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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Acidgen FG3

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:

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

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1657	Weatherford Australia Pty Ltd	Acidgen FG3	Yes	≤ 50 tonnes per annum	Filter cake breaker for off-shore oil and gas well drilling

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 of 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*
Serious Eye Damage/Eye Irritation Category 1	H318 – Causes serious eye damage

The environmental hazard classification according to the *Globally Harmonised System of 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 3	H402 - Harmful to aquatic life
Chronic Category 3	H412 - Harmful to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended controls are being adhered to, 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 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:
  – Serious Eye Damage/Eye Irritation Category 1: H318 – Causes serious eye damage

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

- Due to the corrosive properties of the notified chemical, introducers of the chemical should consider their obligations under the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (ADG code) (NTC, 2017).

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 as introduced and as diluted for use:
  - Local exhaust ventilation if the notified chemical is used in an area where vapour build-up is expected

- 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 minimise occupational exposure during handling of the notified chemical as introduced and diluted for use:
  - Avoid contact with skin and eyes
  - Avoid inhalation of vapour
  - Clean up any spills and drips promptly

- 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 as introduced and diluted for use:
  - Gloves
  - Protective clothing
  - Safety glasses, goggles or face shield
  - Respiratory protection if inhalation exposure may occur
  - A shower and eyewash station or similar facilities should be available where the notified chemical is used.

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

- A person conducting a business or undertaking at a workplace should ensure that sufficient controls are in place to minimise occupational exposure to the breakdown products of the notified chemical, both when generated through the intended use of the notified chemical, or when generated accidentally.

- 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.

Environment

- The following control measures should be implemented by the notifier to minimise environmental exposure of the notified chemical:
  - The notified chemical or waste water containing the notified chemical is not to be released unless > 95% by weight of the initial dose is hydrolysed or degraded.

Disposal

- Prior to release to the marine environment, the notified chemical must be hydrolysed to > 95% by weight.

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 chemicals 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 to be used for on-shore gas or oil well drilling;
- additional toxicity data for the notified chemical becomes available;
- the concentration of the chemical used for off-shore drilling applications has increased from 20%, or is likely to increase significantly;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from being a filter cake breaker for off-shore oil and gas well drilling, 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 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(S)
Weatherford Australia Pty Ltd (ABN: 68 008 947 395)
9 Metal Circuit
MALAGA WA 6090

NOTIFICATION CATEGORY
Standard (reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Similar to a chemical that has been previously assessed by NICNAS

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 for all physical-chemical endpoints and all toxicological endpoints except for boiling point, density and flash point.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
U.S. (TSCA, 2014)
EU (REACH, 2014)
Canada (NDSL, 2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Acidgen FG3

MOLECULAR WEIGHT
< 500 g/mol

ANALYTICAL DATA
Reference NMR, IR and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 75%

DEGRADATION PRODUCTS
The notified chemical is designed to slowly degrade during use into Analogue 1 (Exempt Information) and Analogue 2 (formic acid, CAS No. 64-18-6).

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless to pale yellow liquid

Property	Value	Data Source/Justification
Melting Point	< -20 °C	SDS
Boiling Point	132 °C at 101.3 kPa	Measured
Density	1,285 kg/m^3 at 20 °C	Measured
Vapour Pressure	0.386 kPa at 25 °C	Calculated
Water Solubility	≥ 128.5 g/L at ambient temperature	Measured

Property	Value	Data Source/Justification
Hydrolysis as a Function of pH	Stable at pH 4 At pH 7, t ½ = 4-5 days At pH 9, t ½ = ~ 1 hour	Calculated based on analogue data
Partition Coefficient (n-octanol/water)	log Pow = -3.4 at 19.8 – 21.9 °C	Measured
Adsorption/Desorption	Not determined	Expected to remain in the water column given its high water solubility and extremely low log Kow
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	140 °C (Closed cup)	Measured
Flammability	Combustible liquid*	Based on flash point
Autoignition Temperature	Not determined	Expected to be high
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* Based on *Australian Standard AS1940* definitions

DISCUSSION OF PROPERTIES

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

Reactivity

The notified chemical is designed to break down in water during the end use to slowly release Analogue 1 and formic acid. The notified chemical reacts exothermically with acids, bases, and strong oxidizing reagents, and may generate hydrogen when mixed with strong reducing reagents.

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.

The notified chemical has a flash point of 140 °C. Based on *Australian Standard AS1940* definitions for combustible liquids, a liquid that has a flash point of 150 °C or less is a Class C1 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. It will be imported into Australia in neat form (with > 75% purity).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 50	≤ 50	≤ 50	≤ 50	≤ 50

PORT OF ENTRY

Perth (primary), Adelaide, Melbourne, Brisbane, Darwin

IDENTITY OF RECIPIENTS

Weatherford Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The notified chemical will be imported in 210 kg drums or 1,100 bulk containers. No repackaging is expected. The notified chemical will be stored in warehouses and then transported to off-shore drilling sites by truck and ship.

USE

The notified chemical will be used in brine at < 20% concentration as a filter cake breaker for off-shore oil and gas well operations.

OPERATION DESCRIPTION

Storage
The notified chemical will be temporarily stored at holding warehouses at entry ports. The containers containing the notified chemical will be kept in a cool and well-ventilated area with no oxidising reagents nearby, and will be transported by ship to off-shore drilling sites on shrink-wrapped pallets or in totes. Once on-site, the notified chemical will be stored in totes or in drums in the chemical storage area on the rig. The containers containing the notified chemical will be closed when not in use.

Application
On the off-shore oil platform, the containers containing the notified chemical will typically be handled by cranes, forklifts or hoists to be set above one of the pits on the rig for mixing. The notified chemical will be drained by gravity or pumped into the pit, dissolved in the carrier brine of choice at a concentration generally < 20%, and pumped into wells to break the filter cakes. The operations will be performed in ventilated areas, and most handling and use of the notified chemical will occur outdoor.

Retrieval
Upon completion of the job, the entire well volume of the liquid will be pumped back to the surface from the well. This liquid will contain formic acid as one of breakdown products. The fluid will be discharged into the ocean in batch mode. Any remaining unused notified chemical in the pit will be neutralised with sodium hydroxide (caustic soda) or calcium carbonate, and then discharged into the ocean.

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)*
Laboratory technicians	2	24
Blender operators	2	12

EXPOSURE DETAILS
Exposure of workers to the notified chemical or its breakdown products during transport and storage will only occur in the event of an accidental release.

Dermal, ocular and inhalation exposure to the notified chemical may occur during pumping and mixing the notified chemical with the brine in the pits at the off-shore well sites, prior to pumping down the well. Dermal, ocular and inhalation exposure to the notified chemical at concentrations < 20% may occur when handling the mixture containing the notified chemical during the well operations, including during neutralisation and disposal of un-used material. It is expected that workers will wear PPE including impervious rubber gloves, rubber aprons, chemical goggles and, if necessary, face shields to reduce the potential for exposure. The open air environment at the off-shore well sites, infrequent use and relative short time of handling of the notified chemical by the workers will further reduce the likelihood of exposure.

During the end-use in the wells, the notified chemical is expected to breakdown into two hydrolysis products (including formic acid). After the well treatment, the fluid containing the hydrolysis products of the notified chemical will be pumped back to the surface and workers would have potential for dermal, ocular and inhalation exposure to the hydrolysis products, prior to final disposal to the ocean occurs. According to the notifier, appropriate PPE is expected to be used by workers involved in the fluid recovery and disposal operations to reduce the potential for exposure.

6.1.2. Public Exposure
The notified chemical is intended only for use in off-shore oil and gas well drilling and public exposure to the notified chemical or its breakdown products is not expected, unless accidental release of the notified chemical to the public occurs during transport.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical, its breakdown products and analogues are summarised in the following tables.

Summary of toxicological investigations on the notified chemical

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50* = 2,500 mg/kg bw; low toxicity
Rat, repeat dose oral toxicity – 2 years	NOAEL* = 295 mg/kg bw/day (in water) NOAEL* = 75 mg/kg bw/day (in feed)
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Skin corrosion (*in vitro* reconstructed human epidermis test)	non-corrosive

* Calculated based on the toxicity of formates converted to equivalent quantity for the notified chemical

For full details of the investigations on the notified chemical, refer to Appendix B.

Endpoints that are not covered by the data on the notified chemical are assessed using information on the breakdown products and analogues of the notified chemical.

Summary of toxicological investigations on the breakdown products and Analogue 3*

Endpoint	*Result and Assessment Conclusion*	*Source of Information*
Rabbit, eye irritation	severely irritating	Formic acid and Analogue 3
Guinea pig, skin sensitisation – adjuvant test/non-adjuvant test	no evidence of sensitisation	Formic acid and Analogue 1
Mutagenicity – bacterial reverse mutation	non mutagenic	Formic acid, Analogues 1 and 3
Genotoxicity – *in vitro* mammalian chromosome aberration test	non genotoxic	Formic acid and Analogue 1
Genotoxicity – *in vivo* mammalian erythrocyte micronucleus test	non genotoxic	Formic acid

* The breakdown products of the notified chemical include formic acid and Analogue 1.

ANALOGUE 1

Analogue 1 is one of the two hydrolysis products of the notified chemical during proposed off-shore application in the oil and gas well operations. It may also be a metabolite of the notified chemical if systemic exposure occurs.

FORMIC ACID

Formic acid is used as Analogue 2 in this assessment. It is the second hydrolysis product of the notified chemical that is released slowly when mixed with water, and rapidly forms formate salts with cations in the environment. Formic acid may also be a metabolite of the notified chemical in humans if systemic exposure occurs. Effects of formic acid on human health will vary depending on whether it is in acid form or in its formate salt form. Some effects may be directly caused by the acidity of the acid form. The toxicity of formate salts may also vary based on its cation, as the inherent toxicity of each cation may be different.

Based on Hazardous Chemical Information System (HCIS, Safe Work Australia), formic acid is classified as following according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS):

Hazard classification	***Hazard statement***
Acute toxicity – Category 4	H302 – Harmful if swallowed
Acute toxicity – Category 3	H331 – Toxic if inhaled
Specific target organ toxicity (single exposure) – Category 3	H335 – May cause respiratory irritation
Skin corrosion – Category 1	H314 – Causes severe skin burns and eye damage

ANALOGUE 3

Analogue 3 has a similar chemical structure to the notified chemical, and is also susceptible to hydrolysis. The step-wise hydrolysis of Analogue 3 is known to generate formic acid in the same procedure as the notified chemical. Its purpose as an analogue is to predict the effect of a gradual exposure to an equal molar quantity of the acid.

Toxicokinetics, metabolism and distribution
No studies on toxicokinetics, metabolism and distribution were submitted for the notified chemical. The notified chemical is expected to undergo chemical hydrolysis upon contact with water, or enzymatic hydrolysis by esterases if absorbed into the body, and may release Analogue 1 and formic acid as metabolites. Therefore, exposure to the notified chemical can be considered effectively equivalent to being exposed to a mixture of Analogue 1 and formic acid.

Acute toxicity
The notified chemical was found to have low acute dermal toxicity in rats (LD50 > 2,000 mg/kg bw).

No studies were conducted on the acute oral toxicity of the notified chemical. In studies conducted according to, or similar to, OECD TG 401, the LD50 of Analogue 1 was determined to be 27.5 g/kg bw in rats [Reference A, Exempt Information], and the LD50 of the formate anion in sodium formate was determined to be ≥ 7,410 mg/kg bw in rats [Reference B, Exempt Information].

The acute oral toxicity of Analogue 1 and formic acid in rats was used to predict the acute oral toxicity of the notified chemical. It was considered by the notifier that the toxicity of the notified chemical is primarily dominated by the content of formates. The notified chemical is calculated to contain ~46 wt % of formate, so a LD50 ≥ 16,100 mg/kg bw was calculated by the notifier based on the equivalent content of formate.

However, the structurally similar Analogue 3 was found to be harmful based on results from animal studies. The LD50 of Analogue 3 were determined to be 1,510 mg/kg bw in rats, in studies according to, or similar to, OECD TG 401 [Reference A, Exempt Information]. As Analogue 3 contains ~76 wt % in formate, the LD50 of the formate ion is determined to be ~1,150 mg/kg bw based on this study, which calculates to a LD50 = 2,500 mg/kg bw of the notified chemical, indicating that the notified chemical may have low acute oral toxicity in rats.

No information on acute inhalation toxicity was submitted. However, the notified chemical has a relatively low vapour pressure and is expected to be used in off-shore open areas with low possibility for aerosol formation. Therefore, it is unlikely to pose an acute inhalation risk under normal use conditions.

Irritation and sensitisation
Based on studies conducted on the EPISKIN Reconstructed Human Epidermis Model, the notified chemical was considered to be non-corrosive to the skin. In an acute dermal toxicity study conducted according to OECD TG 402, the undiluted notified chemical did not show signs of dermal irritation on the test sites of the animal skin.

No information was submitted on eye irritation for the notified chemical. Available analogue data indicate that Analogue 1 causes no or slight eye irritation [Reference C, Exempt Information]. Formic acid is corrosive to human skin and assumed to be corrosive to eyes based on its strong acidic properties, while formate salts are neither corrosive nor irritating to skin, but can be corrosive or irritating to the eyes [Reference D, Exempt Information]. Analogue 3 has been shown to be severely irritating to the eyes in a test on rabbits [Reference C, Exempt Information].

No information was submitted for the sensitisation of the notified chemical. In studies conducted according to, or similar to, OECD TG 406, there was no evidence of skin sensitisation in guinea pigs observed for Analogue 1 [Reference E, Exempt Information], formic acid and formates [Reference D, Exempt Information]. Based on the lack of evidence of skin sensitisation for either analogue, the notified chemical is not likely to have skin sensitisation potential.

Repeated dose toxicity
No studies were submitted on the repeat dose toxicity of the notified chemical.

Based on animal feeding studies, there were no adverse effects observed from long-term oral exposure to Analogue 1 in rats. A no-observed-effect level (NOEL) of 10,000 mg/kg bw/day in rats for the duration of 1 year was established for the analogue chemical [Reference E, Exempt Information].

Based on several studies carried out according to or similar to OECD TG 453 on potassium hydrogen diformate in feed [Reference D, Exempt Information] and calcium formate in drinking water [Reference B, Exempt Information], the no-observed-adverse-effect level (NOAEL) was determined to be 50 mg/kg bw/day in feed and 200 mg/kg bw/day in drinking water for potassium hydrogen diformate and calcium formate respectively. Some

microscopic changes were observed in the stomach of males at the 2,000 mg/kg bw/day of potassium hydrogen diformate, including increased incidence of limiting ridge hyperplasia in the forestomach, increase of thickness and folding of the squamous epithelium, slightly more basophilic basal layer, and grade 2 lesions. No other malignant effects were observed.

The repeat dose toxicity of the Analogue 1 and formates in rats was used by the notifier to predict the repeat dose toxicity of the notified chemical. Similar to acute toxicity, the toxicity of the notified chemical was considered to be primarily dominated by the content of formates. Potassium hydrogen diformate is calculated to contain 70% formate by weight, and calcium formate is calculated to contain 69% formate by weight. As the notified chemical contains ~46% formate by weight, a NOAEL of 295 mg/kg bw/day in water and 75 mg/kg bw/day in feed was calculated by the notifiers, based on equivalent content of formate.

Mutagenicity/Genotoxicity
No genotoxicity studies were provided for the notified chemical. The notified chemical contains no functional groups or structural alerts for potential mutagenicity or genotoxicity.

The 2 hydrolysis products of the notified chemical were not mutagenic in bacterial reverse mutation tests [References F and G, Exempt Information]. Based on studies conducted according to OECD TG 471, Analogue 3 was not mutagenic in a bacterial reverse mutation test.

Analogues 1 was not considered to be clastogenic in an *in vitro* mammalian chromosome aberration test [Reference F, Exempt Information]. Some positive results in *in vitro* chromosomal aberration tests were observed for formic acid [Reference H, Exempt Information]; however, the study authors stated that this was due to the acidity of the test medium, as no clastogenic effects were observed when the medium was buffered to pH 7.2. The study authors considered that formic acid itself was not clastogenic.

Potassium hydrogen diformate was tested in an *in vivo* rat bone marrow micronucleus test in accordance with OECD TG 474 [Reference D, Exempt Information]. At the 48 hour sampling time, a statistically significant increase of micronucleus in cells was observed. However, the group mean micronucleus frequencies were within the historical negative control range, and not statistically significant compared to the vehicle control group. It was concluded by the study authors that potassium hydrogen diformate did not increase the percentage of micronuclei in this test.

Potassium hydrogen diformate was tested for oncogenicity in rats and mice in feed for 2 years [Reference D, Exempt Information]. The NOAELs were established as 50 mg/kg bw/day in rats and 400 mg/kg bw/day in mice. Apart from limiting ridge hyperplasia in the forestomach, no tumours or incidence of specific target organ carcinogenicity was observed.

Health hazard classification
Based on the available information on the notified chemical and the analogue chemicals, 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***
Serious Eye Damage/Eye Irritation Category 1	H318 – Causes serious eye damage

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified chemical is considered to cause serious eye damage, based on available information on analogue chemicals.

Dermal, ocular and inhalation exposure to the notified chemical by workers, at concentrations up to 100%, may occur during the well operations involving the use of the notified chemical, or if accidental release occurs during transport or storage.

After treatment of the well with the notified chemical, the fluid containing the hydrolysis products of the notified chemical will be pumped back to the surface and workers involved in the operations will have potential for dermal, ocular and inhalation exposure to the hydrolysis products. Worker exposure to formic acid may be

predominantly in salt form after it is pumped out of the well. Exposure to the hydrolysis products could also occur if there was accidental release of notified chemical under conditions where hydrolysis would occur, e.g. contact with water.

The end-use application of the notified chemical is expected to be conducted off-shore by skilled workers. Safe work practices and use of appropriate PPE would reduce the potential for exposure to the notified chemical and its hydrolysis products. Specifically, dermal and ocular exposure would be limited by the use of impervious gloves, protective clothing and safety glasses/goggles. According to the notifier, appropriate first aid facilities in case of accidental worker exposure will be available. Since the operations involving the use of the notified chemical are mostly expected to occur off-shore in open areas, the potential for inhalation exposure would be limited under these conditions.

The potential for exposure to the notified chemical or its hydrolysis products through accidental release would be reduced by safe work practices and appropriate clean-up procedures.

Under the assessed use pattern, and with appropriate controls in place, the notified chemical is not expected to pose an unreasonable health risk to workers.

6.3.2. Public Health

The notified chemical is intended only for use in off-shore oil and gas well drilling and public exposure to the notified chemical and its hydrolysis products is not expected.

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 for end use in off-shore oil and gas well operations. Therefore, no environmental release is expected from the manufacture or reformulation of the notified chemical in Australia. Release from residues in import, storage and shipping containers is expected to be minimal. This is expected to be collected for disposal to landfill with empty containers or treated in the container recycling process in accordance with local government regulations. Accidental spills of the notified chemical is expected to be absorbed with inert absorbent material, swept up and placed into containers and disposed of after appropriate treatment.

RELEASE OF CHEMICAL FROM USE

On the well site or off-shore oil platform, the containers containing the notified chemical will typically be handled by cranes, forklifts or hoists to be set above one of the pits on the rig for mixing. The notified chemical will be drained by gravity or pumped into the pit, dissolved in the carrier brine of choice at a concentration of 20% w/v and pumped into wells to break the filter cakes.

RELEASE OF CHEMICAL FROM DISPOSAL

Upon application, the entire well volume of the liquid will be removed from the well. The notified chemical is expected to rapidly hydrolyse to Analogue 1 and formic acid during use (half-life = 4-5 day at pH 7 and ~ 1 hour at pH 9, with seawater having a pH of ~8 at 25°C). Residual amounts of notified chemical may remain in the fluid. The fluid will be pumped back into one of the pits on the rig and then discharged into the ocean in batch mode. Any remaining acidic hydrolysis product in the pit will be neutralised with sodium hydroxide (caustic soda) or calcium carbonate and then discharged into the ocean.

7.1.2. Environmental Fate

The notified chemical is not expected to persist in the environment as it was measured to be biodegradable (55% biodegradation over 28 days). For the details of the environmental fate study please refer to Appendix C. The notified chemical is expected to rapidly hydrolyse before it would otherwise be biodegraded. The biodegradability test indicates it has potential for ultimate biodegradation in marine environment. Based on its

potential for biodegradation, and the high-water solubility, the notified chemical and its hydrolysis products are not expected to be bioaccumulative in aquatic organisms.

7.1.3. Predicted Environmental Concentration (PEC)

As direct discharge of the notified chemical into seawater is likely from offshore use, the predicted environmental concentration in seawater (PEC_{water}) has been calculated based on the CHARM model (Thatcher et al., 2005) and discharges of notified chemical and mixwater have been identified as the main routes for release. The notified chemical and mixwater are discharged in batches and the greatest effect will occur within a radius (r) of 500 m from the discharge line. Assuming that none of the chemical is depleted or transformed between addition and discharge, the discharge concentration equals to the initial concentration (dosage, mg/L). For the worst case scenario, the PEC_{water} in the water column due to mixwater discharge is calculated using following equation:

$$PEC_{water} = C_{i,mixwater} \times D_{batch,mixwater}$$

In this relationship,
PEC_{water} = Predicted Environmental Concentration in the water column (mg/L);
C_i = Initial concentration of the notified chemical in mixwater (dosage; mg/L);
$D_{batch,\ mixwater}$ = Batchwise dilution factor of mixwater.

The initial dosage of the notified chemical in mixwater is up to 20% w/v. Therefore, the original dose for the notified chemical in mixwater is calculated to be 200 g/L. The default dilution factor is set at 7.7×10^{-5} in the CHARM model under the batch-wise discharge scenario (Thatcher et al., 2005, p. 49).

Therefore, the resulting PEC_{water} is calculated to be:

$$PEC_{water} = C_{i,mixwater} \times D_{batch,mixwater} = 200 \text{ g/L} \times 7.7 \times 10^{-5} = 1{,}540 \times 10^{-5} \text{ g/L} = 15{,}400 \text{ µg/L}$$

The $PEC_{sediment}$ for a batch-wise discharge scenario is not calculated in the CHARM model because it is assumed that there would be insufficient time to allow the establishment of equilibrium between the high short-term levels of notified chemical in the water column arising from batch-wise release of mud and the levels of the notified chemical in sediments near the discharge point. Furthermore, as the notified chemical is highly water soluble and is expected to readily disperse and biodegrade in the aqueous compartment, it is not expected to reach ecotoxicologically significant concentrations in the sediment compartment. Therefore, the $PEC_{sediment}$ has not been calculated for this assessment.

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	96 h LC50 > 74.31 mg/L	Harmful to Fish
Aquatic Invertebrates	48 h EC50 = 215.65 mg/L	Not harmful
Algal Toxicity	72 h EC50 = 74.31 mg/L	Harmful to algae
Amphipods	10 d LC50 = 13,485 mg/kg dry weight	Not harmful to amphipods

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified chemical is harmful to fish and algae. Therefore, the notified chemical is formally classified as "Acute Category 3, Harmful to aquatic life" under the GHS. Based on its lack of rapid degradability and acute endpoints, the notified chemical is formally classified as "Chronic Category 3, Harmful to aquatic life with long lasting effects" under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the acute toxicity of the notified chemical [alga 72 h EC50 = 74.31 mg/L] and an assessment factor of 100 is used (EPHC 2009).

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 for alga	74.31	mg/L
Assessment Factor	100	
PNEC	743	µg/L

7.3. Environmental Risk Assessment

Assuming no hydrolysis occurs during use, the Risk Quotient (PEC/PNEC) for off-shore use may be calculated as 20.7 (being 15,400 ÷ 743). However, the notified chemical hydrolyses rapidly during use down well and only a residual amount is expected to be discharged into the ocean. Provided that the residual amount is less than 5% by weight of the initial dose, the Q will be below 1.

The length of time that the treatment fluid containing the notified chemical is held in the well during the holding period is tailored to the specific well conditions. The holding periods to be used in the Australian treatments are 5 days at 61°C and 1 day at 85°C. The proportion of the notified chemical hydrolysed during the holding period may be estimated from the hydrolysis rate at 25°C. Under pH 8 of seawater, the half-life of the chemical is estimated to be > 1 hour but < 4 - 5 days at 25°C. Using an estimate of 4 days for the half-life at 25°C, an extrapolation may be made according to the Arrhenius equation. For most reactions relevant to organic chemistry, the rate of reaction increases between 2 and 3 times for every increase of 10 °C (Atkins, 1986). The predicted half-lives for the notified chemical under various conditions are presented below.

Temperature (°C)	*Reaction rate based on 25°C (times)*	*Half-life (days)*
25	1×	4
35	2×	2
45	4×	1
55	8×	0.5
61	**12.1×**	0.33
65	16×	0.25
75	32×	0.13
85	64×	**0.063**

Under normal use conditions, the numbers of half-lives elapsed in 5 days at 61°C and 1 day at 85°C may be estimated and, the therefore, the percentage of residual of the notified chemical after use may be calculated as below.

Use temperature (°C)	*Number of half-lives elapsed (cycles)*	*Residual (%)*
61	15 (in 5 days)	< 0.01
85	16 (in 1day)	< 0.01

The estimated residual is well below the 5% required to achieve Q of < 1. The chemical is also expected to continue to hydrolyse in seawater. Therefore, based on the Q value determined from the proposed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point 132 °C at 101.3 kPa

Method	OECD TG 103 Boiling Point
Remarks	Dynamic reflux method
Test Facility	EsterChem (2017a)

Density 1,285 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids
Remarks	Measured using a density hydrometer
Test Facility	EsterChem (2017b)

Vapour Pressure 0.386 kPa at 25 °C

Method	OECD TG 104 Vapour Pressure
Remarks	Calculated using the Modified Watson Correlation
Test Facility	Intertek

Water Solubility ≥ 128.5 g/L at ambient temperature

Method	OECD TG 105 Water Solubility EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Flask Method
Test Facility	EsterChem (2017c)

Partition Coefficient (n-octanol/water) log Pow = -3.4 at 19.8 – 21.9 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	HPLC Method extrapolated beyond retention time of reference products
Test Facility	OPUS (2014a)

Flash Point 140 °C at 101.3 kPa

Method	EC Council Regulation No 440/2008 A.9 Flash Point
Remarks	Closed cup method
Test Facility	EsterChem (2017d)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

The estimation of the acute oral toxicity of the notified chemical was provided. The toxicity of the notified chemical was considered to be directly related to the weight % of formate in the chemical. The LD50s of several formate salts and Analogue 3 were known and were adjusted based on the formate weight %. The lowest value of the weight adjusted LD50 of the analogues was used to calculate the LD50 of the notified chemical.

Substance	*Original LD50 (mg/kg bw)*	*Formate wt %*	*Weight Adjusted LD50 (mg/kg bw) (Original LD50 × Formate wt %)*
Sodium formate	11,200	64	7,140
Potassium formate	5,500	54	2,950
Calcium formate	1,920	68	1,330
Analogue 3	1,510	76	1,148*

* Figure used to calculate the LD50 of the notified chemical

LD50 of the notified chemical = Lowest weight adjusted formate LD50 / Formate wt % of the notified chemical
= 1,148 / 45.8%
= 2,507 (mg/kg bw)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test EC Council Regulation No 440/2008 B.3 Acute Toxicity (Dermal) – Limit Test
Species/Strain	Rat/Wistar (RccHan)
Vehicle	None. The notified chemical was directly applied.
Type of dressing	Semi-occlusive.
Remarks - Method	GLP Certificate No significant protocol deviations

RESULTS

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

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	No signs of dermal irritation were observed.
Signs of Toxicity - Systemic	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were found at necropsy.
Remarks - Results	The animals showed expected body weight gain over the observation period.
CONCLUSION	The notified chemical is of low acute toxicity via the dermal route.
TEST FACILITY	Envigo (2017)

B.3. Corrosion – skin (*in vitro* reconstructed human epidermis test)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 431 *In vitro* Skin Corrosion – Reconstructed Human Epidermis Test EC Council Regulation No 440/2008 B.40. *In vitro* Skin Corrosion – Reconstructed Human Epidermis Test

Vehicle	None. The notified chemical was directly applied.
Remarks - Method	GLP Certificate No significant protocol deviations EPISKIN Model Negative control (0.9% w/v sodium chloride solution) and positive control (glacial acetic acid) data were used as reference, but not conducted in parallel with the test substance.

RESULTS

3 Minute Exposure

Test material	*Mean OD_{562} of duplicate tissues*	*Relative mean Viability (%)*
Test substance	0.926	89.6

1 Hour Exposure

Test material	*Mean OD_{562} of duplicate tissues*	*Relative mean Viability (%)*
Test substance	0.924	89.4

4 Hour Exposure

Test material	*Mean OD_{562} of duplicate tissues*	*Relative mean Viability (%)*
Negative control	1.033	100
Test substance	0.885	85.7
Positive control	0.045	4.4

OD = optical density; SD = standard deviation

Remarks - Results	Because the relative mean tissue viability was > 35% after the 3 minute treatment and > 15% after the 1 hour treatment with the notified chemical, it is categorised as non-corrosive according to the test guidelines. The test substance did not show colour interference and direct MTT reduction under the conditions of the tests. The mean OD_{562} from the negative control and positive control were within the historical control values. Therefore, it is concluded by the study authors that the test conditions of this study were adequate and functioned properly.
CONCLUSION	The notified chemical was non-corrosive to the skin under the conditions of the test.
TEST FACILITY	Harlan (2014)

B.4. Repeat dose toxicity – oral

The estimation of the repeated dose oral toxicity of the notified chemical was provided. The toxicity of the notified chemical was considered to be directly related to the weight % of formate in the chemical. NOAELs of several formate salts were known and were adjusted based on the formate weight %. The weight adjusted NOAEL of the analogues was used to calculate the NOAEL of the notified chemical.

Substance	*Original NOAEL (mg/kg bw/day)*	*Formate wt %*	*Weight Adjusted NOAEL (mg/kg bw/day) (NOAEL × wt % Formate)*
Potassium diformate (in feed)	50	69	34.5
Calcium formate (in water)	200	68	136

NOAEL in feed = Weight adjusted NOAEL of analogue in feed / Formate wt % of the notified chemical
= 34.5 / 45.8%
= 75 (mg/kg bw/day)

NOAEL in water = Weight adjusted NOAEL of analogue in water / Formate wt % of the notified chemical
= 136 / 45.8%
= 297 (mg/kg bw/day)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	Aerobic Biodegradation in Seawater using the Closed Bottle Procedure (In accordance with OECD TG 306)
Inoculum	Marine microorganisms
Exposure Period	28 days
Auxiliary Solvent	Not reported
Analytical Monitoring	Not reported
Remarks - Method	The test was conducted according to the guidelines above using good laboratory practice (GLP). No significant deviations from the test guidelines were reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	57	7	72
14	57	14	73
28	55*	21	71

* biodegradation and hydrolysis were not differentiated

Remarks - Results	All validity criteria for the test were satisfied. The reference compound, sodium benzoate, reached the 60% pass level by day 7 indicating the suitability of the inoculum. The toxicity control exceeded 25% biodegradation within 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degrees of degradation of the notified chemical after the cultivation period was 55%. It did not reach the pass level within the 10-day window. Therefore, the test substance is not classified as readily biodegradable according to the OECD (306) guideline.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	OPUS (2014b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OSPAR Commission 2006 Part B.Protocol for a fish acute toxicity test
Species	*Cyprinodon variegatus*
Exposure Period	96 hour
Auxiliary Solvent	None
Salinity	~ 33‰
Analytical Monitoring	Not reported
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. The above stated test guideline is very similar to OECD TG 203. A 1000 mg/L stock was prepared in filtered seawater, and the resulting mixture was stirred for one hour. Appropriate volumes were taken from

this stock to prepare subsequent test concentrations which were brought to volume with culture medium.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*Mortality*			
		24 h	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0
> 74.31*	10	0	0	0	0

* Limit test

LC50 > 74.31 mg/L at 96 hours

Remarks – Results All validity criteria for the test were satisfied. The dissolved oxygen was maintained at 98-102%.

One of the control fish was found to be above the guideline length at the end of the test (0.3cm above criterion). As the fish displayed no adverse effects, and all other fish were within the guideline limits, this is not thought to have affected the test.
The results are based on nominal concentrations.

CONCLUSION The notified chemical at worst harmful to fish.

TEST FACILITY OPUS (2014c)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD ISO 14669 (1999) Water Quality - Determination of acute lethal toxicity to marine copepods

Species *Acartia tonsa*
Exposure Period 48 hours
Auxiliary Solvent None reported
Salinity 34.9‰
Analytical Monitoring None reported
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. The above stated test guideline is very similar to OECD TG 202.

A 1000 mg/L stock was prepared in filtered seawater, and the resulting mixture was stirred for one hour. Appropriate volumes were taken from this stock to prepare subsequent test concentrations which were brought to volume with culture medium.

RESULTS

Concentration mg/L Nominal	*Number of A. tonsa*	*Number Immobilised*	
		24 h	*48 h*
10	20	1	1
32	20	0	0
100	20	0	0
320	21	20	20
1,000	19	19	19

EC50 = 215.65 mg/L at 48 hours

Remarks - Results All validity criteria for the test were satisfied. The result is based on

	nominal concentrations and was calculated by Linear Interpolation within the ToxCalc suite of statistical analysis.
CONCLUSION	The notified chemical is not toxic to marine invertebrates.
TEST FACILITY	OPUS (2014d)

C.2.3. Chronic toxicity to marine Amphipod

TEST SUBSTANCE	Notified chemical
METHOD	OSPARCOM guidelines (2006) Part A. A sediment bioassay using an amphipod
Species	*Corophium volutator*
Exposure Period	10 day
Auxiliary Solvent	None reported
Salinity	33-36‰
Analytical Monitoring	None reported
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. A 1000 mg/L stock was prepared in filtered seawater, and the resulting mixture was stirred for one hour. Appropriate volumes were taken from this stock to prepare subsequent test concentrations which were brought to volume with culture medium. A control and five treatment concentrations for the test substance were prepared. Predetermined amounts of the test substance were added to the test vessels containing the wet sediment and mixed thoroughly.

Results

Nominal dry weight Concentration (mg/kg)	*Number of C. volutator*	*Number Immobilised*
Control	100	10
14.61	60	6
147.17	60	16
470.17	60	13
1437.9	60	14
13485	60	23

LC50	> 13,485 mg/kg at 10 days
NOEC	1437.9 mg/kg at 10 days
Remarks - Results	All validity criteria for the test were satisfied. The result is based on nominal concentrations and was calculated by Linear Interpolation within the ToxCalc suite of statistical analysis.
CONCLUSION	The notified chemical is not harmful to sediment re-worker.
TEST FACILITY	OPUS (2014e)

C.2.4. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	ISO 10253 2006 Water quality – Marine algal growth inhibition test
Species	Marine Alga (*Skeletonema costatum*)
Exposure Period	72 hours
Concentration Range	Nominal: 1, 10, 100 and 1000 mg/L
Auxiliary Solvent	None reported
Salinity	34.4 – 34.5‰
Analytical Monitoring	None reported

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. The above test guideline is similar to the OECD TG 201 Alga, Growth Inhibition Test. A 1000 mg/L stock was prepared in filtered seawater, and the resulting mixture was stirred for one hour. Appropriate volumes were taken from this stock to prepare subsequent test concentrations which were brought to volume with culture medium.

RESULTS

Growth	
E_rC50 (mg/L)	*NOEC (mg/L)*
74.31	*32*

Remarks - Results	All validity criteria for the test were satisfied. The coefficient of variation of average growth rate during the whole test period (72 h) was 8.29% which is within the acceptable value of less than 10% for species which are less frequently tested. At 0h, the pH of the dilution water was out with the pH range of 8 ± 0.3. This was adjusted with either 1M HCl or NaOH as is appropriate. A reference test was conducted concurrently using 3,5 Dichlorophenol at 0.10, 0.32, 1.0, 1.8 and 3.2 mg/L which were prepared from a main stock of 100 mg/L A reference test with 3,5 Dichlorophenol was conducted within the previous three months (result no recorded). The result is based on nominal concentrations and was calculated by Linear Interpolation within the ToxCalc suite of statistical analysis.
CONCLUSION	The notified chemical is not harmful to marine algae.
TEST FACILITY	OPUS (2014f)

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