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November 2018

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical in Satacen 3

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 and Energy.

This Public Report is 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

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
STD/1664	A.S Harrison & Co Pty Ltd	Chemical in Satacen 3	ND*	≤ 15 tonnes per annum	Fuel additive

*Not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the limited available information, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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

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

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

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

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation processes:
  - Avoid skin 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 chemical during reformulation processes:
  - Protective clothing
  - Impervious gloves
  - Respiratory protection if inhalation exposure may occur

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of 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

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
  - the concentration of the notified chemical exceeds 0.04% in diesel fuel;

or

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

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

Safety Data Sheet
The SDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
A.S Harrison & Co Pty Ltd (ABN: 89 000 030 437)
75 Old Pittwater Road
BROOKVALE NSW 2100

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

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: hydrolysis as a function of pH, dissociation constant, flammability, repeated dose toxicity and chromosome damage *in vitro*.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
Previous permit (NICNAS)

NOTIFICATION IN OTHER COUNTRIES
ECHA (2004), REACH (2010)

2. IDENTITY OF CHEMICAL

MARKETING NAME
Satacen 3 (product containing the notified chemical at ≤ 20% concentration)

MOLECULAR WEIGHT
< 500 g/mol

ANALYTICAL DATA
Reference HPLC spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
> 80 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Red-brown viscous liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -100 °C	Measured
Boiling Point	323.7 °C at 101.3 kPa	Measured
Density	1,197 kg/m^3 at 20 °C	Measured
Vapour Pressure	1.7 × 10^{-8} kPa at 25 °C	Measured
Water Solubility	< 5 x 10^{-5} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	No hydrolysable functionality
Partition Coefficient (n-octanol/water)	log Pow = 4.6 at 20 °C	Measured
Adsorption/Desorption	log Koc = 4.49 ± 0.01 at 22 °C	Measured
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	119 °C	Measured
Flammability	Predicted not flammable	Estimated

Autoignition Temperature	275 °C	Measured
Explosive Properties	Not explosive	Predicted based on chemical structure
Oxidising Properties	Not oxidising	Predicted based on chemical structure

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

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

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

The notified chemical has a flash point of 119 ºC which is greater than 93 °C but less than its boiling point (323.7 ºC). Based on *Australian Standard AS1940* definitions for combustible liquid, the notified chemical may be considered as a Class C2 combustible liquid.

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. The notified chemical will be imported into Australia as a component of a diesel fuel additive package at ≤ 20% concentration.

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

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

PORT OF ENTRY
Melbourne, Sydney, Brisbane and Perth

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a component of a diesel fuel additive package at ≤ 20% concentration in 2.5 L bottles, 28 L pails, 200 L metal drums, 1,000 L intermediate bulk containers (IBCs) or in appropriate ISO intermodal freight containers, and will primarily be transported throughout Australia by rail and road.

USE
The notified chemical will be used as a diesel fuel additive at ≤ 0.04% concentration.

OPERATION DESCRIPTION
Using automated processes and fixed transfer lines the diesel fuel additive package containing the notified chemical at ≤ 20% concentration will be directly injected into the delivery road tanker at the same time as the fuel to which it is being added at refineries and fuel distribution terminals. The injection is volumetric and includes a blending action in a single step resulting in a blended fuel in the delivery tanker that contains the notified chemical at ≤ 0.04% concentration. The fuel will then be transported to service stations for sale to the public.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS

Transport and storage of fuel additive package
Transport and storage workers may come into contact with the notified chemical at ≤ 20% concentration only in the unlikely event of accidental rupture of containers.

Reformulation
Dermal and ocular exposure to the notified chemical at ≤ 20% concentration may occur during reformulation when connecting and disconnecting transfer lines and during sample testing. Dermal and ocular exposure should be mitigated through the stated use by the notifier of personal protective equipment (PPE) including protective clothing, eye protection and impervious gloves.

Transport of fuel
Dermal and ocular exposure to the notified chemical at ≤ 0.04% concentration may occur during transfer of fuel containing the notified chemical to storage tanks at service stations when connecting and disconnecting transfer lines. Given the very low concentration of the notified chemical in the final fuel exposure to the notified chemical will be negligible. Furthermore, exposure is expected to be minimised through the recommended use of appropriate PPE.

End-use
Service station workers and mechanics may experience dermal and possibly ocular exposure to the notified chemical at ≤ 0.04% concentration during vehicle maintenance or in the event of a spill. Given the very low concentration of the notified chemical in the final fuel, exposure to the notified chemical will be negligible.

6.1.2. Public Exposure
The fuel additive package containing the notified chemical at ≤ 20% concentration will not be made available to the public.

The public may experience dermal and possibly ocular exposure to the notified chemical at ≤ 0.04% concentration while pumping fuel containing the notified chemical into fuel tanks at service stations or during vehicle maintenance. Given the very low concentration of the notified chemical in the final fuel, exposure to the notified chemical will be negligible.

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics
Given the low water solubility (< 5×10^{-5} g/L at 20 °C) and high partition coefficient (log Pow = 4.6 at 20 °C) of the notified chemical, dermal absorption is expected to be limited. Due to its low vapour pressure (1.7×10^{-8} kPa at 25 °C), exposure by inhalation is not expected, unless aerosols/mists are formed.

Acute toxicity
The notified chemical was found to be of low acute oral and dermal toxicity in rats.

Irritation and sensitisation
The notified chemical is slightly irritating to the skin and eyes based on studies conducted in rabbits.

In a guinea pig maximisation test the notified chemical was found not to be a skin sensitiser.

Repeated dose toxicity
No studies were submitted for repeated dose toxicity or reproductive/developmental toxicity of the notified chemical.

The product containing the notified chemical has been classified for reproductive toxicity (Reproductive Category 1B, H360FD) and systemic toxicity (Specific target organ toxicity – repeated exposure, Category 2, H373) on the supplied SDS based on the results from an analogue chemical. However, no information or toxicity studies on the analogue chemical were provided to support these classifications.

Mutagenicity
The notified chemical was negative in a bacterial reverse mutation assay.

Health hazard classification
Based on the limited available information, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the toxicological information provided, the notified chemical may present as a slight skin and eye irritant. No repeat dose toxicity data of the notified chemical was provided. Based on an analogue chemical the notified chemical may have concerns for reproductive and systemic toxicity.

Reformulation
During reformulation, workers may be exposed to the notified chemical at ≤ 20% concentration. At the proposed use concentration, significant irritation effects are not expected.

The expected low vapour pressure of the notified chemical is expected to reduce the likelihood of inhalation exposure, and aerosols/mists are not expected to be generated during the reformulation process. Furthermore, reformulation is likely to be conducted in outdoor areas. The notifier states the risk to reformulation workers will be minimised through the use of PPE (coveralls, impervious gloves and safety glasses) and engineering controls (enclosed automated processes and adequate ventilation). Respiratory protection is expected to be used in places with poor ventilation.

End-use
Service station workers and mechanics may experience dermal and possibly ocular exposure to the notified chemical at ≤ 0.04% concentration during vehicle maintenance or in the event of a spill. Given the very low concentration of the notified chemical in the final fuel, exposure to the notified chemical will be negligible.

Therefore, provided the stated control measures are in place to minimise exposure to the notified chemical during reformulation processes, the risk to the health of workers from use of the notified chemical as described is not expected to be unreasonable.

6.3.2. Public Health
The public may experience dermal and possibly ocular exposure to the notified chemical at ≤ 0.04% concentration while pumping fuel containing the notified chemical into fuel tanks at service stations or during vehicle maintenance.

Given the very low concentration of the notified chemical in the final fuel, exposure to the notified chemical will be negligible. Therefore, when used in the proposed manner, the notified chemical is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported into Australia for use as an additive in diesel fuel. No significant release of the notified chemical is expected from transportation and storage.

Using automated processes and fixed transfer lines the diesel fuel additive package containing the notified chemical will be directly injected into the delivery road tanker. The injection is volumetric and includes a blending action in a single step resulting in a blended fuel in the delivery tanker. The fuel will then be transported to service stations for sale to the public.

RELEASE OF CHEMICAL FROM USE
When used as an additive in diesel fuel, the majority of the notified chemical will be consumed during the combustion of the fuel by vehicles or machinery.

RELEASE OF CHEMICAL FROM DISPOSAL
Accidental leaks and spillages is expected to be cleaned up promptly with absorbents and put into containers for disposal. Import containers, such as ISO tanks, IBCs and drums, are anticipated to be sent for cleaning and reconditioning by a licensed company. The resultant washings from such companies are typically passed to an on-site waste treatment facility and any waste sludge is likely to be sent to landfill.

7.1.2. Environmental Fate
Most of the notified chemical in diesel fuel will be consumed and thermally decomposed during use.

Minor amounts of the notified chemical are expected to be disposed of to landfill as residues in containers or collected waste. Given that the notified chemical has high log Koc (4.49) and its low water solubility, the notified chemical sent to landfill is expected to be immobile. Based on the biodegradability, the notified chemical is not expected to be readily biodegradable (3% in 28 days for the analogue). In landfill, the notified chemical is expected to eventually degrade via abiotic and biotic processes to form water and oxides of carbon and iron. Details of the environmental fate studies can be found in Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)
As significant aquatic exposure is not expected at any stage of the notified chemical's life-cycle within Australia, the predicted environmental concentration (PEC) has not been calculated.

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 > 0.45 mg/L	Not harmful to fish up to its water solubility limit
Daphnia Toxicity	EC50 > 0.36 mg/L	Not harmful to aquatic invertebrates up to its water solubility limit
Algal Toxicity	EC50 > 0.36 mg/L	Not harmful to algae up to its water solubility limit
Inhibition of Bacterial Respiration	EC50 > 1000 mg/L	Not inhibitory to bacterial respiration

It is concluded that the notified chemical is not expected to be harmful to aquatic life up to the limit of its solubility in water. Therefore, the notified chemical is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) for acute and chronic effects.

7.2.1. Predicted No-Effect Concentration
The predicted environmental concentration (PEC) has not been calculated, as significant release of the notified chemical to the aquatic environment is not expected, based on its reported use as a fuel additive.

7.3. Environmental Risk Assessment
The calculation of the Risk Quotient (Q = PEC/PNEC) was not possible as the PEC and PNEC were not calculated. The notified chemical is not expected to pose an unreasonable risk to the environment based on the

assessed use pattern indicating low potential for release to the aquatic environment, and the absence of any observed ecotoxicological effects to aquatic organisms.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point < -100 °C

Method	OECD TG 102 Melting point/melting range
Remarks	Determined using differential scanning calorimetry. No endothermic effects, at -100 to 50 °C, or exothermic effects, at 25 to -100 °C, were observed.
Test Facility	Siemens (2004a)

Boiling Point 323.7 °C at 101.3 kPa

Method	OECD TG 103 Boiling Point (adopted July 1995)
Remarks	Capillary tube method
Test Facility	LAB (2004a)

Density 1,197 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids
Remarks	Determined using a gas comparison pycnometer
Test Facility	LAB (2004b)

Vapour Pressure 1.7×10^{-8} kPa at 25 °C

Method	OECD TG 104 Vapour Pressure
Remarks	Effusion method
Test Facility	Siemens (2004b)

Water Solubility < 0.05 g/L at 20 °C

Method	OECD TG 105 Water Solubility EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	The water solubility of the test substance was estimated to be below 0.01 g/L in a preliminary test and therefore the column elution method was used in the main test. The saturation concentration of the test item was below the quantification limit of the test item (LOD: 0.05 mg/L). Therefore, the water solubility of the test substance was determined to be below 0.05 mg/L at 20 °C ± 1.
Test Facility	LAB (2004c)

Partition Coefficient (n-octanol/water) log Pow = 4.6 ± 0.18 at 22 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	Flask Method
Test Facility	LAB (2004d)

Adsorption/Desorption log K_{oc} = 4.49 ± 0.01 at 22 °C

Method	OECD TG 121 Estimation of the Adsorption Coefficient on Soil and on Sewage sludge using HPLC.
Remarks	The log Koc obtained in the first experiment was 4.49 ± 0.01. Since the peak identification for the test substance was not unambiguous due to further peaks appearing in the chromatogram, a confirmatory experiment was performed using different eluent composition and more concentrated test substance solution were used in order to confirm the identity of the relevant HPLC peak. The result of the confirmatory experiment does not deviate significantly from the result of the first experiment. Therefore, the log Koc obtained in the first experiment (4.49 ± 0.01) was considered to be valid.
Test Facility	LAB (2004e)

Flash Point 119 °C

Method	EEC Directive 92/69 Annex V A.9 Flash Point
Remarks	Closed cup method
Test Facility	LAB (2004f)

Autoignition Temperature 275 °C

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases)
Test Facility	LAB (2004g)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical (84.3% purity)

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method
- Species/Strain: Rat/CRL (WI) BR Wistar rats
- Vehicle: Sunflower oil
- Remarks - Method: No protocol deviations.

RESULTS

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

- LD50: > 2,000 mg/kg bw
- Signs of Toxicity: Slight to moderate reduction in activity, hunchback posture, piloerection and increased respiration rate were observed in all treated animals at the 1 hour observation. Symptoms persisted in all animals at the day 1 observation and all signs of toxicity were resolved at the day 2 observation.
- Effects in Organs: At necropsy slight (grade 1) pulmonary emphysema was observed in lungs in all treated animals. The study authors claimed this effect was not substance related and may be due to the method of anaesthesia. Two treated animals also showed slight (grade 1) hydrometra in uterus. The study authors state this condition sporadically occurs in experimental rats.
- Remarks - Results: The body weight gain of the treated animals was normal throughout the duration of the study.

CONCLUSION: The notified chemical is of low acute toxicity via the oral route.

TEST FACILITY: LAB (2004h)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified chemical (84.3% purity)

METHOD: OECD TG 402 Acute Dermal Toxicity
- Species/Strain: Rat/CRL (WI) BR Wistar rats
- Vehicle: None
- Type of dressing: Semi-occlusive
- Remarks - Method: No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5M/5F	2,000	0/10

- LD50: > 2,000 mg/kg bw
- Signs of Toxicity - Local: No dermal irritation was observed.
- Signs of Toxicity - Systemic: No systemic toxicity was observed.
- Effects in Organs: During necropsy, slight (grade 1) pulmonary emphysema in lungs was observed in two males and three females and haemorrhage in lungs was observed in three males and two females. The study authors claimed that these effects were not test substance related and probably due to the method of anaesthesia.

  Slight hydrometra was observed in uterus in one female. The study authors

	state this condition was sporadically observed in experimental rats.
Remarks - Results	All animals showed expected body weight gain during the study.
CONCLUSION	The notified chemical is of low acute toxicity via the dermal route.
TEST FACILITY	LAB (2004i)

B.3. Irritation – skin

TEST SUBSTANCE	Notified chemical (84.3% purity)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion
Species/Strain	Rabbit/New Zealand White
Number of Animals	3M
Vehicle	None
Observation Period	72 hours
Type of Dressing	Occlusive
Remarks - Method	No protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1.0	0.7	0.3	3	< 72 h	0
Oedema	0.0	0.0	0.0	1	< 24 h	0

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

Remarks - Results	No mortality occurred during the study period. Moderate to severe erythema (grade 3) was observed in two animals and well defined erythema (grade 2) was observed in one animal at the 1 hour observation. These effects were resolved by 48 hours in two animals and by 72 hours in the other animal. Very slight (barely perceptible) oedema was observed in two animals at the 1 hour observation and the symptom was resolved at the 24 hour observation. No abnormal body weight changes were observed during the study.
CONCLUSION	The notified chemical is slightly irritating to the skin.
TEST FACILITY	LAB (2004j)

B.4. Irritation – eye

TEST SUBSTANCE	Notified chemical (84.3% purity)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion
Species/Strain	Rabbit/New Zealand White
Number of Animals	3M
Observation Period	72 hours
Remarks - Method	No protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.3	1.0	1.3	2.0	< 72 h	0.0
Conjunctiva: chemosis	0.0	0.0	0.0	1.0	< 24 h	0.0
Conjunctiva: discharge	0.3	0.7	0.3	3.0	< 48 h	0.0
Corneal opacity	0.0	0.3	0.3	1.0	< 48 h	0.0
Iridial inflammation	0.0	0.0	0.0	0.0	-	0.0

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

Remarks - Results

At the 1 hour observation, all treated animals showed moderate (grade 2) reddening of the conjunctiva. Slight (in one animal) to moderate (in two animals) reddening of the conjunctiva persisted in all animals at the 24 hour observation. At the 48 hour observation, one animal showed slight and another animal showed moderate reddening of conjunctiva. No signs of conjunctival redness were observed at the 72 hour observation.

Slight (grade 1) chemosis was observed in all treated animals at the 1 hour observation which was resolved at the 24 hour observation.

Severe (grade 3, two animals) to moderate (grade 2, one animal) ocular discharge was observed at the 1 hour observation. At the 24 hour observation, slight (in two animals) to moderate (in one animal) ocular discharge was observed. No ocular discharge was observed at the subsequent observations.

Slight (grade 1) corneal opacity was observed in all treated animals at the 1 hour observation which persisted in two animals at the 24 hour observation. No signs of corneal opacity were observed at the 48 hour observation.

No iridial effects were observed at any of the observation period.

All signs of irritation were resolved at the 72 hour observation.

No abnormal body weight changes were observed during the study. No unscheduled mortality or clinical signs of systemic toxicity was observed.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY LAB (2004k)

B.5. Skin sensitisation – Guinea Pig Maximisation Test

TEST SUBSTANCE Notified chemical (84.3% purity)

METHOD OECD TG 406 Skin Sensitisation – Magnusson-Kligman Method

Species/Strain Guinea pig/Dunkin Hartley

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 0.1%
topical: 100%

MAIN STUDY

Number of Animals Test Group: 10M Control Group: 5M

Vehicle For intradermal induction, the test substance was diluted in sunflower oil. For topical induction and challenge, undiluted test substance was used. Sunflower oil was used for control animals.

Positive control Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using potassium dichromate.

INDUCTION PHASE	Induction Concentration: intradermal: 5% topical: 100%
Signs of Irritation	Not stated
CHALLENGE PHASE	
1st challenge	topical: 100%
Remarks - Method	10% sodium lauryl sulphate in vaseline (0.5 mL) was applied to all animals 24 hours prior to topical induction. No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st Challenge		*2nd Challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	0/10	0/10	Not conducted	Not conducted
Control Group	100%	0/5	0/5	Not conducted	Not conducted

Remarks - Results	No death and no clinical signs of systemic toxicity were observed in the animals during the study. No skin reaction was observed in either treated or control animals. The positive control animals gave satisfactory response confirming the validity of the test.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	LAB (2004l)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical (84.3% purity)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test
Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA100, TA98 *Escherichia coli*: WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 31.62, 100, 316.2, 1,000, 2,500 and 5,000 µg/plate b) Without metabolic activation: 31.62, 100, 316.2, 1,000, 2,500 and 5,000 µg/plate
Vehicle	Acetone
Remarks - Method	A preliminary test at a concentration range of 3.162 to 5,000 µg/plate (with or without metabolic activation) was conducted on TA98 and TA100. The plate incorporation method was used for the preliminary toxicity test and initial mutation test (test 1) and pre-incubation method was used for the confirmatory mutation test (test 2). Negative control: acetone and distilled water Positive control: With metabolic activation: 2-aminoanthracene (TA98, TA100, TA1535, TA1537 and WP2uvrA) Without metabolic activation: sodium azide (TA100 and TA1535), 9-aminoacridine (TA1537), 4-nitro-o-

phenylenediamine (TA98) and methyl methanesulfonate (WP2uvrA)

No significant protocol deviations.

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 was observed, however, micro-drops were observed at 2,500 and 5,000 µg/plate (both with or without metabolic activation) in the preliminary test, test 1 and test 2. The study authors claim this effect was due to the colloidal nature of the test substance.

In both tests, no signs of toxicity towards the tested strains could be observed. The background lawn was visible and the number of revertant colonies was not substantially reduced.

No substantial increase in revertant colony numbers of any of the five tester strains was observed following treatment with the test substance at any dose level, with or without metabolic activation. There were also no dose dependent increases in mutation rates.

The positive controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION

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

TEST FACILITY

LAB (2004m)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical Oxygen Demand (BOD)
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Test Substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	1	7	51
14	2	14	73
21	4	21	77
28	3	28	82

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound, sodium acetate, surpassed the threshold level by 14 days, therefore, the test indicates the suitability of the inoculum. The percentage degradation of the toxicity control reached the threshold level of 26% by 14 days (28% in 28 days), showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The mean biodegradation of test substance was 3% during the 28 days period. The test substance is therefore not considered to be readily biodegradable
CONCLUSION	The test substance is not readily biodegradable.
TEST FACILITY	LAB (2004n)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi static
Species	*Brachydanio rerio* (Zebrafish)
Exposure Period	96 hours
Auxiliary Solvent	Acetone
Water Hardness	178.3 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	A limit test was performed in accordance with the guidelines to demonstrate that the test substance has no toxic effect on the test fish up to the nominal concentration of 0.5 mg/L. Test fish were exposed in a semi-static test (with 24 hour water renewal periods) to aqueous test media containing the test substance at a nominal concentration of 0.5 mg/L (measured 0.45 mg/L). 100 mg test substance was dissolved in 25 mL acetone and this solution was dispersed homogeneously into ~5 litre test water by intense stirring to

make the stock solution. The test concentration of nominal 0.5 mg/L of the notified chemical was prepared by dilution of this stock solution.

RESULTS

Concentration (mg/L)		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control		7	0	0	0	0
Solvent control		7	0	0	0	0
0.5	> 0.45	7	0	0	0	0

LC50 > 0.45 mg/L at 96 hours

Remarks – Results Oxygen saturation was always > 90%. All validity criteria were met.

The test substance concentrations in the analysed test media varied in the range from 76% to 106% of the nominal concentration, thus greater than 20% deviation from the nominal concentration during the test. Therefore, all reported biological results are based on the mean measured concentrations (0.45 mg/L) of the test substance.

CONCLUSION The test substance is not harmful to fish up to its limit of water solubility.

TEST FACILITY LAB (2004o)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Semi - static

Species *Daphnia magna*

Exposure Period 48 hours

Auxiliary Solvent Acetone

Water Hardness 168.4 mg $CaCO_3$/L

Analytical Monitoring HPLC

Remarks - Method A limit test was performed with a nominal test substance concentration of 0.5 mg/L. This concentration level was above the water-solubility of test substance in pure water (< 0.05 mg/L). A semi-static test method was used, because the test substance concentration was not stable during the 48-hour static pre-test. Daphnia were exposed in a semi-static test (with 24 hour water renewal periods) to aqueous test media containing the test substance at a nominal concentration of 0.5 mg/L (actual concentration: 0.36 mg/L).

100 mg test substance was dissolved in 25 mL acetone and this solution was dispersed homogeneously into ~5 L test water by intense stirring to make the stock solution. The nominal test concentration of 0.5 mg/L of the notified chemical was prepared by dilution of this stock solution.

RESULTS

Concentration (mg/L)		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control		20	0	0
Solvent control		20	0	0
0.5	> 0.36	20	0	0

EC50 > 0.36 mg/L at 48 hours

Remarks - Results All validity criteria met. The oxygen saturation was always > 60%

satisfying the requirement that it is greater than 3 mg/L [≡ 33% oxygen saturation in fresh water at 20.1°C (U.S. Geological Survey, 2011)].

The test substance concentrations in the analysed test media varied from 60% to 83% of the nominal concentration thus greater than 20% deviation from the nominal concentration during the test. Therefore, all reported biological results are based on the mean measured concentrations (0.36 mg/L) of the test substance.

CONCLUSION The test substance is not harmful to aquatic invertebrates up to its limit of water solubility.

TEST FACILITY LAB (2004p)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test

Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 0.5 mg/L Actual: 0.36 mg/L
Auxiliary Solvent	Acetone
Water Hardness	Not given
Analytical Monitoring	HPLC
Remarks - Method	A limit test was performed with a nominal test substance concentration of 0.5 mg/L. This concentration level was above the water-solubility of test substance in pure water (< 0.05 mg/L). 100 mg test substance was dissolved in 25 mL acetone and this solution was dispersed homogeneously into ~1 L test water by intense stirring to make the stock solution. The test concentration of nominal 0.5 mg/L of the test substance was prepared by dilution of this stock solution. A toxicity control ($K_2Cr_2O_7$) was run less than six months prior to the current study.

RESULTS

Biomass		*Growth*	
E_bC50	*NOEC*	*E_rC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
> 0.36	ND	> 0.36	ND

Remarks - Results The experiment is valid because the cell density in the control cultures increased by a factor of 47.0 within 72 hours and the algae in the control media showed exponential growth throughout the duration of the test.

The test substance concentrations in the analysed test media varied from 71% to 73% of the nominal concentration. The deviation from the nominal value was greater than 20% during the test. Therefore, all reported biological results are based on the mean measured concentrations (> 0.36 mg/L) of the test substance. The 72 h ErC50 for the toxicity control was 0.86 mg/L.

CONCLUSION The test substance is not harmful to algae limit of water solubility.

TEST FACILITY LAB (2004q)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test
Inoculum	
Exposure Period	3 hours
Concentration Range	Nominal:10, 32, 100, 320, and 1000 mg/L
Remarks – Method	The test was conducted according to the test guideline above with no significant deviation from the protocol
RESULTS	
EC50	> 1000 mg/L
Remarks – Results	All validity criteria for the test are satisfied. The respiration rates of the two controls differed by 1.8%. The 3-hour EC 50 of the reference item 3,5-Dichlorophenol was determined to be 8.5 mg/L. The measured concentration of dissolved oxygen was 2.6.
CONCLUSION	The test substance is not inhibitory to micro-organisms respiration.
TEST FACILITY	LAB (2004r)

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