File No: STD/1482

November 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

EnviroGem 360 Surfactant

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

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

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

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

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/1482	IMCD Australia Limited	EnviroGem 360 Surfactant	Yes	< 5 tonnes per annum	Component of paints

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Eye Irritation (Category 2)	H319 – Causes serious eye irritation
Skin Irritation (Category 2)	H315 – Causes skin irritation
Skin Sensitisation (Category 1)	H317 – May cause an allergic skin reaction

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

R36 Irritating to eyes
R38 Irritating to skin
R43 May cause sensitisation by skin contact

The environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute (Category 2)	H401 - Toxic to aquatic life
Chronic (Category 2)	H411 - Toxic to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended occupational health and safety control measures are being adhered to, under 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 PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Eye Irritation (Category 2): H319 – Causes serious eye irritation

- Skin Irritation (Category 2): H315 – Causes skin irritation
- Skin Sensitisation (Category 1): H317 – May cause an allergic skin reaction

Health Surveillance

- As the notified chemical is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

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:
  - Enclosed, automated processes, where possible
  - Adequate 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:
  - Avoid contact with skin and eyes
  - Avoid inhalation of aerosol

- 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:
  - Protective clothing
  - Impervious gloves
  - Safety glasses

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.

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

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

Disposal

- The notified chemical should be disposed of to landfill.

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

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 chemical is proposed to exceed 1% concentration in paint products;

or

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

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

No additional secondary notification conditions are stipulated.

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

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS and the Department of the Environment.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
IMCD Australia Limited (ABN: 44 000 005 578)
Level 1, 372 Wellington Road
MULGRAVE VIC 3170

NOTIFICATION CATEGORY
Standard (reduced fee notification): 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, analytical data, degree of purity, impurities, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: dissociation constant, flammability and acute inhalation toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2012)
USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
EnviroGem 360 Surfactant

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference NMR, FTIR, UV-Vis and GC-MS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 ºC AND 101.3 kPa: Light yellow liquid

Property	Value	Data Source/Justification
Freezing Point	8 °C	Measured (Directive 92/69/EEC A1)
Boiling Point	355 °C	Measured (Directive 92/69/EEC A2)
Density	1010 kg/m^3 at 20 °C	Measured (Directive 92/69/EEC A3)
Vapour Pressure	6.4 × 10^{-7} kPa at 25 °C	Measured (Directive 92/69/EEC A4)
Surface Tension	31.4 mN/m at 21 °C	Measured (Directive 92/69/EEC A5)

Water Solubility	0.643 g/L at 20 °C	Measured (Directive 92/69/EEC A6)
Hydrolysis as a Function of pH	t½ > 1 year at 25 °C pH (4 – 7) t½ = ~1 year at pH 9	Measured (Directive 92/69/EEC C7)
Partition Coefficient (n-octanol/water)	Log K_{ow} = 3.66	Measured (Directive 92/69/EEC A8)
Adsorption/Desorption	Log K_{oc} = 2.77	Measured (Directive 2001/59/EC C19)
Dissociation Constant	Not determined	Does not contain dissociable functionalities.
Flash Point	175 °C at 101.3 kPa (closed cup)	Measured (Directive 92/69/EEC A9)
Flammability	Not expected to be highly flammable	Based on measured flash point
Autoignition Temperature	254 °C	Measured (Directive 92/69/EEC A15)
Explosive Properties	Predicted negative	Measured (Directive 92/69/EEC A14)
Oxidising Properties	Predicted negative	Measured (Directive 92/69/EEC Draft A21)

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties that have not been assessed by Canada, 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 for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported as a liquid in the neat form at > 99% concentration.

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

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

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The notified chemical will be imported into Australia in 200 L plastic drums and stored in original containers within a bunded warehouse prior to reformulation.

USE
The notified chemical will be used as a component of water-based paints at < 1% concentration.

OPERATION DESCRIPTION

Reformulation
At a typical reformulation site, the notified chemical (> 99% concentration) will be transferred from the import container or intermediate bulk container to a measuring bucket using drum taps or drum pumps, followed by transfer into an open-tank mixer for mixing with other substances. The finished paints (containing < 1% notified chemical) will be dispensed from the mixing tank via the tap to paint cans for end-use. Manual handling is expected to occur for the majority of reformulation/packaging operations performed. However, closed and/or automated systems may be used in some or all of the steps at some reformulation sites.

End-use
The finished paints containing the notified chemical at < 1% concentration will be used by professional painters and do-it-yourself (DIY) users. Professional painters will likely apply the paint by roller and spray whereas the DIY users are expected to primarily use brush or roller.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport (2 personnel)	6	2
Mixing operations (2 personnel)	4	10
QA sampler/tester (2 personnel)	2	10
Vessel cleaner (2 personnel)	6	10
Professional end-users	8	200

EXPOSURE DETAILS
Transport and storage workers may come into contact with the notified chemical (> 99%% concentration) or as a component of paints products (< 1% concentration) only in the event of accidental rupture of containers.

Reformulation will be typically manual. Workers may be exposed (dermal and ocular) to the notified chemical at up to 99% concentration during transfer to the mixing vessel, and at up to 1% concentration during packing off. Service technicians and quality control staff may come into contact with the notified chemical at up to 99% concentration during equipment maintenance and quality control analysis, respectively.

Dermal and ocular exposure to workers should be mitigated through the use of personal protective equipment (PPE) including protective coveralls, impervious gloves and goggles. Inhalation exposure is not expected given the low vapour pressure of the notified chemical unless aerosols are formed.

End-use
Professional painters may be exposed (dermal and ocular) to the notified chemical at < 1% concentration during application of the finished paints. Dermal and ocular exposure should be mitigated through the use of PPE including coveralls, gloves and goggles. Inhalation exposure is expected to be negligible given that the notified chemical has a low vapour pressure and is present at a low concentration in consumer paints. In addition, in applications by spray, inhalation should be further minimised by the use of respiratory protection.

Once the paints are dried, the notified chemical will be bound within a polymer matrix and will not be available for exposure.

6.1.2. Public Exposure
The general public may be exposed (dermal and ocular) to the notified chemical at < 1% concentration during application of the finished paints by brush or roller. Inhalation exposure is expected to be negligible given that the notified chemical has a low vapour pressure and is present at a low concentration in consumer paints. Spray application by members of the public is only expected to occur infrequently.

The general public may also come into contact with paints containing the notified chemical at < 1% concentration after application to surfaces. However, once the paints are dried, the notified chemical will be bound within a paint matrix and will not be available for exposure.

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the notified chemical are summarised in the following table.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity

Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation – adjuvant test	limited evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOEL = 150 mg/kg/day NOAEL = 1000 mg/kg/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration	non genotoxic

Acute Toxicity
Acute oral and dermal toxicity studies were carried out using the notified chemical in rats. The notified chemical displayed low toxicity (LD50 > 2000 mg/kg bw) in both studies and no adverse clinical signs were noted in either study.

Inhalation data was not provided.

Irritation
The notified chemical was tested for ocular and dermal irritation. In the dermal irritation study, rabbits were dosed with 0.5 mL notified chemical (undiluted) on the back for 3 minutes, 1 hour, and 4 hours under semi-occlusive bandages. Results indicated that following the 1 and 4 hour exposures, animals exhibited minimal to well-defined irritation that lasted until 72 hours following patch removal. Based on the results of this study, the notified chemical is irritating to the skin.

In the eye irritation study, rabbits were exposed to 0.1 mL undiluted notified chemical instilled in one eye. Following the single exposure, corneal opacity, iritis, and conjunctival irritation were noted in all animals. All signs had cleared by the end of the 14 day observation period. Based on the results of this study, the notified chemical is irritating to the eye.

Sensitisation
In a Magnusson-Kligman assay, 10 male and 10 female guinea pigs received intradermal inductions consisting of paired injections of 50% Freund's Complete Adjuvant (FCA) in water, 1% notified chemical in corn oil, and a mixture of 50% FCA and 1% notified chemical. Control animals (5 of each sex) received the similar treatment with vehicle in place of the notified chemical. Seven days following the intradermal inductions, all animals received pretreatment with 10% sodium lauryl sulfate to induce irritation, and then topical induction with 0.2 mL notified chemical (control animals received vehicle instead). Test sites were occluded for 48 hours. Two weeks after the topical induction both control and test animals received two separate topical challenges; 0.1 mL of 50% notified chemical to one flank, and vehicle to the opposite flank. Both areas were occluded for 24 hours. Test sites were evaluated 24 and 48 hours after intradermal induction, immediately following removal of topical induction patches, and 24 and 48 hours after removal of challenge patches. Results indicated that following intradermal induction, both control and test animals exhibited erythema that ranged from absent to moderate. Following topical induction, both control and test animals exhibited erythema that ranged from absent to intense. Following the challenge, control animals exhibited no signs of erythema at either the test substance site or the vehicle site. Ten per cent (2/20; one male/one female) test animals exhibited signs of erythema at the test substance site. No signs of erythema were noted in test animals at the vehicle site. Based on these results, there is limited evidence of sensitisation by the notified chemical.

In a local lymph node assay, groups of 5 mice were treated with the notified chemical at concentrations of 10%, 25%, or 50% v/v in dimethyl formamide. Mice received daily application of 25 µL of the notified chemical to the dorsal surface of each ear for three consecutive days. A further group of 5 mice received the vehicle alone in the same manner. Five days following the first topical application, all mice were injected via the tail vein with 250 µl of phosphate buffered saline containing ^{3}HTdR, giving a total of 20 µCi to each animal. Five hours following the administration of ^{3}HTdR all mice were asphyxiated and the draining auricular lymph nodes were excised and processed. ^{3}HTdR incorporation was measured by β-scintillation counting. Stimulation indices for each dose group were calculated as follows: 10% dose group SI = 1.02, 25% dose group SI = 2.36, 50% dose group SI = 5.06. The EC3 value was calculated to be 31%, indicative of a weak sensitizer.

Repeated Dose Oral Toxicity
A 28-day repeated dose oral toxicity study was performed using 4 groups of Sprague Dawley rats (5 rats/dose/sex, plus an additional 5 rats of each sex, in each of the control and high dose groups to serve as

recovery groups). The notified chemical was administered by daily gavage for 28 days at doses of 0, 25, 150, and 1000 mg/kg bw/day, dissolved in arachis oil BP. Following the 28 day treatment period, all animals were sacrificed except those in the control and high dose recovery groups, which were left untreated for a further 14 days.

Clinical Signs: Noisy respiration, increased salivation immediately after dosing, and generalised red/brown staining of the external body surface were noted during the treatment period in all high-dose animals.

Body Weight, Food & Water Consumption: No effects were observed in any dose group.

Clinical Chemistry: Decreased bilirubin was noted in high-dose males. Increased total protein, albumin, and cholesterol were noted in high-dose females.

Organ Weights: Elevated liver weights were noted in all high-dose animals. High-dose females also showed increased kidney weights.

Necropsy: No toxicologically significant macroscopic abnormalities were noted.

Histopathology: In the liver, treatment-related centrilobular hepatocyte enlargement was noted in high-dose animals; this effect was found to be reversible following the 14-day recovery period. Treatment-related thyroid follicular cell hypertrophy was noted in high-dose females; this effect was also reversible following the 14-day recovery period. The reversibility of the effects indicated that they were adaptive in nature.

Administration of the notified chemical resulted in treatment-related effects at 1000 mg/kg bw/day. As all treatment-related effects observed were considered to be adaptive in nature, the No Observed Adverse Effect Level (NOAEL) was determined to be 1000 mg/kg bw/day, and the No Observed Effect Level was determined to be 150 mg/kg bw/day. The notified chemical displayed low repeated dose toxicity in rats.

Genotoxicity
In an Ames assay, *S. typhimurium* strains TA98, TA100, TA1535, and TA1537, and *E. coli* strain WP2uvrA were exposed to varying concentrations (ranging from 5 - 5000 μg/plate) of the notified chemical in the presence and absence of metabolic activation. The plate incorporation method was used. No significant increase in the frequency of revertant colonies was noted for any strain at any of the dose levels, in either the presence or absence of metabolic activation. It was determined that the notified chemical does not display *in vitro* mutagenic potential.

In a chromosome aberration assay, Chinese Hamster cells were exposed to concentrations of the notified chemical ranging from 20.63 - 82.5 μg/plate in both the presence and absence of metabolic activation. Two separate experiments were carried out, with exposure times of either 6 or 24 hours, both with a total incubation time of 24 hours. No statistically significant increases in the frequency of aberrations were noted in either experiment in the presence or absence of metabolic activation. The notified chemical was determined to be non-clastogenic *in vitro*.

Health hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Eye Irritation (Category 2)	H319 – Causes serious eye irritation
Skin Irritation (Category 2)	H315 – Causes skin irritation
Skin Sensitisation (Category 1)	H317 – May cause an allergic skin reaction

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

R36: Irritating to eyes.
R38: Irritating to skin.
R43: May cause sensitisation by skin contact.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified chemical is irritating to the skin and eye and is a weak skin sensitiser.

Reformulation

Reformulation workers may be at risk of irritating and skin sensitising effects when handling the notified chemical as introduced at > 99% concentration. However, the risk is expected to be minimised by the use of appropriate PPE including coveralls, impervious gloves, and eye protection. In addition, the risk will be further minimised in cases where enclosed and automated processes are used during reformulation.

Provided control measures are in place to limit exposure, the risk to the health of reformulation workers is not considered to be unreasonable.

End-use

Professional painters may be exposed to the notified chemical at < 1% concentration during application of paints by brush, roller and spray. However, given the relatively low concentration of the notified chemical in paint products and the expected use of PPE including respiratory protection during spray operations, the risk to the health of professional painters from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

The general public may be exposed to the notified chemical at < 1% concentration during application of paints by brush, roller and possibly spray. However, given the infrequent exposure and the relatively low concentration of the notified chemical in paint products, the risk to the public from use of the notified chemical is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia; however, the imported notified chemical will be reformulated in a fully bunded facility. Therefore, the release from reformulation is expected to be limited. Accidental spills and leaks, container residues and waste water from equipment washings (0.5% of the imported volume) of the notified chemical are expected to be contained in a storage pit to be collected by a licensed waste contractor or disposed of to landfill. Equipment washings will be collected and reused in subsequent batches if possible.

RELEASE OF CHEMICAL FROM USE

The release of the notified chemical during end-use by professional and DIY users is expected as a result from overspray (0.6% of the total volume) and spills and leaks (0.5% of the import volume). Spills and overspray are expected to be collected with absorbent material. The collected wastes and empty containers are expected to be disposed of to landfill. It is estimated by the notifier that up to 2% of the import volume of the notified chemical is expected to be released to sewer during end-use from the washing of application equipment.

RELEASE OF CHEMICAL FROM DISPOSAL

Discarded end use articles containing the notified chemical within the cured paint film and residues in the containers are expected to be disposed of to landfill.

7.1.2. Environmental Fate

The notified chemical is expected to enter landfill as collected wastes and residues as well as with the substrates to which the product containing the notified chemical is applied. The majority of the notified chemical is expected to be cured within an inert matrix adhering to articles following its use in coating applications. Notified chemical that is disposed of to landfill is expected to remain associated with the substrate to which it has been applied. In its cured form it is not expected to be mobile, bioavailable or biodegradable.

Three studies for ready biodegradation (OECD 301F – Manometric Respiratory Test) were submitted. Two of the tests were completed by RCC Ltd. (“test 1” and “test 2”), while the third one was completed by SafePharm

Laboratories ("test 3"). In test 2 and test 3, the notified chemical was first adsorbed onto silica gel then dispersed into the test medium, which yielded biodegradation of 70 and 45% respectively. A reasoning for the differences between the test results of test 2 and test 3 was not provided. In test 1, the notified chemical was dissolved in water directly through sonication, which yielded a biodegradation of 62%. A ready biodegradation test conducted according to OECD 301B – CO_2 Evolution test guideline was also submitted. According to the test result the notified chemical achieved a biodegradation level of 70.7% over 41 days. In addition, a biodegradation test conducted according to Yakushokuhatsu No.1121002, Heisei 15.11.13 Seikyoku No. 2, Kanpokihatsu No. 031121002 guideline was provided. The test showed a biodegradation of 50% over 28 days. Based on the report, the author predicted three possible structures for the degraded substance and also suggested that it is likely that the products were degraded further into other products.

For the sample to be considered readily biodegradable the sample must have degraded more than 60 % in a 10-day window after reaching a degradation level of 10 %. Based on the criteria set out in the ready biodegradability test, all of the tests provided didn't meet the criteria for ready biodegradability; however, the notified chemical is considered inherently biodegradable due to the high % degradation.

In addition, a sea water biodegradation (OECD 306) test was also provided. This test is not a ready biodegradation study but does give an indication of the substance stability in sea water. It is reported that the notified chemical reached a biodegradation level of 70% over 28 days.

Based on the biodegradability studies of the notified chemical, it is not classified as ready biodegradable. However, it has a potential to degrade in the aquatic environment. The notified chemical has a low log Kow value of 3.66. Additionally, the notified chemical is a surfactant, which suggests that the notified chemical is not expected to bioaccumulate. It has a tendency to sorb to surface boundaries based on its surface activity. Therefore, a significant portion of the notified chemical is expected to partition to sludge during waste water treatment processes in sewage treatment plants (STPs). The notified chemical that is released to surface waters in the treated effluent is expected to partition to suspended solids and disperse. Hence, the notified chemical is not expected to be significantly bioavailable in the aquatic environment. Ultimately, the notified chemical is expected to degrade via biotic and abiotic processes in the surface waters to form water and oxides of carbon and sulphur.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. Based on the reported use in paints for professional and DIY users, a conservative release of 5% from equipment washings is assumed to be released to sewer on a nationwide basis over 365 days per year. It is also conservatively assumed that 0% of the notified chemical is removed from influent during STP processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	250	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.68	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.15	µg/L
PEC - Ocean:	0.02	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 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.15 µg/L may potentially result in a soil concentration of approximately 1.0 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 5.0 µg/kg and 10.1 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. For full details of the inhibition of microbial activity study, refer to Appendix C.

Endpoint	Result	Test Method	Assessment Conclusion
Fish			
Fresh Water, Carp	LC50 (96 h) = 5.4 mg/L*	OECD 203	Toxic to fish
Marine, Sheephead Minnow	LC50 (96 h) = 8.6 mg/L**	PARCOM 1995 – Part B	
Daphnia			
Daphnia (Study 1)	LL50 (48 h) = 7.6 mg/L**	EPA 821-R-02-012	Toxic to aquatic invertebrates
Daphnia (Study 2)	EC50 (48 h) = 25 mg/L[#]	OECD 202	Harmful to aquatic invertebrates
Algae			
Fresh Water Algae	E_rC50 (72 h) = 13 mg/L***	OECD 201	Harmful to algae
Marine Algae	E_rC50 (72 h) = 2.4 mg/L**	ISO 10253 (1998)	Toxic to algae
Microorganisms			
Inhibition of Bacterial Respiration	EC50 (72 h) = 210 mg/L[#]	OECD 209	Not classified under GHS
Marine Crustaceans			
Amphipod (Marine Sediment Dweller)	LC50 (10 d) = 49.4 mg/kg	PARCOM 1995	Not classified under GHS
Copepod (Marine Shrimp)	LC50 (48 h) = 9.8 mg/L**	ISO 14669 (1999)	Toxic to aquatic invertebrates

* Time weighted average
** WAF (Water Accommodated Fraction)
*** Geometric mean concentration
[#] Nominal Concentration

The notifier provided three marine and four fresh water ecotoxicity tests for the notified chemical. They include a full basis set for fresh water species (fish, algae, and daphnia), along with tests for marine fish toxicity, marine shrimp toxicity and for a marine sediment dweller. All of the tests reported either water accommodated fraction (WAF) or nominal concentrations of the notified chemical.

For the fish ecotoxicity test provided by the notifier, test solutions of the notified chemical were prepared by stirring the notified chemical at 1.0, 1.8, 3.2, 5.6, and 10 mg/L for at least 24 h prior to filtration through a 0.2 µm filter. The test solutions were clear and colourless throughout the test period. The concentrations were monitored by gas chromatography. The concentrations of freshly prepared samples were in a range between 85 and 113% of the nominal concentrations. Concentrations at 24 h and 48 h ranged from 84-96% of nominal at higher concentrations (5.6 and 10.0 mg/L). For lower concentrations (1.0 1.8, and 3.2 mg/L) at 24 h and 48 h, the concentrations ranged from 75-79%. Concentrations at 72 h and 96 h ranged from < LOQ to 81% of nominal. The decline in concentrations of notified chemical at lower concentrations was attributed to the possibility that the notified chemical was metabolized by the fish, which allowed further uptake of the notified chemical. The notified chemical was tested in an OECD TG 203 Fish, Acute Toxicity Test under semi-static conditions. The nominal 96 h LC50 was 7.5 mg/L and the time weighted average 96 h LC50 was 5.4 mg/L.

The daphnia test was conducted according to OECD 202 Daphnia, Acute Toxicity Test under semi-static conditions. The test solutions of the notified chemical were prepared by stirring the substance at 10, 18, 32, 56, and 100 mg/L for at least 24 h prior to filtration through a 0.2 µm filter. The test solutions were clear and colourless throughout the test period. The concentrations were monitored by gas chromatography, and freshly prepared samples had concentrations between 89 and 99% of the nominal concentrations. Concentrations at 24 h and 48 h ranged from 82-91% of nominal at higher concentrations. For 10 mg/L at 24 h, the measured concentration was reported to be 69% of nominal. For 18 mg/L at 48 h, the concentration was reported to be 70% of nominal. The decline was attributed to the possibility of slight degradation. However, after evaluating the information provided, it could be seen that for the 10 mg/L, after the solution was renewed with freshly prepared test solution, the concentration did not drop as dramatically during the next 24 h. Similarly, for 18

mg/L at 48 h, the significant decline in concentration was not observed before the solution was renewed. Both of these observations indicate that it is more likely that there was a measurement error, rather than degradation of the notified chemical. The nominal 48 h EC50 was 25 mg/L.

The notifier also provided another daphnia test, conducted according to US EPA. 2002. Methods for measuring the acute toxicity of effluents and receiving waters to freshwater and marine organisms (EPA-821-R-02-012). Minimal information was provided within the report. The test condition was slightly different than the previous test. The test temperature was higher at 26 °C and with a water hardness of 88 mg/L $CaCO_3$. The 48 h LL50 was 7.6 mg/L.

The algae test was conducted according to OECD 201 Algae, Acute Toxicity Test static conditions. The test solutions of the notified chemical were prepared by stirring the notified chemical at 6.25, 12.5, 25, 50, and 100 mg/L for at least 24h prior to filtration through a 0.2 µm filter. The test solutions were clear and colourless throughout the test period. The concentrations were monitored by gas chromatography, and freshly prepared samples had concentrations between 83 and 94% of nominal. Concentrations at 72 h ranged from 47-96% of nominal. The decline was attributed to the possibility of adsorption. The nominal 72 h EbC50 and E_rC50 was 10 mg/L and 16 mg/L, respectively. As the concentration decreased during the duration of the test, the geometric mean of 72h E_bC50 and E_rC50 was reported to be 7.9 mg/L and 13 mg/L, respectively.

Based on the endpoints for the notified chemical, it is considered toxic to fish, aquatic invertebrates and algae. Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009), the notified chemical is formally classified as Acute Category 2; Toxic to aquatic life. Based on the acute toxicity and lack of ready biodegradability of the notified chemical, it has been formally classified under GHS as Chronic Category 2; Toxic to aquatic life with long lasting effects.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated using the most sensitive endpoint (marine algae) for the notified chemical and the assessment factor of 100. The factor of 100 was used since ecotoxicological endpoints for three trophic levels for the notified chemical were available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (Algae)	2.4	mg/L
Assessment Factor	100	
PNEC:	24.0	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.15	24	0.006
Q - Ocean:	0.02	24	0.001

The Risk Quotients (Q = PEC/PNEC) for a conservative discharge scenario have been calculated to be less than 1 for both the riverine and marine compartments. Based on the biodegradation study of the notified chemical, it is not ready biodegradable, however, it has a potential to biodegrade. It is also not expected to bioaccumulate. Although the notified chemical is toxic to aquatic species, it is unlikely to result in ecotoxicologically significant concentrations for the assessed use pattern, and there is no unreasonable risk to the aquatic environment from the assessed use scenario.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Flash Point 175 °C at 101.3 kPa

Method	EU Commission Directive 92/69/EEC A.9 Flash Point.
Remarks	Determined by closed cup equilibrium method
Test Facility	SafePharm Laboratories (2006a)

Autoignition Temperature 254 °C

Method	EU Commission Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Test Facility	SafePharm Laboratories (2006a)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 45, 80, 140, 250 and 450 mg/L
Remarks – Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.
RESULTS	
NOEC	80 mg/L
EC50	210 mg/L
Remarks – Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not expected to inhibit microbial respiration at concentrations less than 80 mg/L.
TEST FACILITY	Safepharm (2006b)

BIBLIOGRAPHY

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

SWA (2012) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/spray-painting-and-powder-coating.

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

SafePharm (2006a) Determination of hazardous physico-chemical properties (Project No. 0936/0074, June, 2006). Derbyshire, UK, SafePharm Laboratories Limited (Unpublished report submitted by notifier).

Safepharm (2006b) Assessment of the Inhibitory Effect On the Respiration of Activated Sewage Sludge (Project No. 0936/0085, March, 2006). Derbyshire, UK, SafePharm Laboratories Limited (Unpublished report submitted by notifier).

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