File No: STD/1250

May 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

FPC-200

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

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

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

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Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

FPC-200

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Hewlett-Packard Australia Ltd (ABN 74 004 394 763)
31-41 Joseph Street. Blackburn
Victoria 3130
Australia

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (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, Spectral Data, Purity, Hazardous and Non-hazardous Impurities, Additives/Adjuvants, Identity of Manufacturer/Recipients and Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Dissociation Constant, Bioaccumulation, Acute Inhalation Toxicity and Induction of Germ Cell Damage

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
Japan (2002), Belgium (2002), and USA (2004).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
FPC-200 (containing 20-30% of the notified chemical)

MOLECULAR WEIGHT
>500

ANALYTICAL DATA
Reference NMR, IR, HPLC, UV spectra were provided. Major peaks are consistent with the structure of the notified chemical.

3. COMPOSITION

DEGREE OF PURITY
>90% (manufactured as an aqueous solution containing 20-30% of the notified chemical)

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa:
Pale yellow liquid (aqueous solution containing 20-30% of the notified chemical)

The properties below were measured using aqueous solution containing 20-30% of the notified chemical. No correction was made for the concentration of the notified chemical.

Property	Value	Data Source/Justification
Freezing Point	-1.6°C	Measured
Boiling Point	99-101°C at 101.3 kPa	Measured
Density	1100 kg/m^3 at 20°C	Measured
Vapour Pressure	2.2 kPa at (20°C)	Measured
Water Solubility	Not determined	Manufactured as an aqueous water solution containing 20-30% of the notified chemical
Hydrolysis as a Function of pH	>1 year at pH 4, 7 and 9 at 25°C	Measured
Partition Coefficient (n-octanol/water)	log $P_{ow} \leq$ -6 at 20°C	Estimated
Adsorption/Desorption	log $K_{oc} \leq$ -2.10 (worst case value)	Calculated
Dissociation Constant	Not determined	Estimated*
Particle Size	Not applicable	The notified chemical is a liquid at room temperature.
Surface Tension	73.0 mN/m at 20°C	Measured
Flash Point	Not found	The notified chemical solution started to boil at 101°C.
Flammability	Not flammable	Estimated based on the structure
Autoignition Temperature	>650°C	Measured
Explosive Properties	Not explosive	Estimated based on the structure

*The notified chemical contains a number of strong acid functionalities which are expected to remain deprotonated throughout the environmental pH range (4-9).

DISCUSSION OF PROPERTIES

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

Reactivity

There are no known hazardous decomposition products or incompatibility with other substances. However, the notified chemical is combustible and will burn in a fire, evolving noxious fumes such as oxides of carbon, sulphur, and nitrogen.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured in Australia. It will be imported as a component of printing inks in pre-packed ink jet cartridges.

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

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

PORT OF ENTRY

Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

Recipient site located in Blackburn, Victoria

TRANSPORTATION AND PACKAGING

The notified chemical will be imported in sealed ink cartridges. Each ink jet cartridge contains approximately 18g of ink. The cartridges will be packed in sturdy cardboard boxes and normally be transported and distributed to customers by road.

USE
The notified chemical is used as an ingredient of water-soluble inks for use in ink-jet printers manufactured for use with plain paper. The printing inks contain <3% of the notified chemical and are used both commercially by large printing businesses and by the general public.

OPERATION DESCRIPTION
No manufacturing, reformulation, filling or refilling of cartridges will occur in Australia. When replacing ink cartridges, the public, office staff or a trained engineer will follow replacement procedures recommended by the manufacturer. This will involve removing the seal tape and inserting the cartridge into printers. The printing process will be a fully automated and enclosed system. Service engineers may be involved in maintenance of the printer intermittently.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Importation/Waterside workers	10	4 hours/day	70 days/year
Storage and transport	100	6 hours/day	240 days/year
Office worker/Service technician	10000	<0.1 hour/day	Intermittently

EXPOSURE DETAILS
During transport and storage, workers are unlikely to be exposed to the notified chemical in ink except when the packaging is accidentally breached.

Office staff and service engineers may be intermittently exposed to the notified chemical (<3%) in printer ink via skin contact when replacing the spent cartridges, cleaning paper jams or during maintenance and servicing. The service engineers typically will wear gloves and receive appropriate training in servicing techniques. Dermal and possible ocular exposure could also occur when handling faulty or ruptured cartridges. Contact with paper printed with the ink containing the notified chemical is unlikely to result in dermal exposure as the chemical will be bound within the matrix of the paper and become inert, except if the paper or other substrate is handled before the ink has dried.

Workers' exposure to the notified chemical via inhalation is unlikely due to its structure and properties (relatively high molecular weight and high water solubility). In addition, it is not expected that the notified chemical will be released during printing as the cartridge is confined within the body of the ink jet printer. Ocular exposure is also expected to be unlikely, as the ink is only released in minute amounts within the confines of the printer.

6.1.2. Public exposure
The scenarios by which the public may be exposed to the notified chemical would involve home use of printers, and are similar to those for office workers. However, it is expected that the public will be using the printer less often than workers.

6.2. Human health effects assessment

The results from toxicological investigations conducted using an aqueous solution containing 20-30% of the notified chemical are summarised in the table below. No correction was made for the concentration of the notified chemical in these studies. Details of these studies can be found in Appendix B.

Endpoint	*Result andAssessment Conclusion*
Rat, acute oral	LD50 >2000 mg/kg bw low toxicity
Rat, acute dermal	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 – 28 days	NOAEL = 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	non genotoxic

Toxicokinetics, metabolism and distribution
Based on the toxicokinetic assessment (see details in Appendix B section B.9) and its structure, the notified chemical is not expected to be absorbed through the skin, gastrointestinal wall and lungs due to its high water solubility, low P_{ow}, and relatively high molecular weight (>500).

Health effects
The notified chemical as a 20-30% solution has a low acute oral and dermal toxicity in rats (LD50>2000 mg/kg/bw). It is not irritating to the skin and eyes of the rabbit. However, erythema, scales and/or scabs were seen in 3/5 treated females in the acute dermal study indicating a potential for skin irritation. It shows no sensitising activity in an adjuvant study in guinea pigs. The NOAEL was established to be 1000 mg/kg bw/day, which was the highest dose tested in a 28-day repeat dose oral study in rats. The solution containing the notified chemical was not mutagenic in a bacterial reverse mutation assay, and did not reveal any genotoxic potential in an in vitro test. As all toxicity studies were conducted using an aqueous water solution containing 20-30% of the notified chemical, testing of the pure chemical may have yielded different results.

Based on the available data the solution containing 20-30% of the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) (Criteria). The notified chemical cannot be classified under the Criteria.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Given the low hazard of the notified chemical, low likelihood of absorption via all exposure routes, low concentration of the notified chemical in the ink cartridge (<3%), and limited worker exposure, the notified chemical is not expected to pose an unacceptable risk to workers.

Regarding the potential for causing dermal irritation, this effect was found in the acute dermal study using a dose of 2000 mg/kg bw under the occlusive dressing for 24 hours. At workplaces, workers' exposure to the notified chemical is limited, therefore, the risk of skin irritation is considered low. Nevertheless, cautions should be taken to avoid skin contact, especially for service engineers and when handling faulty and ruptured cartridges.

6.3.2. Public health
Based on the similar use and exposure pattern to the workers, plus potentially less frequent exposure to the public than workers, the notified chemical is not expected to pose an unacceptable risk to the general public.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Printer ink is imported in ready-to-use cartridges (containing <3% notified chemical). No release is expected as manufacturing and reformulation of the ink containing the notified chemical will not take place in Australia. Environmental release of the notified chemical is unlikely during importation, storage, transportation and spillage during a transport accident is the most likely reason for environmental release. Individual container capacity, container and packaging specifications would limit the extent of release.

RELEASE OF CHEMICAL FROM USE

Release of the ink solution to the environment is not expected under normal use as ink cartridges are designed to prevent leakage. Spent cartridges will be replaced by service technicians, office workers or the public. However, if leakage or spillage does occur, the ink will be contained with absorbent material, which is likely to be disposed of in a landfill site.

Ultimately, all the notified chemical will be released to the environment. Paper towhich the notified chemical will be bound will eventually be buried in landfill or incinerated, or the chemical may be released in effluent from de-inking processes. Residues left in empty cartridges will most likely be disposed of to landfill.

Recycling of treated paper may result in the release of a proportion of the notified chemical to the aquatic compartment.

RELEASE OF CHEMICAL FROM DISPOSAL

The total import volume of the notified chemical will ultimately be disposed as normal office/domestic waste that will end up in either landfill or be incinerated. Some waste paper printed with the ink may be disposed of directly to landfill with the notified chemical bound to the paper. Some will enter the paper recycling process. Used cartridges may be sent to recycling and disposal centres. The cartridges will be broken down into component parts for recycling. Residual ink (<3% of the notified chemical) left in the empty cartridges will be separated from the cartridges and incinerated during the recycling of the cartridges.

Recycling of treated paper may result in the release of a proportion of the notified chemical to the aquatic compartment. Waste paper is repulped using a variety of chemical treatments, which result in fibre separation and ink detachment from the fibres. The waste is expected to go to trade waste sewers. Approximately 50% of the ink printed on paper will enter paper recycling of which, based on its high water solubility, only a small proportion of the notified chemical is expected to be recovered during recycling. While most may partition to water, due to the low percentage of the notified chemical in these inks and the widespread use, release to the aquatic compartment from any given recycling plant will still be low based on worst case assumptions. Any chemical absorbed to sludge during recycling process will be disposed of to landfill.

The notified chemical that is incinerated is expected to thermally decompose to form predominantly simple organic compounds and various salts. Similarly, the notified chemical that is disposed of to landfill should eventually degrade.

7.1.2 Environmental fate

A single ready biodegradability test was submitted, which showed the notified chemical achieved 10% biodegradation after 28 days. Therefore, the notified chemical cannot be considered to be readily biodegradable according to the OECD criteria. For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

Manufacture, reformulation and packaging into end-use containers occurs overseas, and release is not expected. After use, printed-paper may be disposed of by incineration, to landfill or be recycled. The notified chemical disposed of to landfill, may be mobile, however, the low proposed annual import volume, and diffuse release throughout Australia will mitigate any potential exposure while the notified chemical slowly degrades.

In Australia, approximately 50% of printed-paper is recycled. The following Predicted Environmental Concentration calculation assumes this 50% recycling, and as a worst case scenario assumes no recovery within STPs.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	1.37	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.32	µg/L
PEC - Ocean:	0.03	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/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 1300 kg/m^3). Using these assumptions, irrigation with a concentration of 0.324 µg/L may potentially result in a soil concentration of approximately 2.490 X 10^{-3} mg/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 1.245 X 10^{-2} mg/kg and 2.490 X 10^{-2} mg/kg, respectively.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted using an aqueous solution containing 20-30% of the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 >100 mg/L	Not Harmful
Daphnia Toxicity	E_iC50 >100 mg/L	Not Harmful
Algal Toxicity	E_rC50 >100 mg/L	Not Harmful
Inhibition of Bacterial Respiration	E_iC50 >100 mg/L	Not Harmful

7.2.1 Predicted No-Effect Concentration

Aquatic ecotoxicity data were provided for three trophic levels. The following Predicted No-Effect Concentration has been calculated using an assessment factor of 100.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga)	>100	mg/L
Assessment Factor	100	
PNEC	>1,000	µg/L

7.3. Environmental risk assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated.

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	0.32	>1000	<0.00032
Q - Ocean:	0.03	>1000	<0.00003

This indicates that the current import volume and use pattern is not expected to pose an unacceptable risk to the aquatic environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the solution containing 20-30% of the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). The notified chemical cannot be classified under the Criteria.

Human health risk assessment

Under the conditions of the occupational settings and public uses described, the notified chemical is not considered to pose a risk to the workers and the general public.

Environmental risk assessment

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the imported ink cartridges:
  - Use of appropriate PPE by printer service technicians to avoid dermal exposure.

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

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

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

Environment

- The notified chemical should be disposed of to landfill in accordance with State/Territory waste disposal regulations.

- Spills/release of the notified chemical should be contained with an absorbent, inert material (soil, sand, sawdust, vermiculite) and collected in sealable, labelled containers for 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 notified chemical is introduced at a concentration >30%.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from ink component, or is likely to change significantly;
- the amount of chemical being introduced has increased from one tonne, or is likely to increase, significantly;
- if 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 MSDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

All tests below were conducted using an aqueous solution containing 20-30% of the notified chemical. No correction was made for the concentration of the notified chemical.

Freezing Point -1.6°C

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks At a temperature of -0.6°C and -0.4°C, the notified chemical became cloudy and started to freeze. At a temperature of -1.6°C, it was completely solid.
TEST FACILITY Notox (2002b)

Boiling Point 99-101°C at 101.3 kPa

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks The test was performed using a differential scanning calorimeter. The boiling residue reacts or decomposes at >275°C.
TEST FACILITY Notox (2002c)

Density 1100 kg/m^3 at 20 ± 0.5°C

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks The test was performed using a glass pycnometer at a nominal volume of 10mL.
TEST FACILITY Notox (2002d)

Vapour Pressure 2.2 kPa at 20°C

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks The vapour pressure at 20°C was extrapolated from the vapour pressure curve using static vapour pressure measurements made with a capacitance manometer. They are 5.9 kPa at 37.02°C, 4.3 kPa at 31.52°C, and 3.1 kPa at 25.62°C.
TEST FACILITY Notox (2002e)

Hydrolysis as a Function of pH Hydrolytically stable

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ <hours or days>*
4	25	>1 year
7	25	>1 year
9	25	>1 year

Remarks Less than 10% hydrolysis (HPLC) was observed at 50°C after 5 days in all buffer solutions. Hence, the notified chemical is hydrolytically stable.
TEST FACILITY Notox (2002g)

Partition Coefficient (n-octanol/water) log P_{ow} ≤ -6 at 20°C

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks The Estimation method was used.
The solubility of the notified chemical at 20°C was ≤0.6x10^{-3} g/L in n-octanol and >1000 g/L in water. The partition coefficient (n-octanol/water), P_{ow}, calculated as a quotient of the n-octanol solubility and water solubility of the notified chemical, is

$\leq 6x10^{-7}$ ($\log P_{ow} \leq -6$).
TEST FACILITY Notox (2002h)

Adsorption/Desorption $\log K_{oc} \leq -2.10$ (worst case value)

METHOD Expert Statement – calculated using the QSAR method described in the Technical Guidance Document on Risk Assessment (European Commission, 1996).
Remarks For calculation of adsorption/desorption of the notified chemical, several chemical classes such as non hydrophobics (I), alcohols (II) and triazines (III) having different QSARs and a $\log P_{ow} \leq -6.0$ for the notified chemical were used:
(I) $\log K_{oc} = 0.52 \log P_{ow} + 1.02 \leq -2.10$
(II) $\log K_{oc} = 0.39 \log P_{ow} + 0.50 \leq -1.84$
(III) $\log K_{oc} = 0.30 \log P_{ow} + 1.50 \leq -0.30$
$\log K_{oc} \leq -2.10$ (worst case value ie lowest adsorption to soil, based on the $\log P_{ow}$ of the notified chemical). In conclusion, the different QSARs give different outcomes of the $\log K_{oc}$. For risk assessment purposes, the worst case calculated value should be used, in view of all uncertainties using QSAR.
TEST FACILITY Notox (2002i)

Dissociation Constant Not determined

Remarks The notified chemical contains a number of strong acid functionalities which are expected to remain deprotonated throughout the environmental pH range (4-9).

Surface Tension 73.0 mN/m at 20 ± 0.5°C

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Concentration: 1.199 g/L. A ring tesnsiometer was used. Based on the criteria as outlined in the guideline, the notified chemical should not be regarded as a surface active material.
TEST FACILITY Notox (2002j)

Flash Point No flash point found

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks The test was performed using a Pensky-Martens closed cup apparatus. The notified chemical solution started to boil at 101°C.
TEST FACILITY Notox (2002k)

Autoignition Temperature >650°C

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks No auto-ignition temperature was found at a temperature range of 200-650°C.
TEST FACILITY Notox (2002m)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Test was not performed, as the notified chemical does not contain any chemically unstable or highly energetic groups that might lead to an explosion.
TEST FACILITY Notox (2002n)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

All tests below were conducted using an aqueous solution containing 20-30% of the notified chemical. No correction was made for the concentration of the notified chemical.

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar Crl:(WI) BR
Vehicle	Undiluted as supplied
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 females	2000	0/3
II	3 males	2000	0/3

LD50	>2000 mg/kg bw
Signs of Toxicity	Lethargy was noted among all females and in one male on day 1. The mean body weight gain by the animals over the study period was considered to be normal.
Effects in Organs	No abnormalities were found at macroscopic post mortem examination of the animals.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Notox (2002o)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/Wistar Crl:(WI) BR
Vehicle	Undiluted as supplied
Type of dressing	Occlusive dressing for females only. Semi-occlusive for males.
Exposure duration	24 hours
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 females	2000	0/3
II	5 males	2000	0/3

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Erythema, scales and/or scabs were seen on the treated skin area of three out of five females during the observation period (15 days).
Signs of Toxicity - Systemic	The males were calm on day 1. No signs of systemic toxicity were noted in the females. The changes noted in body weight gain in all test animals

	were within the range expected for rats used in this type of study and were therefore considered not indicative of toxicity.
Effects in Organs	No abnormalities were found at macroscopic post mortem examination of the animals.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Notox (2002p)

B.3. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	Undiluted as supplied
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks – Method	No significant protocol deviations.
RESULTS	
Remarks - Results	There was no evidence of dermal corrosion or irritation caused by 4 h exposure to the notified chemical. No staining of the treated skin was observed. No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	Notox (2002q)

B.4. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Observation Period	72 hours
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	Instillation of 0.1 mL of the notified chemical into one eye of each of three rabbits did not result in irritation of the conjunctivae in any of the animals. No iridial irritation or corneal opacity was observed, and treatment of the eyes with 2% fluorescein 24 h after instillation of the notified chemical revealed no corneal epithelial damage in any of the animals. There was no evidence of ocular corrosion. No staining of (peri) ocular tissues by the notified chemical was observed. No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.
CONCLUSION	The notified chemical is non-irritating to the eye.
TEST FACILITY	Notox (2002r)

B.5. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation – Maximisation Test. EC Directive 96/54/EC B.6 Skin Sensitisation – Maximisation Test.
Species/Strain	Guinea pig/Dunkin Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: <10% test solution topical: 100% test solution
MAIN STUDY	
Number of Animals	Test Group: 10 females Control Group: 5 females
INDUCTION PHASE	Induction Concentration: intradermal: 100% test solution at 1:1 mixture with Freund's Complete Adjuvant or vehicle (Milli-U water) topical: 100% test solution
Signs of Irritation	During induction, erythema (scores of 1 and 2) was noted in both test and control animals (6/10 vs 3/5 for intradermal; 4/10 vs 3/5 for epidermal). The reactions noted after the epidermal induction were considered to be enhanced by the SDS (10% sodium-dodecyl-sulfate) treatment.
CHALLENGE PHASE	
1st challenge	topical: 100% test solution
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	No skin reactions were evident after the challenge exposure in the test and control animals. No mortality occurred and no symptoms of systemic toxicity were observed. A separate positive control study with alpha-hexylcinnamic aldehyde confirmed the sensitivity of the test system.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Notox (2002s)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
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/Wistar Crl:(WI) BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 0 day
Vehicle	Milli-U water
Remarks - Method	The following protocol deviations were noted: 1) Deviations from the maximum level of temperature occurred (with a maximum of 0.5°C); 2) On day 7, the maximum time between the earliest and latest dose was exceeded by approximately 45 minutes; 3) Cervix and vagina were examined microscopically from all control and high dose females. These deviations were considered not to have affected study integrity.
RESULTS	

Group	*Number and Sex of Animals*	*Dose* mg/kg bw/day*	*Mortality*
control	5 per sex	0	0/10
low dose	5 per sex	50	0/10
mid dose	5 per sex	150	0/10
high dose	5 per sex	1000	0/10

*No correction was made for the purity of the notified chemical.

Mortality and Time to Death

No mortality occurred during the study period.

Clinical Observations

There were no clinical signs of toxicity or behavioural changes over the 28-day observation period that were considered to be related to treatment.

Incidental findings that were noted included alopecia and/or brown staining among females of the low and high dose groups. These findings are commonly noted in rats of this age and strain which are housed and treated under the conditions in this study. At the incidence observed, these were considered to be of no toxicological significance. No clinical signs were noted among the other animals.

No changes were observed in hearing ability, pupillary reflex, static righting reflex and grip strength in the animals treated with the notified chemical, when compared to control animals. The variation in motor activity did not indicate a relationship with treatment.

Body weight and body weight gain of treated animals remained in the same range as controls over the 4-week study period.

Food consumption before or after allowance for body weight between treated and control animals was similar.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematological parameters of treated rats were considered not to have been affected by treatment. Statistically significant lower white blood cell count of animals receiving 50 mg/kg/day were considered to have arisen by chance and not to represent a change of biological significance.

There were no differences noted in clinical biochemistry between control and treated rats that were considered to be related to treatment.

The increased mean potassium value of high dose females was within the normal range and was not supported by other findings. Values in males of the intermediate dose groups achieving a level of statistical significance when compared to controls did so in the absence of a dose related response. Also, values were similar to comparable studies. Therefore, these changes were considered to be of no toxicological significance.

Effects in Organs

Organ weights and organ:body weight ratios of treated animals were considered to be similar to those of control animals. Statistically significant changes between relative thymus weights of males of the 150 mg/kg/day group and control males were considered not to be a sign of toxicity.

Macroscopic observations at necropsy did not reveal any alterations that were considered to have arisen as a result of treatment. Incidental findings among control and treated animals included red discolouration of the lungs, thymus or mandibular lymph node, an accentuated lobular pattern or diaphragmatic hernia of the liver, pelvic dilation of the kidneys, nodules on the epididymides and fluid in the uterus. These findings are occasionally seen among rats used in these types of studies and in the absence of correlated microscopic findings and/or a dose-related response, therefore, they were considered changes of no toxicological significance.

All microscopic findings were within the range of background pathology encountered in Wistar rats of this age and strain and occurred at similar incidences and severity in both control and treated rats.

Remarks – Results

There were no changes at determination of clinical appearance, performance of functional observations, body

weight and food consumption measurements, or alterations during haematological investigations, macroscopic examination, organ weight determination and microscopic examination that were considered to be an effect of treatment.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day, which is the highest dose tested in this study.

TEST FACILITY Notox (2002t)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

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

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP*2uvrA*
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 3, 10, 33, 100, 333, 1000, 3330, 5000 µg/plate b) Without metabolic activation: 3, 10, 33, 100, 333, 1000, 3330, 5000 µg/plate
Vehicle	Milli-Q-water
Remarks – Method	Two independent tests were conducted, each in triplicate.

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 (TA100 & WP*2uvrA*)	>5000 (other strains)	>5000	Negative
Test 2	--	>5000 (all strains)	>5000	Negative
Present				
Test 1	>5000 (TA100 & WP*2uvrA*)	>5000 (other strains)	>5000	Negative
Test 2	--	>5000 (all strains)	>5000	Negative

Remarks - Results All other bacterial strains showed negative responses over the entire dose range, ie no dose-related, two-fold increase in the number of revertants in two independently repeated experiments. The vehicle and positive controls responded appropriately.

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

TEST FACILITY Notox (2002u)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity – In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line	Peripheral human lymphocytes
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Vehicle	F10 medium buggered with 20mM HEPES
Remarks - Method	Two independent tests were conducted, each in triplicate.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1000*, 3330*, 5000*	3 h	24 h
Test 2	1000*, 3330*, 5000*	24 h and 48 h	24 h and 48 h
Present			
Test 1	1000*, 3330*, 5000*	3 h	24 h
Test 2	1000*, 3330*, 5000*	3 h	48 h

*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	>5000	>5000	>5000	Negative
Test 2	--	>5000	>5000	Negative
Present				
Test 1	>5000	>5000	>5000	Negative
Test 2	--	>5000	>5000	Negative

Remarks - Results The number of cells with chromosomal aberrations found in the vehicle control cultures were within the laboratory historical control data range. Both in the presence and absence of S9-mix, the notified chemical did not induce a statistically significant or biologically relevant increase in the number of cells with chromosomal aberrations in two independent experiments. In test 1, several polyploid cells were observed, but since these cells were also observed in cultures treated with vehicle, and since the number of polyploid cells did not increase with dose, this observation was regarded not biologically relevant. The vehicle and positive controls responded appropriately.

CONCLUSION The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY Notox (2002v)

B.9. Toxicokinetic assessment

TEST SUBSTANCE Notified chemical

ASSESSMENT

The acute oral and dermal toxicity of a solution containing 20-30% of the notified chemical is low (LD50>2000 mg/kg bw). The 28-day toxicity study also revealed that it has a relatively low toxicity, with a NOAEL of 1000 mg/kg/day. Therefore, an extensive toxicokinetic assessment is considered of limited value.

The notified chemical is soluble in water, caused by the presence of the strongly polar sulfonic acid groups. The strong polarity of these groups makes it very unlikely that this compound easily passes the gastrointestinal wall. Therefore, it is to be expected that the oral bioavailability, and thus the systemic exposure, of the notified chemical will be low.

In the case absorption of the chemical occurs, extensive hydroxylation of the aromatic rings is anticipated, followed by a rapid sulphation or glucuronidation. Another possibility is that dealkylation at the secondary amines occurs. The resulting metabolites, as well as the parent compound will be extensively excreted via urine or bile.

The notified chemical will show a low volume of distribution equalling extracellular body water (approximately 0.7 L per kg bw). Accumulation in fatty tissues is not anticipated. The plasma protein binding is expected to be low.

Since the bioavailability of dermally applied compounds can be assumed to be zero for substances with a log P_{ow} below -1 and over 5 or a relative molecular mass over 700, it is not to be expected that the notified chemical will be absorbed through the skin.

Based on the expected kinetic behaviour in the body, as described above, the notified chemical will hardly be absorbed after oral administration, because of the presence of strongly polar groups in the molecule. If absorption occurs, the notified chemical will be extensively metabolised in the liver. Therefore, accumulation in the body during prolonged exposure will be very low.

This is supported by the low systemic toxicity observed in both the acute and subacute toxicity studies.

TEST FACILITY Notox (2002w)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

All tests below were conducted using an aqueous solution containing 20-30% of the notified chemical. No correction was made for the concentration of the notified chemical.

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. Directive 92/69/EEC, C.4/C.4C
Inoculum	Activated sludge freshly obtained from a municipal sewage treatment plant "Waterschap de Maaskant" 's Hertogenbosch, The Netherlands. The sludge was kept under continuous aeration until further treatment. Before use, the sludge was allowed to settle for 30-90 minutes and the liquid decanted for use as inoculum at the rate of 10mL/L of mineral medium.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Carbon dioxide produced during the test was reacted with barium hydroxide in a gas scrubbing bottle and precipitated as barium carbonate. The amount of carbon dioxide was determined by titrating the remaining barium hydroxide with 0.05M standardised hydrochloric acid solution.
Remarks - Method	No significant deviations were reported.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	1	2	6
5	1	5	43
7	3	7	62
9	5	9	75
14	5	14	88
19	6	19	94
23	6	23	98
27	10	27	100
29	10	29	100

Remarks - Results	The relative degradation values calculated from the measurements performed during the test period revealed 16% degradation of the test substance in test bottle A and no significant degradation in test bottle B (5%). The mean degradation in both bottles was 10%. Hence, the test material did not meet the criteria for ready biodegradability. The reference substance passed the criterion and in the toxicity control the test substance was found to be not inhibitory on microbial activity.
CONCLUSION	The test substance cannot be considered to be readily biodegradable according to the OECD criteria
TEST FACILITY	Notox (2002aa)

C.1.2. Bioaccumulation

No bioaccumulation data were provided. However, the bioaccumulation potential of the notified chemical is low due to its high water solubility and the low lipid solubility and log P_{ow}.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static.
Species	Carp (*Cyprinus carpio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Analysis of the samples taken during the range-finding study showed that the measured concentration of the notified chemical was in agreement with nominal at the start of the test (90%) and did not decrease by more than 20% during the 96-hour test period (93% after 24 hours of exposure and 99% after 96 hours of exposure).

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*4 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	7	0	0	0	0	0
100	100	7	0	0	0	0	0

LC50	>100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	Under the conditions of the study, the notified chemical did not induce lethal effects in carp at 100 mg/L after 96 hours of exposure. Thus, the LC50 96 h for Carp exposed to the notified chemical is >100 mg/L. At 24 h all fish were observed swimming at the bottom of the tank in the test vessel containing 100 mg/L. This was not observed at later times.
CONCLUSION	The notified chemical is very slightly toxic to *Cyprinus carpio* (carp) according to Mensink *et al.* (1995).
TEST FACILITY	Notox (2002bb)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Analysis of the samples taken during the pre-test showed that the measured concentration of all samples taken at the start of the test were between 98 and 102 mg/L. During the exposure period the measured concentration of the samples taken from the vessels which were kept in the dark remained constant. Therefore the study was continued with a

range-finding test and a limit test, which were both performed in the dark. All test solutions were clear and colourless. Oxygen content (8.7-9.2 mg O_2/L), pH (7.9-8.2) and temperature (19.8-20.7°C) were satisfactorily maintained.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h**
0		10	0	0
3.5		10	0	0 (1)
10		10	0	0 (1)
35		10	0	0
100		10	0	0 (1)

* Between brackets: number of daphnids observed trapped at the surface of the test solutions. These daphnids were reimmersed in the respective solutions before scoring of mobility.

EC50	>100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks – Results	The data show no immobility in the blank-control and no immobility in the test concentrations after 48 hours of exposure.

CONCLUSION The notified chemical is very slightly toxic to *Daphnia magna* according to Mensink *et al.* (1995).

TEST FACILITY Notox (2002cc)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.
ISO Standard 8692, 1st Edition, 15 November 1989

Species	Fresh water Algae *Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range Nominal	0, 0.1, 1.0, 10 and 100 mg/L
Concentration Range Actual	Not measured.
Auxiliary Solvent	Not applicable
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	No significant deviations from the test protocol were reported.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOEC mg/L*	*E_rC50 mg/L at 72 h*	*NOEC mg/L*
>100	100	>100	100

Remarks – Results The EC_{50} values could not be estimated for both growth inhibition E_bC50 (0-72h) and growth rate reduction E_rC50 (0-72h) as both were above a loading of 100mg/L.

CONCLUSION Under the conditions of the study with *Selenastrum capricornutum,* no inhibition of cell growth or reduction of growth rate was recorded at 100 mg/L of the notified chemical.

TEST FACILITY	Notox (2002dd)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 67/548 amended 1987 (87/302) Part C, Publication No L133, adopted May 30, 1988.
Inoculum	Municipal sewage treatment plant "Waterschap de Maaskant" 's Hertogenbosch, The Netherlands.
Exposure Period	0.5 hours
Concentration Range Nominal	100 mg/L
Remarks – Method	No significant protocol deviations were reported.
RESULTS	
IC50	>100 mg/L
NOEC	100 mg/L
Remarks – Results	No significant inhibition of respiration rate of the sludge was recorded at 100 mg/L of the notified chemical. A duplicate measurement confirmed the result. The EC50 of the reference substance was 11 mg/L, and thus the test was considered valid.
CONCLUSION	Under the conditions of the test, the notified chemical was not toxic to waste water (activated sludge) bacteria at a concentration of 100 mg/L
TEST FACILITY	Notox (2002ee)

BIBLIOGRAPHY

Mensink BJWG, Montforts M, Wijkhuizen-Maslankiewicz L, Tibosch H and Linders JBHJ (1995) Manual for summarising and evaluating the environmental aspects of pesticides. National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands. Report No. 679101022.

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

Notox (2002a) Analytical data for FPC-200. Project no. 340807. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002b) Determination of the freezing temperature of FPC-200. Project no. 340548. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002c) Determination of the boiling temperature of FPC-200. Project no. 346343. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002d) Determination of the density of FPC-200. Project no. 340559. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002e) Determination of the vapour pressure of FPC-200. Project no. 340561. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002f) Determination of the water solubility of FPC-200. Project no. 340583. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002g) Determination of the hydrolysis of FPC-200 as a function of pH. Project no. 351833. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002h) Determination of the partition coefficient (n-octanol/water) of FPC-200. Project no. 340594. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002i) Adsorption/Desorption of FPC-200. Project no. 340651. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002j) Determination of the surface tension of an aqueous solution of FPC-200. Project no. 340572. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002k) Determination of the flash point of FPC-200. Project no. 340605. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002l) Determination of the flammability (contact with water) of FPC-200. Project no. 340616. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002m) Determination of the auto-ignition temperature of FPC-200. Project no. 340649. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002n) Statement of the explosive properties of FPC-200. Project no. 340638. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002o) Assessment of acute oral toxicity with FPC-200 in the rat. Project no. 340662. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002p) Assessment of acute dermal toxicity with FPC-200 in the rat. Project no. 340673. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002q) Primary skin irritation/corrosion study with FPC-200 in the rabbit. Project no. 340684. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002r) Acute eye irritation/corrosion study with FPC-200 in the rabbit. Project no. 340694. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002s) Assessment of contact hypersensitivity to FPC-200 in the albino guinea pig. Project no. 340706. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002t) Subacute 28-day oral toxicity with FPC-200 in the rabbit. Project no. 340728. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002u) Evaluation of the mutagenic activity of FPC-200 in the *S. typhimurium*: and *E. coli* mutation assay. Project no. 340739. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002v) Evaluation of the ability of FPC-200 to induce chromosome aberration in cultured peripheral human lymphocytes. Project no. 340741. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002w) Toxicokinetic assessment of FPC-200. Project no. 340829. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002aa) Determination of ready biodegradability: CO2 evolution test (modified sturm test) with FPC-200. Project no. 340774. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002bb) 96-Hour acute toxicity study in carp with FPC-200 (static). Project no. 340752. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002cc) Acute toxicity study in *Daphnia magna* with FPC-200 (static). Project no. 340763. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002dd) Fresh water algal growth inhibition test with FPC-200. Project no. 340785. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).

Notox (2002ee) Activated sludge respiration inhibition test with FPC-200 (contact time: 30 minutes). Project no. 340796. Hertogenbosch, Netherlands, Notox Safety & Environmental Research B.V. (unpublished report submitted by the notifier).