30 November 2016

QGC - ADDENDUM TO HYDRAULIC STIMULATION CHEMICAL ASSESSMENT

Chemical Hazard Assessment - Four SLB Products

Some parts of this report have been redacted to maintain the confidentiality of commercially sensitive information

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ADDENDUM

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Golder Associates

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127635006-008-R-Rev0-07000	25 July 2016	-
127635006-008-R-Rev1-07000	30 November 2016	Some information redacted to maintain confidentiality

1.0 INTRODUCTION

QGC has requested that Golder Associates Pty Ltd (Golder) undertake a hazard assessment of four stimulation chemicals listed in recent stimulation fluid product disclosures. The assessment is in regards to the potential toxicity of the fluid to human health and ecological receptors in aquatic and terrestrial environments.

This document presents the hazard assessment of the four (4) chemicals, as identified in Table 1.

1.1 Background

Golder has previously assessed a number of hydraulic stimulation chemicals for human health and ecological hazards for QGC. The assessments are documented in the report*: Human Health and Ecological Chemical Assessment – Hydraulic Stimulation Chemical Assessment – QGC Surat and Bowen Basin Operation* (Golder Ref. 127635006-004-R-Rev3) hereafter referred to as 'HSCA report'. This assessment is provided as an addendum to that report.

1.2 Chemicals to be assessed

QGC provided Golder with Chemical Abstract Service Registry Numbers (CAS RN) for four chemicals that were identified in recent stimulation fluid product disclosures.

The chemicals provided by QGC were reviewed by Golder and found to have not been previously assessed. These four chemicals are shown in Table 1.

Table 1: Additional Stimulation Chemicals

CAS RN	Chemical Name
9002-84-0	Poly (tetrafluoroethylene)
61789-76-2	Amines, dicoco alkyl
304443-60-5	Polyvinyl acetate, partially hydrolysed*
127-09-3	Sodium acetate

Note: CAS RN - Chemical Abstracts Service Registry Number.

*Polyvinyl alcohol (CAS RN: 9002-89-5) was used as a surrogate for polyvinyl acetate, partially hydrolysed in the environmental assessment

1.3 Scope of Work

The approach applied for chemical hazard assessment is documented in the HSCA report (Golder, 2016). This approach was applied to the hazard assessment of the chemicals listed in Table 1.

As a part of this assessment, the following scope of work was completed:

- Preparation of human health toxicological profiles (results presented in Appendix A).
- A review of environmental hazards (where possible) using measures of persistence (P), bioaccumulation (B) and toxicity (T) (PBT) and preparation of chemical information sheets and hazard summaries (results presented in Appendix B).
- Mass balance calculations.
- Preparation of this addendum.

2.0 SODIUM ACETATE, ANHYDROUS

2.1 Overview

Sodium acetate, anhydrous, is the anhydrous sodium salt form of acetic acid. It is an odourless white crystalline powder that readily dissociates in water to form sodium and acetate ions. It occurs naturally in both animal and plant tissues. Uses of sodium acetate include in pharmaceuticals and medication, as a preservative in food, in electroplating, in tanning and textile dying and as a commonly used laboratory reagent for precipitation of nucleic acids and preparation of gel stains for protein gel electrophoresis (ECHA 2016; Santa Cruz Biotechnology 2016). The molecular structure of sodium acetate, anhydrous, in shown in Figure 1 below.

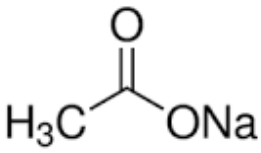

Figure 1: Molecular structure of Sodium acetate, anhydrous

2.2 Human health hazard assessment

The toxicity classifications for some of the health end-points for sodium acetate are based on the dissociated form (acetic acid), other salts (calium acetate, calcium diacetate, potassium acetate), surrogate chemicals (citric acid, fumaric acid, glycol acid) and read-across approaches.

Based on the data available, sodium acetate is not classified as hazardous for the following health end-points: acute oral, dermal or inhalation toxicity, mutagenicity/genotoxicity, reproductive and developmental toxicity. Furthermore, it is not classified as a skin sensitiser or an agent that causes corrosion of the skin and the eyes, however it can cause redness/mild irritation of the eyes/skin. Data is lacking for the classification of neurotoxicity and respiratory sensitisation.

While there was lack of reliable repeat dose studies to allow classification of sodium acetate within the Global Harmonised System of Classification and Labelling of Chemicals (GHS), some oral repeat studies have been provided and deemed valid with restrictions by the Organisation for Economic Co-operation and Development (OECD SIDS 2005). One of these oral repeat studies has provided a Lowest Observable Adverse Effect Level (LOAEL) of 21 mg/kg for a 3 month rat study which results in sodium acetate being classified as a Hazard Band 2. However, it is noted that acetic acid, sodium acetate and other acetic acid salts are listed as ingredients used as flavouring agents and adjuvant, and as a pH control agent in numerous food substances by the United States Food and Drug Administration (US FDA). As these substances have been used in food for a long period of time it is deemed appropriate to classify sodium acetate with a Hazard Band of 1.

2.3 Environmental hazard assessment

2.3.1 Fate and behaviour in the environment

Sodium acetate, anhydrous rapidly dissociates to sodium and acetate ions in water. In terrestrial environments this compound has low volatility, a short half-life and have a low potential to bioaccumulate (ECHA 2016).

2.3.2 Aquatic

An environmental hazard assessment was undertaken on sodium acetate, based on persistence (P), bioaccumulation (B) and toxic (T) potential (hereafter referred to as PBT). The environmental hazard assessment categorizes a chemical as having potential to pose a high, moderate or low hazard to the

environment. The chemical information sheet or ecotoxicology profile for sodium acetate (provided in Appendix B) presents the available physical and chemical information, in addition to available ecotoxicological data for freshwater organisms.

Table 2 below summarises the overall hazard score for sodium acetate.

Table 2: Hazard score for sodium acetate

Chemical	Bioaccumulation Score	Persistence Score	Toxicity Score	Overall Hazard Score
Sodium acetate	1.0	1.1	1.0	1.0

Based on the toxicity assessment, sodium acetate has been given an overall hazard score of 1 (1 = lowest, 3 = highest), indicating that is expected to pose a low hazard to the aquatic environment.

2.3.3 Terrestrial

The chemical information sheet (Appendix B) presents the physical and chemical information for sodium acetate in addition to available ecotoxicological data for terrestrial organisms.

For sodium acetate terrestrial toxicity data were available for mammals. Additionally QSARs were used to predict toxicity to plants (lettuce) and earthworms. Based on review of the primary literature it is important to note that the quantitative-structure activity relationship (QSAR) models may not be reliable and may underestimate toxicity at log Kow < 1 mg/L. For sodium acetate the log Kow is -3.72.

Table 3 below summarises the terrestrial toxicity for sodium acetate.

Table 3: Terrestrial toxicity data for sodium acetate

Chemical	Mammalian LD50	ECOSAR earthworm LC50	QSAR lettuce EC50	QSAR earthworm LC50
	mg/kg	mg/L	mg/L	mg/kg
Sodium acetate	3,500	1,649	91,701	27.5

Soil half-life, Henry's Law Constant and Log K_{ow} were collated to assess persistence and bioaccumulation in terrestrial ecosystems. Sodium acetate has low volatility, a short half-live and has low potential to bioaccumulate.

Based on the review of the available physico-chemical and terrestrial ecotoxicological data, the potential hazard to the terrestrial environment posed by sodium acetate is low.

3.0 AMINES, DICOCOALKYL

3.1 Overview

Dicocoalkyl amines are used in many industry processes including froth flotation, anti-caking, pigment dispersion and in oil drilling including hydraulic fracturing (Chemical Land 21, 2016). The molecular structure of sodium acetate, anhydrous, is shown in Figure 2.

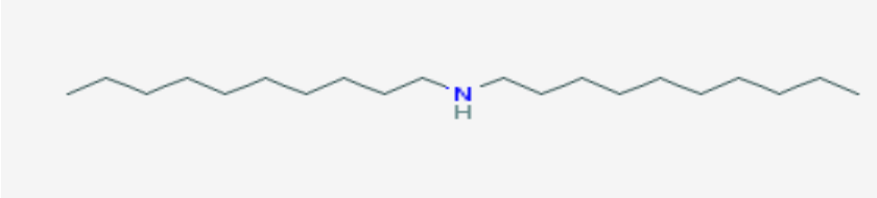

Figure 2: Molecular structure of dicocoalkyl amine

3.2 Human health hazard assessment

Dicocoalkyl amine is a fatty acid alkyl amine derived from coconut oil by hydrogenation with a nitrogen source. There is insufficient information to characterise the human health hazards of dicocoalkyl amine. However there is sufficient information to characterise the hazards of coco alkyl amines (CAA) as a group. CAA have a low to moderate order of acute toxicity. They are corrosive to skin and eyes and can cause adverse effects to the immune and gastrointestinal system following repeated oral exposure. They are not classified by the European Chemicals Agency (ECHA) as skin or respiratory sensitisers though it is noted that there is insufficient information to be confident in these classifications. CAA are not classified as mutagenic, reproductive or carcinogenic chemicals. Based on the human health assessment undertaken, dicocoalkyl amine is classified as Hazard Band 3.

3.3 Environmental hazard assessment

3.3.1 Fate and behaviour in the Environment

Dicocoalkyl amine is insoluble but readily biodegradable in water. In terrestrial environments it is highly volatile with a moderate half-life and a high potential to bioaccumulate (Chem International, Inc. 2013).

3.3.2 Aquatic

An environmental hazard assessment based on PBT was undertaken on dicocoalkyl amine. The chemical information sheet is provided in Appendix B.

An overall score (the environmental hazard score) was calculated based on aquatic hazard and is presented below in Table 4.

Table 4: Hazard score of surrogates for Dicocoalkyl amine

Chemical	Bioaccumulation Score	Persistence Score	Toxicity Score	Overall Hazard Score
Dicocoalkyl amine	2.0	1.6	3.0	2.2

Based on the toxicity assessment, dicocoalkyl amine been given an overall hazard score of 2.2 (1 = lowest, 3 = highest), indicating that it is expected to pose a moderate hazard to the aquatic environment.

3.3.3 Terrestrial

The chemical information sheets (Appendix B) present the physical and chemical information for dicocoalkyl amine in addition to available ecotoxicological data for terrestrial organisms.

Terrestrial toxicity data was available for only mammals. QSARs could not be used to predict toxicity to plants (lettuce) and earthworms as the Log Kow is greater than 4 which therefore excludes assessment.

The mammalian LD_{50} for rats exposed (oral exposure) to dicocoalkyl amine is 2,000 mg/kg.

Soil half-life, Henry's Law Constant and Log K_{ow} were collated to assess persistence and bioaccumulation in terrestrial ecosystems. Dicocoalkyl amine has highly volatility, a moderate half-life and a high potential to bioaccumulate.

Based on the review of the available physico-chemical and terrestrial ecotoxicological data the potential hazard to the terrestrial environment of dicocoalkyl amine was assessed to be moderate to high.

4.0 POLYVINYL ACETATE

4.1 Overview

Polyvinyl acetate is a high molecular weight polymer. It occurs as a transparent solid with softening at 35-50ºC. Uses include as an adhesive and binder for paints, wood, glass, metals and porcelain, in textile finishing, as paper and paperboard coating, as a component of lacquers and as a strengthening agent for cements (HSDB, 2002).

In water polyvinyl acetate is hydrolysed to polyvinyl alcohol. Given the similar properties of the chemicals, polyvinyl alcohol has also been assessed as a part of the human health profile and has been used as a surrogate for polyvinyl acetate for the environmental assessment.

The molecular structure of polyvinyl acetate is shown in Figure 3 below.

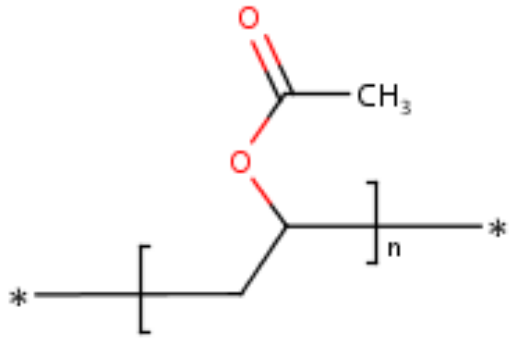

Figure 3: Molecular structure of polyvinyl acetate

4.2 Human health hazard assessment

The International Agency for Research on Cancer (IARC) has classified polyvinyl acetate as not classifiable as a carcinogen to humans. Polyvinyl acetate has been found to be non-mutagenic in the Ames assay (with and without activation) and in the Chinese Hamster fibroblast cell assay. Due to the high molecular weight of both polyvinyl acetate and its surrogate polyvinyl alcohol (>1000 g/mol) the polymers are unlikely to cross biological membranes and are therefore generally regarded as non-hazardous for systemic health end-points. This is supported the by the high LD_{50} acute oral toxicity values of polyvinyl alcohol (14,270 – 23,854 mg/kg).

The monomer, vinyl acetate, has been used as a surrogate for the point of contact endpoints. As vinyl acetate is not classified as a skin sensitiser or as causing corrosion/irritation to the skin and the eye it is inferred that the polymer is not classifiable as an irritant to the eyes/skin or a skin sensitiser. Based on the human health assessment undertaken polyvinyl acetate is classified as Hazard Band 1.

4.3 Environmental hazard assessment

4.3.1 Fate and behaviour in the Environment

Polyvinyl alcohol is insoluble in water. In the terrestrial environment it has a short half-life, is not volatile and is not likely to bioaccumulate.

4.3.2 Aquatic

An environmental hazard assessment was undertaken on polyvinyl alcohol, based on PBT. The chemical information sheet is provided in Appendix B.

An overall score (the environmental hazard score) for polyvinyl alcohol was calculated based on aquatic hazard. Table 5 below summarises the overall hazard score for polyvinyl alcohol.

Table 5: Hazard score for polyvinyl alcohol

Chemical	Bioaccumulation Score	Persistence Score	Toxicity Score	Overall Hazard Score
Polyvinyl alcohol	1.0	1.6	1.0	1.2

Based on the toxicity assessment, polyvinyl alcohol has been given an overall hazard score of 1.2 (1 = lowest, 3 = highest), indicating that it is expected to pose a low hazard to the aquatic environment.

4.3.3 Terrestrial

The chemical information sheet (Appendix B) presents the available ecotoxicological data on polyvinyl alcohol for terrestrial organisms.

For polyvinyl alcohol, terrestrial toxicity data were available for mammals. Additionally QSARs were used to predict toxicity to plants (lettuce) and earthworms. As mentioned above the QSAR models may underestimate toxicity at log Kow < 1 mg/L. For polyvinyl alcohol the log Kow is -5.3.

Table 6: Terrestrial toxicity data for polyvinyl alcohol

	Mammalian LD50	ECOSAR earthworm LC50	QSAR lettuce EC50	QSAR earthworm LC50
	mg/kg bw	mg/L	mg/L	mg/kg
Polyvinyl alcohol	14,270	4,830	7,467,600	105,000,000

Soil half-life, Henry's Law Constant and Log K_{ow} were collated to assess persistence and bioaccumulation in terrestrial ecosystems. Polyvinyl alcohols have low volatility, short half-lives and a low potential to bioaccumulate.

Based on the review of the available physico-chemical and terrestrial ecotoxicological data, the potential hazard to the terrestrial environment was assessed to be low.

5.0 POLY(TETRAFLUOROETHYLENE)

5.1 Overview

Poly(tetrafluoroethylene) (PTFE) is an extremely inert polymer with excellent thermal, chemical and flame resistance. PFTE or Teflon (brand name) is made up of very long chains of carbon and fluorine units with a very high molecular weight. The carbon-fluorine bond of PFTE is the reason that it is one of the most stable and inert plastics. Uses of PFTE are varied and include in cooking (pan coatings, baking sheets), medical

applications (heart patches, cardiovascular grafts) and in chemical processing (tubings and coatings). Properties of PTFEs include high melting point (342^{0}C), high thermal stability, insolubility in water, chemically inert, low water ab/adsorptivity and non-degradable between -260 and 260^{0}C (Molyneaux and Ebnesajjad 2004).

The molecular structure of polytetrafluoroethylene is shown below in Figure 4.

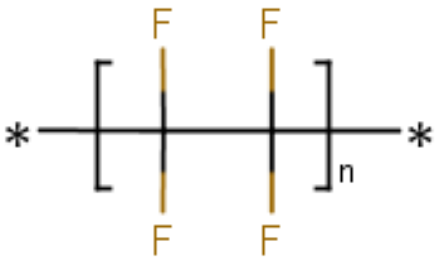

Figure 4: Molecular structure of polytetrafluoroethylene

5.2 Human health hazard assessment

IARC has evaluated PTFE as not classifiable as a carcinogen to humans. Due to the high molecular weight of PTFE (>1000 g/mol) the polymer is unlikely to cross the biological membranes and is therefore generally regarded as non-hazardous for systemic health end-points. The monomer, tetrafluoroethylene, has been used as a surrogate for the point of contact endpoints. As tetrafluoroethylene is not classified as a skin sensitiser or as causing corrosion/irritation to the skin and the eye it is inferred that the polymer is not classifiable as a skin irritant to the eyes/skin or a skin sensitiser.

As for all fine powders, PTFE dust can cause skin effects (discomfort, itching, redness or swelling), eye effects (tearing, redness and discomfort) and respiratory tract irritation. Thermodegradation products of PTFE that form at 300-500°C can produce polymer-fume in humans and repeated episodes of polymer-fume fever may result in persistent lung effects. Notwithstanding this, based on the human health assessment undertaken PTFE is classified as Hazard Band 1.

5.3 Environmental hazard assessment

Limited published information was available on the physical and chemical characteristics for PTFE. Additionally, no toxicity data was available for aquatic or terrestrial organisms at the time of reporting. Based on the limited available data (inertness and insolubility) for this chemical hazards of this chemical to aquatic and terrestrial organisms were considered to be limited.

6.0 MASS BALANCE

The mass fraction for each chemical in a standard stimulation fluid was provided to Golder (S. Kearney pers. comm. May 2016). As the Fluid Disclosure Sheet (FDR) for these chemicals was not available, the density of each of the chemicals was used to estimate a mass of chemical in a standard stimulation fluid. Assuming an injected fluid volume of 800,000 L (0.8 ML), the following was estimated:

- Concentration of each of the chemicals in the stimulation fluid
- Injected mass of each of the chemicals during a stimulation event
- Residual mass of each of the chemicals following a stimulation event.

However, the mass balance calculations have not been include to maintain the confidentiality of commercially sensitive information. As a summary, the following is provided.

Following completion of the hydraulic stimulation process, a percentage fraction of the injected hydraulic stimulation fluids are recovered upon flowback and production of the well. However, it should be noted that most of the additives would have undergone chemical transformations in the sub-surface. In addition, the formation also contributes a certain amount of water and dissolved salts to the flowback and production of the well. If it is conservatively assumed that 20% of the hydraulic stimulation fluid volume remains in the formation (reasonable “worst case”) this would correspond to the estimated “Residual Mass” of 2 kg or less for each of the chemicals.

7.0 SUMMARY AND CONCLUSIONS

Golder assessed four chemicals (poly(tetrafluoroethylene; amines, dicoco alkyl; polyvinyl acetate; and sodium acetate) based on exposure hazards to humans, aquatic and terrestrial ecology. Mass balance calculations were also undertaken. Based on the findings in this report, poly(tetrafluoroethylene), polyvinyl acetate and sodium acetate were considered to present a low to moderate hazard for ecological receptors and/or human health.

Dicoco alkyl amine was categorized as human health Hazard Band 3, due to its potential to cause adverse effects to the immune and gastrointestinal system following repeated oral exposure, and was ranked as moderate to high environmental hazard, based on mammal toxicology results and physical-chemical characteristics. Based on the hazard band rating, consideration should be given to water quality analysis for this compound in the event of a potential or actual release. However, it is noted that the concentration of dicoco alkyl amine in the inflow stimulation fluid is low and will be substantially lower in flowback fluid. Therefore, given plausible exposure pathways to this compound in stimulation fluid and flowback fluid, the environmental and human health risks of this compound are likely to be limited.

8.0 UNCERTAINTY ANALYSIS

The evaluation of the human health and ecological hazards is limited to the quantity and quality of information available in the information sources reviewed and the literature received by Golder from the provider. A measure of the data completeness across the toxicological and hazard parameters used has been estimated expressed as a percentage of the parameters for which data were available. These are presented in each summary in Appendix A and Appendix B.

For the chemicals assessed in this report, the conclusions on ecological hazard were based on a mix of modelled and measured data. Modelled data have higher degree of uncertainty than measured data, and may over- or under-estimate risks. Conclusions based on modelled data should therefore be carefully made. Should measured data for these compounds become available, it is recommended that the hazard assessment be revised.

An assessment of the quality of the available data is beyond the scope of this work. In the absence of such a review Golder has relied on primary literature sources from established, robust and reputable sources such as the WHO, Organisation for Economic Cooperation and Development (OECD) and US EPA where available. As new toxicological data are generated and become available in the published literature, the information presented in this hazard evaluation and the associated conclusions may be subject to change. On this basis the hazard profiles are dated to enable future review as may be appropriate. This is particularly pertinent across human health parameters within the highest Hazard Band category (4) which includes such areas as endocrine disruption potential and carcinogenicity.

9.0 EXCLUSIONS

This document provides a hazard assessment which reflects the potential concerns associated with the intrinsic toxicity of the substances reviewed. This does not include exposure assessment considerations that may realise the expression of this toxicity, however, comment is made to place exposures into perspective associated with fate and transport properties and specific physico-chemical properties.

10.0 CONCLUSIONS

Table 7 and Table 8 summarise the outcomes of the human health and ecological toxicity reviews, respectively.

Table 7: Summary of Human Health Toxicity Hazard Band Ranking

Compound	Human Health Hazard Band[1]	Comment
Poly (tetrafluoroethylene)	1	Based on the high molecular weight of PTFE the polymer is unlikely to cross the biological membranes and therefore generally is regarded as nonhazardous for systemic health end-points. Its monomer, tetrafluoroethylene, is not classified as a skin sensitiser or as causing corrosion/irritation to the skin and the eye. In its fine powder form PTFE dust can cause slight skin effects, eye effects and respiratory tract irritation.
Amines, dicoco alkyl	3	Based on coco alkyl amines as a group having low to moderate order of acute toxicity, being corrosive to skin and eyes and being able to cause adverse effects to the immune and gastrointestinal system following repeated oral exposure.
Polyvinyl acetate	1	Based on the high molecular weight of polyvinyl the polymer is unlikely to cross the biological membranes and therefore generally is regarded as nonhazardous for systemic health end-points. Its monomer vinyl acetate is not classified as a skin sensitiser or as causing corrosion/irritation to the skin and the eye.
Sodium acetate	1	Based on acetic acid, sodium acetate and other acetic acid salts being used in food for a long period of time.

Notes: 1. A ranking of 1 represents the lowest toxicity and 4 represents the highest toxicity.

Table 8: Summary of Ecotoxicology Ranking

Compound	Aquatic Hazard	Aquatic Hazard Comment	Terrestrial Hazard	Terrestrial Hazard Comment
Poly (tetrafluoroethylene)	Likely to be limited	Based on limited physical-chemical characteristics	Likely to be limited	Based on limited physico-chemical characteristics
Amines, dicoco alkyl	Moderate	Based on persistence, bioaccumulation and toxicity	Moderate to high	Based on mammal toxicology results and physical-chemical characteristics
Polyvinyl acetate (polyvinyl alcohol)	Low	Based on persistence, bioaccumulation and toxicity	Low	Based on mammal, earthworm, QSAR earthworm and lettuce toxicity results and physical-chemical characteristics
Sodium acetate	Low	Based on persistence, bioaccumulation and toxicity	Low	Based on mammal, earthworm, QSAR earthworm and lettuce toxicity results and physical-chemical characteristics

The overall conclusions of the *Human Health and Ecological Chemical Assessment – Hydraulic Stimulation Chemical Assessment – QGC Surat and Bowen Basin Operation* report (Golder, 2016) are not changed by the outcomes of this assessment.

11.0 IMPORTANT INFORMATION

Your attention is drawn to the document titled - “Important Information Relating to this Report”, which is included in Appendix C of this report. The statements presented in that document are intended to inform a reader of the report about its proper use. There are important limitations as to who can use the report and how it can be used. It is important that a reader of the report understands and has realistic expectations about those matters. The Important Information document does not alter the obligations Golder Associates has under the contract between it and its client.

12.0 REFERENCES

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Report Signature Page

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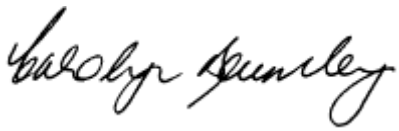

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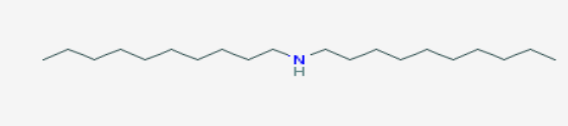
APPENDIX A

Human Health Chemical Profiles

Project number: 127635006
Project name: Hydraulic Stimulation Chemical Assessment, Queensland
Client name: QGC

Name	Amines, dicoco alkyl
Synonyms	Dicoco alkylamines, Dicocamine, dicocoalkylamines, dicoco, cocoalkylamines
CAS number	61789-76-2
Molecular formula	Not applicable – chemical substances of variable composition. Surrogate molecular formula: $C_{20}H_{43}N$
Molecular Structure	Not applicable. Chemical substances of variable composition. Struture shown is for didecylamine (CAS 1120-49-6). 

Overview	References
Amines, dicoco alkyl (Dicocoamine) is a fatty amine (nitrogen derivatives of fatty acids) prepared from coconut fatty acids. It is a secondary alkylamine. Coconut oil fatty acids range between C8 and C22 however are made up predominantly of C10-C14 with the most abundant being C12 accounting for approximately 50% of the content. The human health hazards of dicocamine are not well characterised. The following surrogates have been used to supplement the hazard profile; cocoalkylamines, didecylamine (C12 secondary amine), fatty amines, secondary alkylamines. Fatty amines are prepared from natural materials (in this case coconut) by hydrogenation (at approximately 200-280^{o}C) of a fatty nitrile intermediate. Dicocoamine is a waxy solid at room temperature with a melting point of 43^{o}C. It is insoluble in water. The density ranges from 0.79 g/cm^3 to 0.94 g/cm^3. Dicocoamine is used in cosmetics and as an intermediate in the manufacture of surfactants. For the purposes of hazard classification coco alkyl amines have been assessed by the European Commission as a group. The following hazard classification has been proposed; Harmful if swallowed, very Corrosive (>10% in a mixture), corrosive (when present at 5-10% or greater in mixture), skin and eye irritant at between 1 and 5%. Harmful following repeat exposure.	Kirk-Othmer (2003) ECHA (2011)

Human Health Toxicity Summary	Reference
Carcinogenicity Coco alkyl amines are not classified by ECHA as carcinogenic. *Notes:* ECHA note that neither animal nor human data on the carcinogenicity of coco alkyl amines are available. A lifetime oral rat toxicity study of octadecylamine ('stearamine') was conducted using four groups of 24 rats (12/sex) of rats fed diets containing 20, 100, 200, and 500 ppm	ECHA (2011)

stearamine (Deichmann et al., 1958). A control group of animals was fed the base diet alone. Feed consumption, growth rate, death rate, and blood cell counts for treated animals were comparable to those of the control. The survival rate for this study was 17-33 % for both the control and treatment groups. At necropsy, no significant differences in the incidence and types of lesions observed were found between treated and control groups.	
Mutagenicity/Genotoxicity Coco alkyl amines are not classified by ECHA as mutagens. *Notes:* Dicocoamine was negative when tested according to the Ames test for induction of gene mutations in bacteria (OECD Test Guideline 471). ECHA noted that there is no evidence for mutagenicity of coco alkyl amines from the available gene mutation test in bacteria.	ECHA (2011)
Reproductive Toxicity Coco alkyl amines are not classified by ECHA as reproductive agents. *Notes:* Reproduction toxicity studies according or similar to pertinent OECD test guidelines are only available for tallow alkyl amines (fertility, 1-generation screening test acc. to OECD TG 421) and (Z)-octadec-9-enylamine (developmental toxicity in rats/rabbits, sim. to OECD TG 414). In the one-generation test with tallow alkyl amines, an adverse impact of test substance administration on fertility was only seen at the highest dose level of 150 mg/kg bw/d, which was lethal for more than half of the treated dams. The classification is also supported by observations in repeat dose toxicity studies (14-90 day studies) where adverse effects on reproductive organs were not reported.	ECHA (2011)
Developmental Toxicity/Teratogenicity Coco alkyl amines are not classified by ECHA as reproductive agents. *Notes:* Reproduction toxicity studies according or similar to pertinent OECD test guidelines are only available for (Z)-octadec-9-enylamine (developmental toxicity in rats/rabbits, sim. to OECD TG 414). No observations of developmental toxicity occurred at doses that were not maternally toxic.	ECHA (2011)
Endocrine Disruption Coco alkyl amines has not been identified in the European Commission (EC)'s report, "Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption" as a substance of interest.	ECHA (2011)
Neurotoxicity There was no evidence of neurotoxicity in repeat dose toxicity studies with Coco alkyl amines.	ECHA (2011)
Acute Toxicity (oral, dermal, inhalation) The following oral acute LD_{50} values are summarised by ECHA with respect to Coco alkyl amines: • Armeen C acute oral toxicity study (OECD 401) with Wistar rats: oral LD_{50} 1300 mg/kg (1240 for males and 1390 for female rats). Clinical signs included apathy, slight to pronounced irregular posture and other symptoms reflecting the pathological finding of irritation/corrosion of the gastrointestinal system. • Genamin CC 100D acute oral toxicity study (OECD 401) with Wistar rats: oral LD_{50} >2000 mg/kg (> 2000 for males and 2820 for female rats). Clinical signs included apathy, slight to pronounced irregular posture and other symptoms reflecting gastrointestinal disturbance (most likely irritation/corrosion). The pathological findings included partly darkened liver, brightened spleen and yellow-dark red filling of the gastrointestinal tract. • Armeen CD (40% aqueous solution of coco alkyl amines) acute oral toxicity study (OECD 401) with Sprague Dawley rats: oral LD_{50} 2040 mg/kg (95% confidence limits of 1510 to 2760 mg/kg). Clinical signs included apathy, slight to pronounced irregular	ECHA (2011)

posture and other symptoms reflecting typical signs of irritation/corrosion of the gastrointestinal system. Inhalation acute toxicity studies indicate that the vapours of coco alkyl amines are irritating to the respiratory system and might present an aspiration hazard.	
Chronic/repeat dose toxicity (oral, dermal, inhalation) Coco alkyl amines have been tested in repeat dose (28 day) animal toxicity studies. The general findings indicate that the main adverse effect is delayed mortality due to gastrointestinal distress and immunosuppression (effects on lymph nodes) at 150 mg/kg/d. The following ECHA summary provides a dose response assessment: • Delayed mortalities and erosion of gastrointestinal mucosa at 150 mg/kg bw/d (28-day study, tallow alkyl amines) • Gait abnormalities at non-lethal, non-irritating concentrations (50 mg/kg bw/d, 28-day study, octadecenylamine). • Treatment-related reduction in food consumption (≥ 7-8 mg/kg bw/d, subacute study, • hydrogenated tallow alkyl amines) resulting in growth depression and anorexia. • Accumulation of test material in the intestinal wall and in mesenteric lymph nodes (≥ 12 mg/kg bw/d, 28-day study, rat; 15 mg/kg bw/d, tallow alkyl amines; 1-year dog, octadecylamine). The effect is already present at non-irritating dosages. There is no excretion pathway for intracellular material, some redistribution among cells or among organs may be possible through rephagocytosis or migration of loaden histiocytes. The effect is irreversible. • Disturbance of lipid metabolism (8 mg/kg bw/d, 14-day study, octadecylamine).	ECHA (2011)
Sensitisation of the skin or respiratory system ECHA did not classify coco alkyl amines as skin or respiratory sensitisers according to the GHS classification criteria. ECHA note that no data on respiratory sensitisation are available, while the database is inconclusive with respect to skin sensitisation.	ECHA (2011)
Corrosion (irreversible and reversible)/irritation of the skin or eye Classified as skin or eye irritants at low concentration (1-5%) and corrosive agents (>5%).	ECHA (2011)

Physical hazards	Reference
Flammable Potential Non flammable, combustible liquids (flash point greater than 100°C)	ECHA (2011)
Explosive Potential Based on structure coco alkyl amines are not expected to be explosive.	ECHA (2011)

Toxicity Values	Value	Reference
Human Toxicity Data		
High Chronic/Repeat Dose Toxicity		
LOAEC	No data found.	All proposed data sources
LOAEL	No data found.	All proposed data sources
Animal Toxicity Data		

Acute Toxicity		
LD_{50}		
Rat, oral	Range between 1240 and 2820 mg/kg	ECHA (2011)
New Zealand white rabbits, dermal	2000 mg/kg – corrosion of skin noted.	ECHA (2011)
LC_{50}		
Sprague Dawley rats	>0.0099 mg/L (respiratory irritation)	ECHA (2011)
Repeat Dose Studies		
Oral NOAEL	3.25 mg/kg/d	ECHA (2011)
Dermal LOAEL	12.5 mg/kg/d	ECHA (2011)

Footnotes:
LD_{50} – lethal dose for 50% of experimental population
LC_{50} – lethal air concentration for 50% of experimental population
LOAEL – Lowest Observed Adverse Effect Level
LOAEC – Lowest Observed Adverse Effect Concentration
NDF – No data found within the limits of the search strategy

Human Health Toxicity Ranking*		
	Hazard data	**Comment**
Hazard Band 4		
Carcinogenicity (IARC Group 1 or 2A)	NO	Classified as Group 3 chemical by IARC.
Mutagenicity/Genotoxicity (GHS Category 1A and 1B)	NO	Based on Ames assay (with and without activation) and in the Chinese Hamster fibroblast cell assay.
Reproductive Toxicity/Developmental toxicity (GHS Category 1, 1A and 1B)	NO	
Endocrine Disruption[1]	NO	
Hazard Band 3		
Carcinogenicity (IARC Group 2B)	NO	
Mutagenicity/Genotoxicity (GHS Category 2)	NO	
Reproductive Toxicity/Developmental toxicity (GHS Category 2)	NO	
Acute Toxicity (oral, dermal or inhalation) Very Toxic/Toxic • oral LD_{50} ≤ 300 mg/kg [2] • dermal LD_{50} ≤ 1000 mg/kg • inhalation LC_{50} ≤ 10 mg/L [3] (or mg/m^3) (vapour)	NO	Based on oral studies. No dermal and inhalation studies.
High Chronic/repeat dose toxicity • oral LOAEL ≤ 10 mg/kg/d [2]; • dermal LOAEL ≤ 2 0 mg/kg/d; • inhalation LOAEC (6 h/d) ≤ 50 ppm/d for gases, ≤ 0.2 mg/L/d for vapours or ≤ 0.02 mg/L/d for dust/mists/fumes [3]	YES	Effects on growth and other immune suppression related adverse effects. At higher doses gastrointestinal corrosion.
Corrosive (irreversible effect)	YES	Above 5%
Respiratory sensitiser	NO	
Hazard Band 2		
Harmful chronic/repeat dose toxicity • oral LOAEL > 10 mg/kg and ≤ 100 mg/kg/d • dermal LOAEL > 20 mg/kg/d and ≤ 200 mg/kg/d • inhalation (6-h/d) LOAEC > 50 mg/L ≤ 250 mg/L/d for gases, > 0.2 mg/L ≤ 1 .0 mg/L/d for vapours or > 0.02 mg/L ≤ 0.2 mg/L/d for dust/mists/fumes [3]	YES	There are no repeat dose LD values.
Skin Sensitiser	NO	
Hazard Band 1		
Acute Toxicity-Harmful • oral LD_{50} > 300 mg/kg ≤ 2000 mg/kg • dermal LD_{50} >1 000 mg/kg ≤ 2000 mg/kg; • inhalation LC_{50} (6 h/d) > 10 mg/L ≤ 20 mg/L for vapours) [3]	YES	Based on oral studies. No dermal and inhalation studies.
Irritant (reversible effect)	YES	At low concentrations (1-5%)
Hazard Band 0 **All indicators outside criteria listed in Hazards 1-4**		
Physical Hazards		
Flammable potential	NO	Combustible liquids
Explosive potential	NO	

Hazard Evaluation (highest band) not including physical hazards	3	
Uncertainty analysis /data confidence (out of 12 parameters)	12/12	**100%**

* Based on IMAP Framework [NICNAS (2013) Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework. National Industrial Chemicals Notification and Assessment Scheme. Department of Health and Aging, Canberra].

"[1]*Based on list of endocrine disrupting chemicals from the European Commission's Endocrine Disrupters website.*

[2] *milligrams per kilogram body mass (mg/kg) or milligrams per kilogram body mass per day (mg/kg/d)*

[3] *Based on GHS cut-offs for hazard classification. For chronic/repeat dose toxicity, GHS cut-offs are provided as guidance values (i.e. the dose/concentration at or below which significant health effects are observed)". (p 18, NICNAS 2013).*

Human Health Guidelines		
Media	**Concentration (mg/m^3; mg/L; mg/kg)**	**Reference**
Occupational Exposure Limits		
Air (OEL)		
8-h TWA	No data found.	-
STEL	No data found.	-
Peak Limitation	No data found.	-
Environmental Exposure		
Air, ambient	No data found.	-
Air, indoor	No data found.	-
Water, potable	No data found.	-
Water, recreational	No data found.	-
Soil, residential	No data found.	-
Soil, commercial/industrial	No data found.	-

Footnotes:

OEL = Occupational Exposure Limit

TWA = 8 h Time-Weighted Average

STEL = (15 min) Short-term Exposure Limit

Qualifying Summary Comments

Dicocoamine (Cas No 61789-76-2) is a fatty acid alkyl amine derived from coconut oil by hydrogenation with a nitrogen source. There is insufficient information to characterise the hazards of dicocoamine. However there is sufficient information to characterise the hazards of coco alkyl amines (CAA) as a group. CAA have a low to moderate order of acute toxicity. They are corrosive to skin and eyes and can cause adverse effects to the immune and gastrointestinal system following repeated oral exposure. They are not classified by ECHA as skin or respiratory sensitisers though it is noted that there is insufficient information to be confident in these classifications. CAA are not classified as mutagenic, reproductive or carcinogenic chemicals. Based on the human health assessment undertaken dicocoamine is classified as Hazard Band 3.

References and Notes

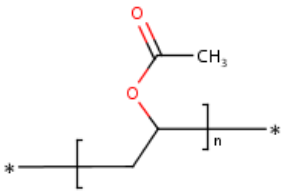
ChemID-plus (2016). TOXNET. Dicocoamine, didecylamine Available at: http://chem.sis.nlm.nih.gov/chemidplus/rn/1120-49-6 [Accessed 17 May 2016]

ECHA (2011) Committee for Risk Assessment RAC, Annex 1, Background document to the Opinion proposing harmonised classification and labelling at Community level of amines, coco alkyl ECHA/RAC/CLH-O-0000002195-77-01/A1 EC number: 262-977-1 CAS number: 61788-46-3 (European Chemicals Agency). Available at: http://echa.europa.eu/documents/10162/13626/rac_annex1_bd_amines_coco_alkyl+5_en.pdf [Accessed 17 May 2016]

Kirk-Othmer (2003). 'Amines, Fatty', Kirk-Othmer Encyclopedia of Chemical Technology. Copyright John Wiley & Sons

Created by:	JF	Date 17/05/2016
Reviewed and edited by:		Date

Project number: 127635006
Project name: Hydraulic Stimulation Chemical Assessment, Queensland
Client name: QGC

Name	Polyvinyl acetate, partially hydrolysed
Synonyms	Acetic Acid Ethenyl Ester, Homopolymer Acetic Acid Vinyl Ester, Polymers
CAS number	304443-60-5 9003-20-7 (Polyvinyl acetate)
Molecular formula	$(C_4\text{-}H_6\text{-}O_2)_n$
Molecular Structure	

Overview	References
Polyvinyl acetate is an odourless and colourless thermoplastic high polymer. It has a molecular weight between 11,000 and 1,500,000 g/mol and a melting point of 35-50° C with softening. The polymer is resistant to weathering and degrades at 220-250 ° C with the principal pyrolysis product being acetic acid. Polyvinyl acetate undergoes hydrolysis to form polyvinyl alcohol. Polyvinyl acetate is soluble in ethanol, 2-propanol, 1-butanol, benzene, acetone, chloroform, carbon tetrachloride, trichloroethylene and methylene chloride. The polymer is insoluble in water, gasoline, higher alcohols, aliphatic hydrocarbons, carbon disulphide, cyclohexane and oils and fats. Polyvinyl acetate is used as adhesives & binders for water-based or emulsion paints; adhesives for paper, wood, glass, metals & porcelain; sealant; shatterproof photographic bulbs; intermediate for conversion of polyvinyl alcohol & acetals; paper coating & paperboard; bookbinding; textile finishing; nonwoven fabric binder; component of lacquers, ink, & plastic wood; and strengthening agent for cements. Polyvinyl acetate is listed on the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Australian Inventory of Chemical Substances (AICS) Listing. As part of the existing chemical prioritisation and screening program NICNAS conducted a Tier 1 Final assessment for polyvinyl acetate in its use as a cosmetic. The Tier I assessment (based on expert validated rules for conducting such an assessment) concluded that there is low concern for human health risk. Polyvinyl alcohol (CAS number 9002-89-5) has been used as a surrogate as it is produced commercially from polyvinyl acetate and is expected to have similar properties. Polyvinyl alcohol is classified into two classes, either as partially hydrolysed and fully hydrolysed. It has a molecular weight of between 26,300 and 30,000. Partially hydrolyzed polyvinyl alcohol is used in the foods and JECFA has evaluated polyvinyl alcohol (partially hydrolysed) as a moisture barrier coating for foods. As part of the *61st JEFCA Chemical and Technical Assessment* is was concluded that under intended conditions of use and storage there would be negligible interaction between polyvinyl alcohol and food constituents. Due to the high molecular weight of both polyvinyl acetate and polyvinyl alcohol (>1000) the polymers are unlikely to cross biological membranes and therefore generally regarded as non hazardous for systemic health end-points. For point of contact endpoints (skin irritation, eye irritation, skin sensitisation) in the absence of information for the polymers data for the monomer, vinyl acetate (CAS number 108-05-4) will be used.	HSDB (2002) NICNAS (2016a) NICNAS (2016b) FAO (2004)

Human Health Toxicity Summary	Reference
Carcinogenicity The International Agency for Research on Cancer classifies polyvinyl acetate as a Group 3 chemical – *Not classifiable as to its carcinogenicity to humans*.	IARC (1987)
Mutagenicity/Genotoxicity Not classifiable as a mutagen given it is not is not absorbed into the body due to its high molecular weight. Polyvinyl Acetate was nonmutagenic in the Ames assay, with and without activation, and in the Chinese Hamster fibroblast cell assay.	IJT(1992)
Reproductive Toxicity Not classifiable as a reproductive toxicant given it is not is not absorbed into the body due to its high molecular weight.	-
Developmental Toxicity/Teratogenicity Not classifiable as a developmental toxicant given it is not is not absorbed into the body due to its high molecular weight.	-
Endocrine Disruption Polyvinyl acetate has not been identified in the European Commission (EC)'s report, "Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption" as a substance of interest. However, vinyl acetate has been classified as a Category III chemical (no evidence of endocrine disrupting activity or no data available).	ECED (2016)
Neurotoxicity Unlikely to result in neurotoxicity as it is not absorbed across biological membranes. .	-
Acute Toxicity (oral, dermal, inhalation) The following oral acute LD_{50} values have been provided for the surrogate polyvinyl alcohol: • Guinea pig – 18,750 mg/kg (Effect: behavioral: muscle weakness; gastrointestinal: hypermotility, diarrhea; liver: other changes). • Mouse – 14,270 mg/kg (Effect: behavioral: muscle weakness; gastrointestinal: "hypermotility, diarrhea; liver: other changes). • Mouse – 14,700 mg/kg (Effect: behavioral: muscle weakness, altered sleep time and general depressed activity) • Rat - >20,000 (Effect: behavioral: altered sleep time and general depressed activity) • Rat – 23,854 mg/kg ((Effect: behavioral: muscle weakness; gastrointestinal: hypermotility, diarrhea; liver: other changes).	ChemIDplus (2016)
Chronic/repeat dose toxicity (oral, dermal, inhalation) Unlikely to result in repeat dose toxicity as it is not absorbed across biological membranes.	-
Sensitisation of the skin or respiratory system Not classified as a skin or respiratory sensitiser according to the GHS classification criteria. . No data found.	ECHA (2016) ICSC (2004)
Corrosion (irreversible and reversible)/irritation of the skin or eye Not classified as a skin or eye irritant/corrosive agent according the GHS classification criteria. Polyvinyl alcohol may cause redness of the eyes.	ECHA (2016) ICSC (2004)

Physical hazards	Reference
Flammable Potential Polyvinyl alcohol is noted as 'combustible' and gives off irritating or toxic fumes (or gases) in a fire.	ICSC (2004)
Explosive Potential No data found.	-

Toxicity Values	Value	Reference
Human Toxicity Data		
High Chronic/Repeat Dose Toxicity		
LOAEC	No data found.	All proposed data sources
LOAEL	No data found.	All proposed data sources
Animal Toxicity Data		
Acute Toxicity		
LD_{50}		
Rat, oral	>20,000 mg/kg (polyvinyl alcohol) 23,854 mg/kg ((polyvinyl alcohol)	ChemIDplus (2016)
Mouse, oral	14,270 mg/kg (polyvinyl alcohol) 14,700 mg/kg (polyvinyl alcohol)	ChemIDplus (2016)
Rabbit, oral		
Guinea pig	18,750 mg/kg (oral, polyvinyl alcohol)	ChemIDplus (2016)
Rat, dermal	No data found.	All proposed data sources
Rabbit, dermal	No data found.	All proposed data sources
Mouse, dermal	No data found.	All proposed data sources
LC_{50}		
LOAEL	No data found.	All proposed data sources
LOAEC	No data found.	All proposed data sources

Footnotes:
LD_{50} – lethal dose for 50% of experimental population
LC_{50} – lethal air concentration for 50% of experimental population
LOAEL – Lowest Observed Adverse Effect Level
LOAEC – Lowest Observed Adverse Effect Concentration
NDF – No data found within the limits of the search strategy

Human Health Toxicity Ranking*		
	Hazard data	**Comment**
Hazard Band 4		
Carcinogenicity (IARC Group 1 or 2A)	NO	Classified as Group 3 chemical by IARC.
Mutagenicity/Genotoxicity (GHS Category 1A and 1B)	NO	Based on Ames assay (with and without activation) and in the Chinese Hamster fibroblast cell assay.
Reproductive Toxicity/Developmental toxicity (GHS Category 1, 1A and 1B)	Not expected	
Endocrine Disruption[1]	NO	
Hazard Band 3		
Carcinogenicity (IARC Group 2B)	NO	
Mutagenicity/Genotoxicity (GHS Category 2)	NO	
Reproductive Toxicity/Developmental toxicity (GHS Category 2)	Not expected	
Acute Toxicity (oral, dermal or inhalation) Very Toxic/Toxic • oral LD_{50} ≤ 300 mg/kg [2] • dermal LD_{50} ≤ 1000 mg/kg • inhalation LC_{50} ≤ 10 mg/L [3] (or mg/m^3) (vapour)	NO	Based on oral studies. No dermal and inhalation studies.
High Chronic/repeat dose toxicity • oral LOAEL ≤ 10 mg/kg/d [2]; • dermal LOAEL ≤ 2 0 mg/kg/d; • inhalation LOAEC (6 h/d) ≤ 50 ppm/d for gases, ≤ 0.2 mg/L/d for vapours or ≤ 0.02 mg/L/d for dust/mists/fumes [3]	Not expected.	There are no repeat dose LD values.
Corrosive (irreversible effect)	NO	
Respiratory sensitiser	NO	
Hazard Band 2		
Harmful chronic/repeat dose toxicity • oral LOAEL > 10 mg/kg and ≤ 100 mg/kg/d • dermal LOAEL > 20 mg/kg/d and ≤ 200 mg/kg/d • inhalation (6-h/d) LOAEC > 50 mg/L ≤ 250 mg/L/d for gases, > 0.2 mg/L ≤ 1 .0 mg/L/d for vapours or > 0.02 mg/L ≤ 0.2 mg/L/d for dust/mists/fumes [3]	Not expected.	There are no repeat dose LD values..
Skin Sensitiser	NO	
Hazard Band 1		
Acute Toxicity-Harmful • oral LD_{50} > 300 mg/kg ≤ 2000 mg/kg • dermal LD_{50} >1 000 mg/kg ≤ 2000 mg/kg; • inhalation LC_{50} (6 h/d) > 10 mg/L ≤ 20 mg/L for vapours) [3]	NO	Based on oral studies. No dermal and inhalation studies.
Irritant (reversible effect)	YES	Polyvinyl alcohol may cause redness of the eyes.
Hazard Band 0 **All indicators outside criteria listed in Hazards 1-4**		
Physical Hazards		
Flammable potential	YES	Based on polyvinyl alcohol.
Explosive potential	No data found.	

Hazard Evaluation (highest band) not including physical hazards	1	
Uncertainty analysis /data confidence (out of 12 parameters)	11/12	**92%**

* Based on IMAP Framework [NICNAS (2013) Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework. National Industrial Chemicals Notification and Assessment Scheme. Department of Health and Aging, Canberra].

"[1]*Based on list of endocrine disrupting chemicals from the European Commission's Endocrine Disrupters website.*

[2] *milligrams per kilogram body mass (mg/kg) or milligrams per kilogram body mass per day (mg/kg/d)*

[3] *Based on GHS cut-offs for hazard classification. For chronic/repeat dose toxicity, GHS cut-offs are provided as guidance values (i.e. the dose/concentration at or below which significant health effects are observed)". (p 18, NICNAS 2013).*

Human Health Guidelines		
Media	**Concentration (mg/m^3; mg/L; mg/kg)**	**Reference**
Occupational Exposure Limits		
Air (OEL)		
8-h TWA	No data found.	-
STEL	No data found.	-
Peak Limitation	No data found.	-
Environmental Exposure		
Air, ambient	No data found.	-
Air, indoor	No data found.	-
Water, potable	No data found.	-
Water, recreational	No data found.	-
Soil, residential	No data found.	-
Soil, commercial/industrial	No data found.	-

Footnotes:

OEL = Occupational Exposure Limit

TWA = 8 h Time-Weighted Average

STEL = (15 min) Short-term Exposure Limit

Qualifying Summary Comments

Polyvinyl acetate is an odourless and colourless thermoplastic high molecular weight polymer. IARC has classified polyvinyl acetate as not classifiable as a carcinogen to humans. Polyvinyl acetate has been found to be nonmutagenic in the Ames assay (with and without activation) and in the Chinese Hamster fibroblast cell assay. Due to the high molecular weight of both polyvinyl acetate and its surrogate polyvinyl alcohol (>1000 g/mol) the polymers are unlikely to cross the biological membranes and are therefore generally regarded as non hazardous for systemic health end-points. This is supported the by the high LD_{50} acute oral toxicity values of polyvinyl alcohol (14,270 – 23,854 mg/kg). The monomer, vinyl acetate, has been used as a surrogate for the point of contact endpoints. As vinyl acetate is not classified as a skin sensitiser or as causing corrosion/irritation to the skin and the eye it is inferred that the polymer is not classifiable as an irritant to the eyes/skin or skin a sensitiser. Based on the human health assessment undertaken polyvinyl acetate is classified as Hazard Band 1.

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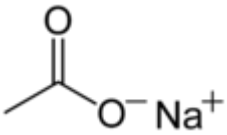
ICSC (2004). International Program on Chemical Safety. IPCS INCHEM. Available at: http://www.inchem.org/documents/icsc/icsc/eics1489.htm [Accessed 13 May 2016]

IJT (1992). International Journal of Toxicology. Vol. 11, No. 4, 1992.

Created by:	JH	Date 13/05/2016
Reviewed and edited by:	JF	Date 16/05/2016

Project number: 127635006
Project name: Hydraulic Stimulation Chemical Assessment, Queensland
Client name: QGC

Name	Sodium acetate
Synonyms	Sodium acetate hydrate Acetic acid, sodium salt Sodium acetate anhydrous Sodium ethanoate
CAS number	127-09-3
Molecular formula	$C_2H_4O_2.Na$
Molecular Structure	

Overview	References
Sodium acetate is an odourless white hygroscopic crystalline powder that is readily soluble in water. It is the sodium salt of acetic acid and occurs naturally in plant and animal tissues. Synthetically it can be prepared by neutralising acetic acid with sodium carbonate and evaporating solution to crystallisation or by treating calcium acetate with sodium sulfate and sodium bicarbonate. Sodium acetate has a molecular weight 82.04, a melting point 324 and density of 1.5 g/cm^3. It decomposes on heating and on contact with strong acids which produces acetic acid fumes. Sodium acetate reacts violently with strong oxidants and the solution in water is a weak base. Sodium acetate has various uses including as a buffer in photography, pharmaceuticals and medication, soaps, purification of glucose, preservative in food (as hydrate), electroplating, as a dehydrating agent, tanning, textile dying and synthesis of cinnamic acid and related compounds. Listed by the FDA (2015) as "Generally Recognised as Safe". Sodium acetate is an ingredient used as a flavouring agent and adjuvant and as a pH control agent. Sodium acetate is used in food at levels not to exceed current good manufacturing practice, including breakfast cereals, fats and oils, grain products and pastas, snack foods, hard and soft candy, jams and jellies, meat products, soups and soup mixes and sweet sauces (FDA 2015). Sodium acetate is not classified as hazardous for the following health end-points: acute oral, dermal or inhalation toxicity, mutagenicity/genotoxicity, reproductive and developmental toxicity. Furthermore, it is not classified as a skin sensitiser or causing corrosion of the skin and the eye, however it causes redness/mild irritation of the eyes/skin. Some repeat dose studies have been provided which are deemed valid with restrictions by the OECD (OECD SIDS 2005). The toxicity classifications for some of the health end-points are based on surrogate chemicals (including acetic acid, citric acid, calcium acetate, fumaric acid, calcium diacetate, glycol acid and potassium acetate) and read-across approach as noted throughout the study summaries.	ECHA (2016) FDA (2015) HSDB (2003) ICSC (2006) DailyMed (2013)

Human Health Toxicity Summary	Reference
Carcinogenicity No data found. *Notes:* Not listed on the ECHA Registered Substances Database as classifiable as a carcinogen.	ECHA (2016) IARC (2015)

No IARC classification has been provided for sodium acetate.	
Mutagenicity/Genotoxicity Sodium acetate is not classified according to the GHS Classification criteria as a germ cell mutagen on the ECHA Registered Substances Database. *Notes:* In-vitro The classification is based upon a read-across approach from acetic acid, which shares the same functional group and also has comparable values for the relevant molecular properties for the genetic toxicity endpoint. Acetic acid was not considered to be mutagenic on S.typhimurium TA 98, TA 100, TA 1535, and TA 97 (with and without metabolic activation) and applying the read-across approach sodium acetate was also considered as not mutagenic under the test conditions (similar to OECD 471 and GLP). In-vivo Testicular DNA-synthesis inhibition test (DSI test) was performed on male mice where sodium acetate was administered as a single oral dose by gavage at concentrations of 200, 500 and 1000 mg/kg. The basis of the method is to measure 3H-thymidine incorporation. No inhibitory effect on DNA-replication was detectable in animals. While this is not a standard genotoxicity test it provided evidence that sodium acetate is not genotoxic in animals.	ECHA (2016) (SIDS 2005)
Reproductive Toxicity Sodium acetate is not classified according to the GHS Classification criteria as a reproductive toxicant on the ECHA Registered Substances Database. *Notes:* In a fertility test female rats were fed diets containing 1.2% citric acid (approximately 600 mg/kg). Exposure began 29 weeks prior to mating and continued for a few months after mating. The reproduction of the rats was investigated when the rats were 32 weeks old and had received the diets for 29 weeks. Eleven weeks later the same rats were mated again. No reproductive effects were detected and the respective NOAEL and LOAEL for reproductive effects were 600 mg/kg and > 600 mg/kg. In another study as summarised in OECD SIDS (2005), 0.025% sodium acetate in the drinking water (approximately 60 mg/kg) was administered to 20 female and 20 male mice for 1 week prior to breeding, during a 9-day breeding period and (females only) throughout pregnancy, lactation and until the offspring were weaned at 3 weeks of age. Examination of the litters revealed no overt deformities at day 1 and day 21. The number of abnormalities seen in either soft or skeletal tissues of the test groups did not differ from the number occurring in the controls and it was concluded that sodium acetate had no effect on parents or offspring when mice were administered 1000 mg/kg by gavage on days 8-12 of gestation. The NOAEL (fertility) was 60 mg/kg.	ECHA (2016) OECD SIDS (2005)
Developmental Toxicity/Teratogenicity Sodium acetate is not classified according to the GHS Classification criteria as a developmental toxicant on the ECHA Registered Substances Database. Notes: The classification is based upon a read-across approach from a one-generation study on acetic acid, the ionic form of sodium acetate. A NOAEL of ≥ 1600 mg/kg was obtained from an experimental results with acetic acid where female Wistar rats were treated for 10 days for maternal toxicity, mortality and body weight gain, and for developmental toxicity, numbers of live and dead fetuses, external and internal examinations. Based on the molecular weights using a read-across approach the NOAEL for sodium acetate was calculated to be ≥ than 2187mg/kg for maternal and developmental toxicity (ECHA 2016). Thirty pregnant mice, approximately 60 days old, were administered a single oral dose of 1000 mg/kg of sodium acetate via gavage on days 8-12 of gestation. There were no general parental toxicity effects or effects on the offspring. The NOAEL (maternal and developmental) for mice was 1000 mg/kg (Kavlock, et al, 1987 as cited in OECD 2005; study noted as valid with restrictions).	ECHA (2016) OECD SIDS (2005)

Endocrine Disruption Sodium acetate has not been identified in the European Commission (EC)'s report, "Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption" as a substance of interest.	ECED (2016)
Neurotoxicity No data found using all proposed data sources.	-
Acute Toxicity (oral, dermal, inhalation) Sodium acetate is not classified according to the GHS Classification criteria as having oral, dermal or inhalation acute toxicity on the ECHA Registered Substances Database. *Notes:* <u>Oral</u> The oral acute toxicity classification is based upon read-across approach from OECD 401 study with the analogue calcium acetate, which shares the same functional group with sodium acetate and also has comparable values for the relevant molecular properties (low log Pow value, similar solubility and molecular weights). Based upon the experimental results of calcium acetate and the molecular weights the LD_{50} values for sodium acetate include ~2015 (female rat) and 3278– 4813 (male rat). <u>Dermal</u> The dermal acute toxicity classification is based upon direct experimental results obtained from a study using fumaric acid and without any extrapolation. Based on a test (not GLP) similar to OECD Guideline 402 (Acute Dermal Toxicity) 0.5 mL of dose of Fumaric Acid was administered via a single skin penetration to three female albino New Zealand rabbits and kept in place by gauze patches under a latex rubber film. The patches remained in place for 4 hours after which the wrap and patches were removed and the test area was observed for visible tissue destruction. No mortality was observed at the high dose of 20000 mg/kg and as a result the LD50 is reported as >20000 mg/kg. <u>Inhalation</u> The inhalation acute toxicity classification is based on test results from a study with a method equivalent to OECD 403 guideline using calcium diacetate. Wistar female (10) and male (10) rats were exposed to calcium diacetate concentrations of 5.6 mg/L (aerosol) for four hours and observed for 14 days. No mortality or clinical signs were observed during the 14 days and >5.6 mg/L air (analytical) was reported as the female LC_{50}.	ECHA (2016)
Chronic/repeat dose toxicity (oral, dermal, inhalation) There is insufficient data for the GHS classification of repeat dose toxicity (ECHA 2016). The following repeat dose studies for sodium acetate were provided in OECD SIDS (2005): • Sodium acetate was administered to rats through feed at a dose of 21 mg/kg for 3 months. There were indications of altered thyroid function and decreased growth was reported. The LOAEL for systemic toxicity was 21 mg/kg (Goldman, 1981; reliability noted as valid with restrictions). • Thirteen male rats were fed ad libitum a 25% protein, vitamin B12-deficient ration containing approximately 3600 mg/kg sodium acetate daily, for 4 weeks. There were no effects on growth or survival and the reported NOAEL was 3600 mg/kg (Dryden and Hartman, 1971; reliability noted as valid with restrictions) • Four groups of 6 male rats were administered a regimen of 50 or 500 ppm sodium acetate (controls) or 50 or 500 ppm lead acetate in distilled water for eight months. No significant effects on survival, reinforcement behaviour, or body weight gain were observed. As the rats treated with acetic acid, sodium salt served as the control for a lead exposure study there were no separate untreated controls. The NOAEL reported is 500 ppm (Cory-Slechta, 1986; reliability noted as valid with restrictions). *Notes:* In a subchronic study sodium acetate was orally administered to 8 male rats at a concentration of 100 ppm (~0.01 mg/kg) in drinking water for 112 days. Complex maze learning was investigated in male adult rats using a latent learning task beginning on day 143. No evidence	ECHA (2016) OECD SIDS (2005)

of impairment of simple task performance was observed. The study is considered to be of limited use in evaluating the toxicity of sodium acetate as: no data on GLP and no guideline was followed, only males were exposed to the substance, the administered doses were low, a small number of animals was used and no separate untreated controls are available for comparison (ECHA 2016).	
Sensitisation of the skin or respiratory system Sodium acetate is not classified according to the GHS Classification criteria as a skin sensitiser on the ECHA Registered Substances Database. There is insufficient data for the classification of the respiratory sensitisation. *Notes:* The classification is based on a modified Draize test involving glycol acid. The species and number of animals is not stated in the study where intradermal injection challenge of 3% and the topical application challenge of 60% was applied. Based on the results glycolic acid was not a sensitiser.	ECHA (2016)
Corrosion (irreversible and reversible)/irritation of the skin or eye Sodium acetate is not classified according to the GHS Classification criteria as causing corrosion/irritation of the skin or eye on the ECHA Registered Substances Database. However, ICSC (2006) note sodium acetate as causing redness to the skin and eye from acute exposure and as well as being mildly irritating to the eyes and skin from short-term exposure. *Notes:* An eye irritation test (72 hours) was conducted on 3 New Zealand White rabbits using 50% water solution of potassium acetate, in accordance with OECD Guideline 405 (Acute Eye Irritation / Corrosion). The study showed potassium acetate was not irritating. A dermal irritation test (72 hours) was conducted on 3 New Zealand White rabbits using 50 % water solution of potassium acetate (inferred to be the same substance as used for the eye irritation test) in accordance with guideline OECD Guideline 404 (Acute Dermal Irritation / Corrosion). No symptoms of skin observation were observed and potassium acetate was classified as not irritating.	ECHA (2016) ICSC (2006)

Physical hazards	Reference
Flammable Potential -Not classified as a flammable solid. Data is lacking for classification of the gas and liquid form. -Noted as 'combustible' by ICSS.	ECHA (2016) ICSC (2006)
Explosive Potential -Not classified as an explosive	ECHA (2016)

Toxicity Values	Value	Reference
Human Toxicity Data		
High Chronic/Repeat Dose Toxicity		
LOAEC	No data found.	-
LOAEL	No data found.	-
Animal Toxicity Data		
Acute Toxicity		
LD_{50}		
Rat, oral	3500 mg/kg 3530 mg/kg ~2015 mg/kg (female rat) ~3278 – 4813 mg/kg (male rat)	HSDB (2015) ChemIDplus (2016) ECHA (2016) (ECHA 2016)
Mouse, oral	4960 mg/kg 6891 mg/kg	HSDB (2015) ChemIDplus (2016)
Rabbit, oral		
Guinea pig		
Rat, dermal		
Rabbit, dermal	>10 gm/kg (>10,000 mg/kg) >20,000 mg/kg	ChemIDplus (2016) ECHA (2016)
Mouse, dermal		
LC_{50}		
Rat	> 30gm/m^3/1H (30,000 mg/m^3) > 5.6 mg/L air (analytical)	ChemIDplus (2016) (ECHA 2016)
High Chronic/Repeat Dose Toxicity		
LOAEL	>600 mg/kg (reproductive effects >60 mg/kg (fertility) > than 2187- mg/kg (maternal and developmental) >1000 mg/kg (maternal and developmental) 21 mg/kg (systemic toxicity) >3600 mg/kg >500 ppm	ECHA (2016) OECD SIDS (2005) ECHA (2016) OECD SIDS (2005) OECD SIDS (2005) OECD SIDS (2005) OECD SIDS (2005)
LOAEC	No data found.	-

Footnotes:
LD_{50} – lethal dose for 50% of experimental population
LC_{50} – lethal air concentration for 50% of experimental population
LOAEL – Lowest Observed Adverse Effect Level
LOAEC – Lowest Observed Adverse Effect Concentration
NDF – No data found within the limits of the search strategy

Human Health Toxicity Ranking*		
	Hazard data	**Comment**
Hazard Band 4		
Carcinogenicity (IARC Group 1 or 2A)	No data found.	Sodium acetate has not been evaluated by IARC.
Mutagenicity/Genotoxicity (GHS Category 1A and 1B)	NO	Based on *in-vitro* and *in-vivo* studies.
Reproductive Toxicity/Developmental toxicity (GHS Category 1, 1A and 1B)	NO	Reproductive studies showed no effects at doses up to 600 mg/kg. Development studies showed no effects at doses up to 2187.47 mg/kg.
Endocrine Disruption[1]	NO	Sodium acetate has not been listed on the Endocrine priority list.
Hazard Band 3		
Carcinogenicity (IARC Group 2B)	No data found.	
Mutagenicity/Genotoxicity (GHS Category 2)	NO	
Reproductive Toxicity/Developmental toxicity (GHS Category 2)	NO	
Acute Toxicity (oral, dermal or inhalation) Very Toxic/Toxic • oral LD_{50} ≤ 300 mg/kg [2] • dermal LD_{50} ≤ 1000 mg/kg • inhalation LC_{50} ≤ 10 mg/L [3] (or mg/m^3) (vapour)	NO	
High Chronic/repeat dose toxicity • oral LOAEL ≤ 10 mg/kg/d [2]; • dermal LOAEL ≤ 2 0 mg/kg/d; • inhalation LOAEC (6 h/d) ≤ 50 ppm/d for gases, ≤ 0.2 mg/L/d for vapours or ≤ 0.02 mg/L/d for dust/mists/fumes [3]	NO (oral)	ECHA (2016) noted insufficient data for repeat dose toxicity. OECD SIDS (2005) provided oral studies noted as valid with restrictions which were taken into account for this classification.
Corrosive (irreversible effect)	NO	
Respiratory sensitiser	No data found.	
Hazard Band 2		
Harmful chronic/repeat dose toxicity • oral LOAEL > 10 mg/kg and ≤ 100 mg/kg/d • dermal LOAEL > 20 mg/kg/d and ≤ 200 mg/kg/d • inhalation (6-h/d) LOAEC > 50 mg/L ≤ 250 mg/L/d for gases, > 0.2 mg/L ≤ 1 .0 mg/L/d for vapours or > 0.02 mg/L ≤ 0.2 mg/L/d for dust/mists/fumes [3]	YES (oral)	OECD SIDS (2005) reported a LOAEL for systemic oral toxicity of 21 mg/kg (valid with restrictions). No repeat dermal and inhalation dose data available.
Skin Sensitiser	NO	
Hazard Band 1		
Acute Toxicity-Harmful • oral LD_{50} > 300 mg/kg ≤ 2000 mg/kg • dermal LD_{50} >1 000 mg/kg ≤ 2000 mg/kg; • inhalation LC_{50} (6 h/d) > 10 mg/L ≤ 20 mg/L for vapours) [3]	NO	
Irritant (reversible effect)	YES	While sodium acetate is not classified as an eye or skin irritant under GHS

		classification it has been noted as causing redness/mild irritation to the eyes and skin by ICSC (2006).
Hazard Band 0 **All indicators outside criteria listed in Hazards 1-4**		
Physical Hazards		
Flammable potential	NO	
Explosive potential	NO	
Hazard Evaluation (highest band) not including physical hazards	2	
Uncertainty analysis /data confidence (out of 12 parameters)	10/12	**83%**

* Based on IMAP Framework [NICNAS (2013) Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework. National Industrial Chemicals Notification and Assessment Scheme. Department of Health and Aging, Canberra].

"[1]*Based on list of endocrine disrupting chemicals from the European Commission's Endocrine Disrupters website.*

[2] *milligrams per kilogram body mass (mg/kg) or milligrams per kilogram body mass per day (mg/kg/d)*

[3] *Based on GHS cut-offs for hazard classification. For chronic/repeat dose toxicity, GHS cut-offs are provided as guidance values (i.e. the dose/concentration at or below which significant health effects are observed)". (p 18, NICNAS 2013).*

Human Health Guidelines		
Media	**Concentration (mg/m^3; mg/L; mg/kg)**	**Reference**
Occupational Exposure Limits		
Air (OEL)		
8-h TWA	No data found.	-
STEL	No data found.	-
Peak Limitation	No data found.	-
Environmental Exposure		
Air, ambient	No data found.	-
Air, indoor	No data found.	-
Water, potable	No data found.	-
Water, recreational	No data found.	-
Soil, residential	No data found.	-
Soil, commercial/industrial	No data found.	-

Footnotes:

OEL = Occupational Exposure Limit

TWA = 8 h Time-Weighted Average

STEL = (15 min) Short-term Exposure Limit

Qualifying Summary Comments

Sodium acetate is an odourless white hygroscopic crystalline powder that is readily soluble in water. Sodium acetate is not classified as hazardous for the following health end-points: acute oral, dermal or inhalation toxicity, mutagenicity/genotoxicity, reproductive and developmental toxicity. Furthermore, it is not classified as a skin sensitiser or an agent that causes corrosion of the skin and the eyes, however it causes redness/mild irritation of the eyes/skin. The toxicity classifications for some of the health end-points are based on the dissociated form (Acetic acid), other salts (calium acetate, calcium diacetate, potassium acetate) and surrogate chemicals (citric acid, fumaric acid, glycol acid) and read-across approach. Data is lacking for the classification of neurotoxicity

and respiratory sensitisation. While there was lack of reliable repeat dose studies to allow GHS classification some oral repeat studies have been provided and deemed valid with restrictions by the OECD (OECD SIDS 2005). One of these oral repeat studies has provided a LOAEL of 21 mg/kg for a 3 month rat study which results in sodium acetate being classified as a Hazard Band 2. However, it is noted that acetic acid, sodium acetate and other acetic acid salts are listed as ingredients used as flavouring agents and adjuvant and as a pH control agent in numerous food substances by the US FDA. These substances have been used in food for a long period of time. Given this it is deemed appropriate to classify sodium acetate with a Hazard Band of 1.

References and Notes

ChemID-plus (2016). TOXNET. Available at http://chem.sis.nlm.nih.gov/chemidplus/rn/127-09-3. [Accessed 12 May 2016]

ECED (2016). European Commission Endocrine Disrupters website. Available at http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm [Accessed 6 May 2016]

ECHA (2016) (European Chemicals Agency). Registered Substances. Available at: http://echa.europa.eu/information-on-chemicals/registered-substances [Accessed 4 May 2016]

DailyMed (2013). Sodium Acetate Injection, USP. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=67dfd0f0-b057-4737-9f68-0445b6b321d6&type=display [Accessed 12 May 2016]

FDA (2015). U.S. Food and Drug Administration. Code of Federal Regulations Title 21, Volume 3, 21CFR184.1721. Chapter I--Food and Drug Administration, Department Of Health And Human Services. Subchapter B--Food For Human Consumption (Continued), Part 184 -- Direct Food Substances Affirmed As Generally Recognized As Safe, Subpart B--Listing of Specific Substances Affirmed as GRAS, Sec. 184.1721 Sodium acetate. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1721 [Accessed 12 May 2016]

HSDB (2003) Hazardous Substances Data Bank. Toxicology Data Network (TOXNET). Available at http://toxnet.nlm.nih.gov/cgi-bin/sis/search2/f?./temp/~D7WaJU:1 [Accessed 12 May 2016]

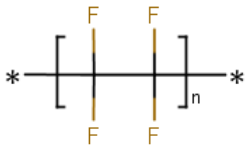
IARC (2016). International Agency for Research on Cancer. Monographs on the Evaluation of Carcinogenic Risks to Humans. Available at: http://monographs.iarc.fr/ENG/Classification/. [Accessed 6 May 2016]

ICSC (2006). International Program on Chemical Safety. IPCS INCHEM. Available at: http://www.inchem.org/documents/icsc/icsc/eics0565.htm [Accessed 4 May 2016]

OECD SIDS (2005). 'Ethyltriacetoxysilane'. SIDS Initial Assessment Report for SIAM 21. Available at: http://www.inchem.org/documents/sids/sids/17689779.pdf [Accessed 12 May 2016]

Created by:	JH	Date 12/05/2016
Reviewed and edited by:	JF	Date 13/05/2016

Project number: 127635006
Project name: Hydraulic Stimulation Chemical Assessment, Queensland
Client name: QGC

Name	Polytetrafluoroethylene
Synonyms	PTFE; Teflon; Ethane, tetrafluoro-, homopolymer; Fluoro-gold; Polytef [USAN]; Ethylene, tetrafluoro-, polymer; Fluorogold; Tetrafluoroethene homopolymer (9CI)
CAS number	9002-84-0
Molecular formula	$(C_2\text{-}F_4)_n$
Molecular Structure	

Overview	References
Polytetrafluoroethylene (PTFE) is a soft, waxy, odourless white solid with a low coefficient friction. The polymer comprises of very long chains of linked C_2F_4 units with a molecular weight of 400,000 – 10,000,000. PTFE is not known to occur as a natural product and it is manufactured commercially by the polymerisation of tetrafluoroethylene in the presence of water and free-radical initiators. PTFE is insoluble in water and no substance has been found which will dissolve the polymer. It is reported to have a density of 2.25 g/cm^3. It ignites in fluorine-oxygen mixtures under extreme conditions.	
PTFE is available in three forms: granular, coagulated dispersions (i.e. fine powders) and aqueous dispersions. PTFE is used in making gaskets, liners, seals, hoses, insulators, wire coatings, bearings, and anti-stick coatings for pots and pans. Other uses of PTFE include filters, coatings for surgical implants and as prosthetic materials.	FDA (2015) Haz-Map (2015)
The Food and Drug Administration (FDA) lists 'Perfluorocarbon resins' as indirect food additives 'for use as basic components of single and repeated use food contact surfaces' subject to the provisions of the regulation (FDA 2015).	HSDB (2002)
Due to the high molecular weight of PTFE (>1000) the polymers are unlikely to cross biological membranes and therefore generally regarded as non hazardous for systemic health end-points. For point of contact endpoints (skin irritation, eye irritation, skin sensitisation) in the absence of information for the polymers, data for the monomer, tetrafluoroethylene (CAS number 116-14-3) will be used.	ChemID plus (2016) IARC (1979)
PTFE is not classified as a hazardous substances. In its fine powder form PTFE dust can cause slight skin effects (discomfort, itching, redness or swelling), eye effects (tearing, redness and discomfort) and respiratory tract irritation.	DuPont (2010)
Hazardous thermal decomposition products of PTFE include acid fluorides, fluorinated compounds, hydrogen fluoride and carbon monoxide. The thermodegradation products of PTFE produce influenza-like symptoms (known as 'polymer-fume fever') in humans. Polymer-fume fever generally occurs when the worker is exposed to polymer at temperatures between 300 and 500 ^oC. These symptoms disappear within a 24- or 48-hour period if the worker is removed from the working environment and rests. Pyrolysis products of PTFE at higher temperatures can cause toxic pneumonitis. Repeated episodes of polymer fume fever may result in persistent lung effects.	

It has also been noted that fluoride levels in urine are greater than normal in workers exposed to fumes of PTFE.	

Human Health Toxicity Summary	Reference
Carcinogenicity The International Agency for Research on Cancer classifies PTFE as a Group 3 chemical – *Not classifiable as to its carcinogenicity to humans*. *Notes:* The 1979 IARC evaluation considered animal studies which showed that PTFE discs, squares, fragments or powder implanted in mice and rats induced local sarcomas. A single case of a fibrosarcoma was also reported in a patient treated with a PTFE/dacron implant ten and a half years after the initial operation. The evaluation concluded that based on this data available there was insufficient evidence to assess the carcinogenic risk of exposure to PTFE in humans.	IARC (1987) IARC (1979)
Mutagenicity/Genotoxicity Not classifiable as a mutagen given it is not is not absorbed into the body due to its high molecular weight.	-
Reproductive Toxicity Not classifiable as a reproductive toxicant given it is not is not absorbed into the body due to its high molecular weight.	-
Developmental Toxicity/Teratogenicity Not classifiable as a developmental toxicant given it is not is not absorbed into the body due to its high molecular weight.	-
Endocrine Disruption PTFE has not been identified in the European Commission (EC)'s report, "Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption" as a substance of interest.	ECED (2016)
Neurotoxicity Unlikely to result in neurotoxicity as it is not absorbed across biological membranes.	-
Acute Toxicity (oral, dermal, inhalation) Unlikely to result in acute dose toxicity as it is not absorbed across biological membranes. An oral LD_{50} value of >11,280 mg/kg for the rat has been reported.	DuPont (2010)
Chronic/repeat dose toxicity (oral, dermal, inhalation) Unlikely to result in repeat dose toxicity as it is not absorbed across biological membranes. *Notes:* A long-term 10-month oral study in rats showed no effect on animals. A short-term study showed that when rats ate feed with 25% fine F4 (Fluoroplastic-4) powder over a 90 day period no toxic effects were noted.	Sheftel (2000)
Sensitisation of the skin or respiratory system The monomer tetrafluoroethylene is not classified as a skin or respiratory sensitiser according to the GHS classification criteria. Therefore, PTFE is not classified as a skin or respiratory sensitiser. The DuPont (2010) Material Safety Data Sheet also notes that a skin patch test on human volunteers did not demonstrate sensitization properties.	ECHA (2016)
Corrosion (irreversible and reversible)/irritation of the skin or eye The monomer tetrafluoroethylene is not classified as a skin or eye irritant/corrosive agent according the GHS classification criteria. Therefore, PTFE is not expected to cause skin or eye corrosion/irritation. However, in fine powder form PTFE can cause skin effects (discomfort, itching, redness or swelling) and eye effects (tearing, redness and discomfort).	ECHA (2016) DuPont (2010)

Physical hazards	Reference
Flammable Potential Non-flammable.	ChemIDplus (2016)
Explosive Potential No data found.	-

Toxicity Values	Value	Reference
Human Toxicity Data		
High Chronic/Repeat Dose Toxicity		
LOAEC	No data found.	-
LOAEL	No data found.	-
Animal Toxicity Data		
Acute Toxicity		
LD_{50}		
Rat, oral	>11, 280 mg/kg	DuPont (2010).
Rabbit, dermal	No data found.	-
LC_{50}		
Rat, inhalation	No data found	
Repeat Dose Toxicity		
LOAEL	No data found.	-
LOAEC	No data found.	-

Footnotes:
LD_{50} – lethal dose for 50% of experimental population
LC_{50} – lethal air concentration for 50% of experimental population
LOAEL – Lowest Observed Adverse Effect Level
LOAEC – Lowest Observed Adverse Effect Concentration
NDF – No data found within the limits of the search strategy

Project number: 127635006
Project name: Hydraulic Stimulation Chemical Assessment, Queensland
Client name: QGC

Human Health Toxicity Ranking*		
	Hazard data	**Comment**
Hazard Band 4		
Carcinogenicity (IARC Group 1 or 2A)	NO	Classified as Group 3 chemical by IARC.
Mutagenicity/Genotoxicity (GHS Category 1A and 1B)	Not expected	
Reproductive Toxicity/Developmental toxicity (GHS Category 1, 1A and 1B)	Not expected	
Endocrine Disruption[1]	NO	
Hazard Band 3		
Carcinogenicity (IARC Group 2B)	NO	
Mutagenicity/Genotoxicity (GHS Category 2)	Not expected	
Reproductive Toxicity/Developmental toxicity (GHS Category 2)	Not expected	
Acute Toxicity (oral, dermal or inhalation) Very Toxic/Toxic • oral LD_{50} ≤ 300 mg/kg [2] • dermal LD_{50} ≤ 1000 mg/kg • inhalation LC_{50} ≤ 10 mg/L [3] (or mg/m^3) (vapour)	Not expected	No dermal and inhalation LD_{50} acute dose values were found.
High Chronic/repeat dose toxicity • oral LOAEL ≤ 10 mg/kg/d [2]; • dermal LOAEL ≤ 2 0 mg/kg/d; • inhalation LOAEC (6 h/d) ≤ 50 ppm/d for gases, ≤ 0.2 mg/L/d for vapours or ≤ 0.02 mg/L/d for dust/mists/fumes [3]	Not expected.	No LOAEL/NOAEL repeat dose values were found.
Corrosive (irreversible effect)	NO	
Respiratory sensitiser	NO	
Hazard Band 2		
Harmful chronic/repeat dose toxicity • oral LOAEL > 10 mg/kg and ≤ 100 mg/kg/d • dermal LOAEL > 20 mg/kg/d and ≤ 200 mg/kg/d • inhalation (6-h/d) LOAEC > 50 mg/L ≤ 250 mg/L/d for gases, > 0.2 mg/L ≤ 1 .0 mg/L/d for vapours or > 0.02 mg/L ≤ 0.2 mg/L/d for dust/mists/fumes [3]	Not expected.	No LOAEL/NOAEL repeat dose values were found.
Skin Sensitiser	NO	
Hazard Band 1		
Acute Toxicity-Harmful • oral LD_{50} > 300 mg/kg ≤ 2000 mg/kg • dermal LD_{50} >1 000 mg/kg ≤ 2000 mg/kg; • inhalation LC_{50} (6 h/d) > 10 mg/L ≤ 20 mg/L for vapours) [3]	Not expected.	No dermal and inhalation LD_{50} acute dose values were found.
Irritant (reversible effect)	YES	In fine powder form PTFE can cause skin effects, eye effects and respiratory tract irritation.
Hazard Band 0 **All indicators outside criteria listed in Hazards 1-4**		
Physical Hazards		
Flammable potential	NO	
Explosive potential	Not expected	On structural and experience grounds it is not classifiable as an explosive agent.

Hazard Evaluation (highest band) not including physical hazards	1	
Uncertainty analysis /data confidence (out of 12 parameters)	12/12	**100%**

* Based on IMAP Framework [NICNAS (2013) Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework. National Industrial Chemicals Notification and Assessment Scheme. Department of Health and Aging, Canberra].

"[1]*Based on list of endocrine disrupting chemicals from the European Commission's Endocrine Disrupters website.*

[2] *milligrams per kilogram body mass (mg/kg) or milligrams per kilogram body mass per day (mg/kg/d)*

[3] *Based on GHS cut-offs for hazard classification. For chronic/repeat dose toxicity, GHS cut-offs are provided as guidance values (i.e. the dose/concentration at or below which significant health effects are observed)". (p 18, NICNAS 2013).*

Human Health Guidelines		
Media	**Concentration (mg/m^3; mg/L; mg/kg)**	**Reference**
Occupational Exposure Limits		
Air (OEL)		
8-h TWA	10 mg/m^3 (total dust) 5mg/m^3 (respirable dust)	DuPont (2010)
STEL	1 mg/m^3 (short-term limit value in Netherlands)	IFA (2016)
Peak Limitation	No data found.	-
Environmental Exposure		
Air, ambient	No data found.	-
Air, indoor	No data found.	-
Water, potable	No data found.	-
Water, recreational	No data found.	-
Soil, residential	No data found.	-
Soil, commercial/industrial	No data found.	-

Footnotes:

OEL = Occupational Exposure Limit

TWA = 8 h Time-Weighted Average

STEL = (15 min) Short-term Exposure Limit

Qualifying Summary Comments

Polytetrafluoroethylene (PTFE) is a soft, waxy and odourless white thermoplastic high molecular weight polymer. IARC has evaluated PTFE as not classifiable as a carcinogen to humans. Due to the high molecular weight of PTFE (>1000 g/mol) the polymer is unlikely to cross the biological membranes and therefore generally regarded as non hazardous for systemic health end-points. The monomer, tetrafluoroethylene, has been used as a surrogate for the point of contact endpoints. As tetrafluoroethylene is not classified as a skin sensitiser or as causing corrosion/irritation to the skin and the eye it is inferred that the polymer is not classifiable as a skin irritant to the eyes/skin or skin sensitiser. As for all fine powders PTFE dust can cause skin effects (discomfort, itching, redness or swelling), eye effects (tearing, redness and discomfort) and respiratory tract irritation. Thermodegradation products of PTFE that form at 300-500^{o}C can produce polymer-fume in humans and repeated episodes of polymer-fume fever may result in persistent lung effects. Notwithstanding this, based on the human health assessment undertaken PTFE is classified as Hazard Band 1.

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Created by:	JH	Date 17/05/2016
Reviewed and edited by:	JF	Date 18/05/2016

APPENDIX B

Ecotoxicology Profiles

Project number: 127635006

ORGANIC

Name	Amines, dicocoalkyl
Synonyms	
CAS Number	61789-76-2
Molecular Formula	C24H51N1

Physical Properties	Value	Reference
PhaseState:		
Molecular Weight (g/mol):	353.68	EPISUITE 2011 v4.1
Melting Point (°C):	130.56	EPISUITE 2011 v4.1
Boiling Point (°C):	402.53	EPISUITE 2011 v4.1
Density / Specific Gravity (Enter Unit):		
Vapour Pressure (mm Hg at 25°C):	0.000000633	EPISUITE 2011 v4.1
Solubility (mg/L):	4.994 E-05	EPISUITE 2011 v4.1
Henry's Law Constant (atm m³/mole):	0.00847	EPISUITE 2011 v4.1
Organic carbon partition coefficient (Koc):	4,425,000.00	EPISUITE 2011 v4.1
Log organic carbon partition coefficient (log Koc):	6.65	EPISUITE 2011 v4.1
Log octanol - water partition coefficient (log Kow):	1.06E+01	EPISUITE 2011 v4.1

Persistance / Bioaccumulation	Value	Reference
Biowin 3 (Ultimate Survey Biodegradation):	3.0387	EPISUITE 2011 v4.1
Biowin 4 (Primary Biodegradation):	3.9189	EPISUITE 2011 v4.1
EPISUITE Ready Biodegradability:	Biodegrades fast	EPISUITE 2011 v4.1
Biowin 7 (Anaerobic Model Prediction):	0.7906	EPISUITE 2011 v4.1
Fugacity_Air: (%)	0.224	EPISUITE 2011 v4.1
Fugacity_Water: (%)	21	EPISUITE 2011 v4.1
Fugacity_Soil: (%)	74	EPISUITE 2011 v4.1
Fugacity_Sediment: (%)	1.47	EPISUITE 2011 v4.1
Bioconcentration factor (BCF):	55.98	EPISUITE 2011 v4.1
Biotransformation half - life (Days):	209.3	EPISUITE 2011 v4.1

Project number: 127635006

ORGANIC

Aquatic Ecotoxicological Data

Acute toxicity data							
SpeciesName	**Common Name**	**Endpoint**	**Effect**	**Effect Measure**	**Test Time (Days)**	**Conc mg/L**	**Reference**
	Fish	Fish LC50	MOR	Mortality	4	5.14E-06	ECOSAR 2012
	Daphnid	Invertebrate LC50	MOR	Mortality	2	6.48E-06	ECOSAR 2012
	Green algae	Plant EC50	GRO	Mortality	4	0.00013	ECOSAR 2012

Terrestrial Ecotoxicological Data

Common Name	**Endpoint**	**Effect**	**Effect Measure**	**Test Time (Days)**	**Conc**	**Reference**	**Units**
Rat	Mammalian LD50	MOR	Mortality		6000	ChemIntID 2013	mg/kg

Created By: Naomi Cooper Date: 17/05/2016

Checked By: Kirsten Broadgate Date: 17/05/2016

Project number: 127635006

ORGANIC

Name	Polyvinyl alcohol
Synonyms	
CAS Number	9002-89-5
Molecular Formula	C22H46O11

Physical Properties	Value	Reference
PhaseState:		
Molecular Weight (g/mol):	486.61	EPISUITE 2011 v4.1
Melting Point (°C):	319.18	EPISUITE 2011 v4.1
Boiling Point (°C):	728.16	EPISUITE 2011 v4.1
Density / Specific Gravity (Enter Unit):		
Vapour Pressure (mm Hg at 25°C):	1.57E-22	EPISUITE 2011 v4.1
Solubility (mg/L):	1,000,000.00	EPISUITE 2011 v4.1
Henry's Law Constant (atm m³/mole):	4.42E-18	EPISUITE 2011 v4.1
Organic carbon partition coefficient (Koc):	886,200.00	EPISUITE 2011 v4.1
Log organic carbon partition coefficient (log Koc):	5.95	EPISUITE 2011 v4.1
Log octanol - water partition coefficient (log Kow):	-5.30E+00	EPISUITE 2011 v4.1

Persistance / Bioaccumulation	Value	Reference
Biowin 3 (Ultimate Survey Biodegradation):	3.8835	EPISUITE 2011 v4.1
Biowin 4 (Primary Biodegradation):	4.5696	EPISUITE 2011 v4.1
EPISUITE Ready Biodegradability:	Biodegrades fast	EPISUITE 2011 v4.1
Biowin 7 (Anaerobic Model Prediction):	0.8443	EPISUITE 2011 v4.1
Fugacity_Air: (%)	0.752	EPISUITE 2011 v4.1
Fugacity_Water: (%)	17	EPISUITE 2011 v4.1
Fugacity_Soil: (%)	48	EPISUITE 2011 v4.1
Fugacity_Sediment: (%)	34.5	EPISUITE 2011 v4.1
Bioconcentration factor (BCF):	3.162	EPISUITE 2011 v4.1
Biotransformation half - life (Days):	0.000000323	EPISUITE 2011 v4.1

Project number: 127635006

ORGANIC

Aquatic Ecotoxicological Data

Acute toxicity data							
SpeciesName	**Common Name**	**Endpoint**	**Effect**	**Effect Measure**	**Test Time (Days)**	**Conc mg/L**	**Reference**
	Fish	Fish LC50	MOR	Mortality	4	1.43E+09	ECOSAR 2012
	Daphnid	Invertebrate LC50	MOR	Mortality	2	4.13E+08	ECOSAR 2012
	Green algae	Plant EC50	GRO	Growth	4	1.9E+07	ECOSAR 2012

Created By: Naomi Cooper Date: 17/05/2016

Checked By: Kirsten Broadgate Date: 17/05/2016

Project number: 127635006

ORGANIC

Name	Sodium acetate
Synonyms	
CAS Number	127-09-3
Molecular Formula	C2H4O2

Physical Properties	Value	Reference
PhaseState:		EPISUITE 2011 v4.1
Molecular Weight (g/mol):	82.03	EPISUITE 2011 v4.1
Melting Point (°C):	148.53	EPISUITE 2011 v4.1
Boiling Point (°C):	392.35	EPISUITE 2011 v4.1
Density / Specific Gravity (Enter Unit):		
Vapour Pressure (mm Hg at 25°C):	0.00000000537	EPISUITE 2011 v4.1
Solubility (mg/L):	1,000,000.00	EPISUITE 2011 v4.1
Henry's Law Constant (atm m³/mole):	0.00000055	EPISUITE 2011 v4.1
Organic carbon partition coefficient (Koc):	1.00	EPISUITE 2011 v4.1
Log organic carbon partition coefficient (log Koc):	0.00	EPISUITE 2011 v4.1
Log octanol - water partition coefficient (log Kow):	-3.72E+00	EPISUITE 2011 v4.1

Persistance / Bioaccumulation	Value	Reference
Biowin 3 (Ultimate Survey Biodegradation):	3.4311	EPISUITE 2011 v4.1
Biowin 4 (Primary Biodegradation):	4.1467	EPISUITE 2011 v4.1
EPISUITE Ready Biodegradability:	Biodegrades fast	EPISUITE 2011 v4.1
Biowin 7 (Anaerobic Model Prediction):	0.9433	EPISUITE 2011 v4.1
Fugacity_Air: (%)	2.73	EPISUITE 2011 v4.1
Fugacity_Water: (%)	35	EPISUITE 2011 v4.1
Fugacity_Soil: (%)	63	EPISUITE 2011 v4.1
Fugacity_Sediment: (%)	0.0611	EPISUITE 2011 v4.1
Bioconcentration factor (BCF):	3.162	EPISUITE 2011 v4.1
Biotransformation half - life (Days):	0.02789	EPISUITE 2011 v4.1

Project number: 127635006

ORGANIC

Aquatic Ecotoxicological Data

Acute toxicity data							
SpeciesName	**Common Name**	**Endpoint**	**Effect**	**Effect Measure**	**Test Time (Days)**	**Conc mg/L**	**Reference**
Pimephales promelas	Fathead minnow	Fish LC50	MOR	Mortality	1	5000	ECOTOX 2012
Daphnia magna	Water flea	Invertebrate LC50	MOR	Mortality	1	7170	ECOTOX 2012
	Green algae	Plant EC50	GRO	Growth	4	4403	ECOSAR 2012

Created By: Naomi Cooper Date: 17/05/2016

Checked By: Kirsten Broadgate Date: 17/05/2016

APPENDIX C

Important Information Relating To This Report

IMPORTANT INFORMATION RELATING TO THIS REPORT

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