have dried, the notified polymer will be bound within an inert matrix and will not be bioavailable, thereby limiting any further potential for exposure.

Therefore, the risk to the public from use of the notified polymer in inks and surface coatings at < 5% concentration is not considered to be 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 blended with other components in Australia to prepare printing inks and coatings. The blending is expected to be largely automated and will occur in enclosed systems. It is estimated that up to 3% of the notified polymer is expected to be released from formulation and cleaning of equipment. This is expected to be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

Inks containing the notified polymer are expected to be printed on paper. Once printing is complete, the notified polymer is expected to be incorporated in an inert matrix and is not expected to be released from the printed paper. Ink cartridges are designed to prevent leakage and are not expected to be opened during transport, use, installation or replacement. Therefore, release of ink containing the notified polymer to the environment is not expected under normal conditions. Waste inks due to equipment cleaning or spillage is expected to be physically contained with absorbent material and disposed of to landfill.

The majority of the coating products containing the notified polymer are expected to be used in industrial facilities, with 25% anticipated to be sold to consumers for do it yourself (DIY) use. Any losses from overspray (estimated at 30% of annual import volume) during industrial use are expected to be collected using standard engineering controls. These losses, together with other wastes generated during use, including residues in application equipment washings and empty containers, are expected to be disposed of in accordance with local regulations, namely to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Printed waste paper containing the notified polymer is expected to be disposed of to landfill or be subjected for paper recycling. The aqueous wastes from paper recycling are expected to be directed to sewage treatment plants (STPs). Coating residues containing the notified polymer used by do-it-yourself (DIY) practitioners may be disposed of to sewer, from the washing of application equipment with water.

Coated articles containing the notified polymer are expected to be thermally decomposed during metal reclamation processes or disposed of to landfill along with the used articles.

Residual ink or paint products left in empty cartridges or empty containers will most likely be disposed of to landfill or be disposed of in compliance with local regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted. Since the notified polymer has a molecular weight much greater than 1000 Da and no significant percentage of low molecular weight constituents, it is not expected to be able to cross biological membranes and therefore is not likely to bioaccumulate.

Most of the notified polymer is expected to be immobilised within a polymeric film on coated articles after printing and coating applications. The notified polymer will be disposed of along with the used article at the end of its useful life, which, in the majority of cases, will be to landfill. In cases where inks containing the notified polymer are used on paper, there is some potential for release of the notified polymer during the de-inking stage of paper recycling. During paper recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. The notified polymer may partition to the supernatant water, which is expected to be released to the sewer, based on its expected property as a dispersant. However, the notified polymer would be expected to be efficiently removed from waste water in waste water treatment plants through adsorption of the ionic polymer to sludge or by flocculation during paper recycling and water treatment processes. Sludge containing the notified polymer is expected to be disposed of to landfill or applied to soil for remediation of agricultural land. The notified polymer is likely to be bound to soil and sludge due to its ionic functions and is not expected to be mobile in the environment. In landfill or water, the notified polymer is expected to undergo biotic and abiotic degradation, eventually forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer is used for ink and coating applications on a variety of substrates, including paper. For the worst case release scenario, it is assumed that 100% of the notified polymer will be used in ink products for paper printing, of which half will be subjected to paper recycling processes. It was assumed that release of the notified polymer to surface water occurs from recycling process over 260 days per annum corresponding to release only on working days. Since most of the notified polymer will be washed into the sewer, and assuming no removal of the notified polymer in the sewage treatment plant, the resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment

Total Annual Import/Manufactured Volume	15,000 kg/year
Proportion expected to be released to sewer	50%
Annual quantity of chemical released to sewer	7,500 kg/year
Days per year where release occurs	260 days/year
Daily chemical release:	28.85 kg/day
Water use	200.0 L/person/day
Population of Australia (Millions)	22.613 million
Removal within STP	0%
Daily effluent production:	4,523 ML
Dilution Factor - River	1.0
Dilution Factor - Ocean	10.0
PEC - River:	6.38 µg/L
PEC - Ocean:	0.64 µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 6.38 µg/L may potentially result in a soil concentration of approximately 42.52 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 216.6 µg/kg and 425.2 µg/kg, respectively.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. Ecotoxicological endpoints for the notified polymer were calculated based on structure-activity relationship (SAR) equations assuming a worst case cation charge density for the polymer (Boethling and Nabholz, 1997). The endpoints are summarised in the table below and have been modified by mitigation factors to account for the anticipated binding of the polymer with organic carbon in surface waters.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
<i>Acute Toxicity</i>		
Fish Toxicity (96 hour)	LC50 = 54.35 mg/L	Harmful
Daphnia Toxicity (48 hour)	EC50 = 135.69 mg/L	Not harmful
Algal Toxicity (96 hour)	EC50 = 17.37 mg/L	Harmful
<i>Chronic Toxicity</i>		

Fish Toxicity	ChV = 3.02 mg/L	Not harmful
Daphnia Toxicity	ChV = 9.69 mg/L	Not harmful
Algae Toxicity	ChV = 4.75 mg/L	Not harmful

Based on the worst case SAR estimations, the notified polymer is potentially harmful or toxic to aquatic organisms in environmental waters with typical levels of total organic carbon. The QSAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer for the purposes of risk assessment. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The estimated hazard data for the notified polymer indicates that, after allowing for the mitigating effects of organic carbon in surface waters, the most sensitive ecotoxicological endpoint is for fish. The endpoint for fish was therefore selected for the calculation of the PNEC below. An assessment factor of 50 was used as a worst-case calculated chronic endpoint was used for determination of the PNEC.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment

Fish (ChV)	3.02	mg/L
Assessment Factor	50	
PNEC:	60.4	µg/L

7.3. Environmental risk assessment

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	6.38	60.4	0.105
Q - Ocean:	0.64	60.4	0.0105

The risk quotient ($Q = PEC/PNEC$) for aquatic exposure is calculated to be < 1 based on the above calculated PEC and PNEC. The Q value of < 1 indicates the notified polymer is not expected to pose an unreasonable risk to the aquatic environment from its proposed use pattern at the proposed maximum import volume.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Water Solubility**

Fully miscible at 21 °C

Method	OECD TG 105 Water Solubility. EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks	Flask Method Test substance (0.5 g, 2.4 g and 4.5 g) was mixed with ultrapure water (4.5 mL, 2.5 mL and 0.5 mL) respectively. All three mixtures resulted in clear solutions indicating that the test substance is fully miscible with water.
Test Facility	Insitut Kuhlmann (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer (< 60%)
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 (pre-experiment and test 1)/Pre incubation procedure (test 2)
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	Pre-experiment/test 1 with and without metabolic activation: 0, 3, 10, 33, 100, 333, 1000, 2500 and 5000 µg/plate Test 2 with and without metabolic activation: 0, 33, 100, 333, 1000, 2500 and 5000 µg/plate
Vehicle	Deionised water
Remarks - Method	No deviations from the protocol.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Pre-experiment Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>	> 5,000			
Test 1		> 5,000	> 5,000	negative
Test 2		> 5,000	> 5,000	negative
<i>Present</i>	> 5,000			
Test 1		> 5,000	> 5,000	negative
Test 2		> 5,000	> 5,000	negative

Remarks - Results

The plates incubated with the test substance showed normal background growth up to 5000 µg/plate with and without S9 mix in both main experiments.

No toxic effects, shown as a reduction in the number of revertants, occurred in the test groups with and without S9 mix.

No substantial increase in revertant colony numbers of any of the five test strains was observed following treatment with the test substance at any dose level, neither in the presence nor absence of S9 mix. There was also no tendency of higher mutation rates with increasing concentrations in the range below the border of biological relevance.

The positive controls produced satisfactory responses, thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

The test substance was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

RCC (2006)

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