

QGC - ADDENDUM TO HYDRAULIC STIMULATION CHEMICAL ASSESSMENT

Chemical Hazard Assessment - Three Products

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

Submitted to:

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Report Number.

127635006-006-R-Rev1-

07000 **Distribution:**

1 e-copy: QGC







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Document Number	Issue Date	Revisions
127635006-006-R-Rev0-07000	22 March 2016	-
127635006-006-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 three chemicals listed in recent stimulation fluid product disclosures. The assessment relates to the potential toxicity of the fluid to human health and ecotoxicity in aquatic and terrestrial environments.

This addendum presents the hazard assessment of the three (3) 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 a Fluid Disclosure Report (FDR)¹, dated 12/2/2016

The FDR has not been included in this report to maintain the confidentiality of commercially sensitive information.

The chemicals listed in the FDR were reviewed by Golder. Three of the chemicals identified in the FDR, have not previously been assessed. These are shown in Table 1.

Table 1: Additional Stimulation Chemicals

CAS RN	Chemical Name
1319-33-1	Boronatrocalcite
7704-73-6	Monosodium fumarate
595585-15-2	Diutan gum

Note: CAS RN - Chemical Abstracts Service Registry Number

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 for the stimulation fluid identified in the FDR.
- Preparation of this addendum.



¹ Fluid name has been redacted to maintain the confidentiality of commercially sensitive information.

2.0 BORONATROCALCITE

2.1 Overview

Boronatrocalcite is the mineral ulexite. Ulexite is a hydrated sodium calcium borate hydroxide mineral. Ulexite is slightly soluble, decomposes and contains approximately 13% boron (WHO, 1998). Ulexite is mined to produce borate products for uses such as insulation, textile grade fiberglass, bleach, fire retardants, agricultural fertilisers and herbicides (as a trace element),and enamels (WHO, 1998). A study of the thermal degradation of ulexite has shown under increased temperature (around 600° C) the crystalline structure will break down to eventually release NaB₃O₅ and NaCaBO₃ (Waclawska, 1990).

Figure 1: Molecular structure of Ulexite

2.2 Human health hazard assessment

Limited toxicology data are available for ulexite; however, an assessment of boron salts was undertaken by WHO (1998) and ECHA (2015). Low concentrations of simple inorganic borates (e.g. boric acid, disodium tetraborate pentahydrate, boric oxide and disodium octaborate tetrahydrate) will predominately exist as undissociated boric acid in aqueous solutions at physiological and acidic pH. At about pH 10 the metaborate anion (B(OH)₄-) becomes the main species in solution. This leads to the conclusion that the main species in the plasma of mammals is un-dissociated boric acid. Since other borates (such as potassium borate) dissociate to form boric acid in aqueous solutions, they too can be considered to exist as un-dissociated boric acid under the same conditions.

Boric acid and borax are absorbed from the gastrointestinal tract and the respiratory tract, as indicated by increased levels of boron in the blood, tissues, or urine or by systemic toxic effects of exposed individuals or laboratory animals. Clearance of boron compounds is similar in humans and animals. Elimination of borates from the blood is largely by excretion; 90% or more of the administered dose is eliminated via the urine, regardless of the route of administration. Excretion is relatively rapid, occurring over a period of a few, or possibly several, days.

Ulexite has been assigned to Hazard Band 4 because of its potential to cause reproductive toxicity (infertility) and its potential for damaging the unborn child. The reproductive toxicity of boric acid and its salts occurs at high doses via the oral route. It is unlikely to present a reproductive toxicity hazard via skin contact and when inhaled as dust below the occupational exposure limit.

2.3 Environmental hazard assessment

2.3.1 Fate and behaviour in the environment

Large borate complexes are soluble and converted to boric acid (B(OH)₃) and borates upon dissolution in water (ECHA, 2015). Low concentrations of simple inorganic borates (e.g. boric acid, disodium tetraborate pentahydrate, boric oxide and disodium octaborate tetrahydrate) will predominately exist as un-dissociated boric acid in aqueous solutions at acidic pH. At about pH 11 the metaborate anion (B(OH)₄-) becomes the main species in solution. In between pH 7 and pH 11, both un-dissociated boric acid and metaborate ions will be present (ECHA, 2015). This leads to the conclusion that the main species in the environment is un-dissociated boric acid, with metaborate ions also potentially present. Since other borates (such as potassium



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borate) dissociate to form boric acid in aqueous solutions, they too can be considered to exist as undissociated boric acid under the same conditions.

2.3.2 Aquatic

A surrogate was assessed for boronatrocalcite; sodium metaborate.

An environmental hazard assessment was undertaken on sodium metaborate, 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 metaborate (provided in Appendix B) presents the available physical and chemical information, in addition to available ecotoxicological data for freshwater organisms.

An overall score (the environmental hazard score) for sodium metaborate was calculated based on toxicity alone. This is because sodium metaborate readily dissociates in water and the approach taken for assessment of inorganic chemicals excludes consideration of bioaccumulation (refer methodology presented in *Human Health and Ecological Chemical Assessment – Hydraulic Stimulation Chemical Assessment – QGC Surat and Bowen Basin Operation* (Golder Ref. 127635006-004-R-Rev3, 2016; HSCA report). Table 2 below summarises the overall hazard score for sodium metaborate.

Table 2: Hazard score for sodium metaborate

Chemical	Bioaccumulation Score	Persistence Score	Toxicity Score	Overall Hazard Score
Sodium metaborate	NA	NA	2	2

NA - Not applicable due to inorganic nature of the compound being assessed, and/or because it readily dissociates in water

Based on the toxicity assessment, sodium metaborate has been given an overall hazard score of 2 (1 = lowest, 3 = highest), indicating that is expected to pose a moderate hazard to the aquatic environment. The moderate hazard classification was based on acute toxicological effects (lethal concentrations, LC) in freshwater invertebrates (water flea) and fish.

2.3.3 Terrestrial

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

Terrestrial toxicity data were only available for mammals, with the lowest mammalian Lethal Dose (LD₅₀) being 2,330 mg/kg for the rat.

For chemicals with few or no data, Quantitative Structure-Activity Relationships (QSARs) have been used to predict toxicity to plants and invertebrates. As sodium metaborate is an inorganic chemical it is not appropriate for QSAR modelling (which relies on relationships related to databases of organic chemicals), therefore plant and invertebrate toxicity could not be predicted.

Persistence and bioaccumulation of organic chemicals in terrestrial ecosystems may be determined using soil half-life, Henry's Law Constant and Log K_{ow} . However, as sodium metaborate is an inorganic persistence and bioaccumulation in terrestrial systems cannot be calculated. Review of the chemical and environmental fate information however, indicates the chemical is highly water soluble, binds to clay and may accumulate in plants (HSDB, 2006 and ECHA, 2015)².

Based on the data available, noting there were gaps, sodium metaborate was assessed to present a low to moderate hazard in terrestrial ecosystems.



² It is noted that the plant bioaccumulation study was undertaken in 1944 and limited information on the study is available (ECHA, 2015)



3.0 MONOSODIUM FUMARATE

3.1 Overview

Monosodium fumarate (referred to as sodium fumarate) is the mono-sodium salt of fumaric acid (CIR, 2009). Fumaric acid is an intermediate in the citric acid cycle used by cells to produce energy in the form of ATP from food. Solubility and pH are likely to increase in the order of fumeric acid, sodium fumerate and disodium fumarate due to increasing polarity and dissociation. The solubility of fumaric acid is 7 g/L (at 25°C).

Figure 2: Molecular structure of monosodium fumarate

3.2 Human health hazard assessment

Sodium fumarate is used in cosmetic ingredients as a buffering agent (pH adjuster) (CIR, 2009). The Cosmetic Ingredient Review (CIR) completed a review of fumaric acid and related salts and esters used in cosmetics in 2009 and concluded that they were safe for use, as described in the review. Fumaric acid and its salts are also approved by the United States Food and Drug Administration (FDA) for use as food additives (FDA, 2016). The human health review of sodium fumarate focused primarily on sodium fumarate. However, where information was available for fumaric acid and disodium fumarate, this information was used to fill data gaps. Sodium fumarate is categorised in Hazard Band 2 on the basis of serious eye irritation (a reversible effect).

3.3 Environmental hazard assessment

3.3.1 Fate and behaviour in the Environment

Sodium fumarate is expected to be soluble, based on the solubility of fumaric acid, and therefore, if released to the environment, it will most likely end up in water systems. Sodium fumarate will likely dissociate at the common pH of environmental waters.

3.3.2 Aquatic

Two chemicals were assessed as surrogates for monosodium fumarate; fumaric acid and disodium fumarate. An environmental hazard assessment based on PBT was undertaken on both of these surrogate chemicals. The chemical information sheets are provided in Appendix B.

An overall score (the environmental hazard score) for both fumaric acid and disodium fumarate was calculated based on aquatic hazard. Table 3 below summarises the overall hazard score for both chemicals.

Table 3: Hazard score of surrogates for monosodium fumarate

Chemical	Bioaccumulation Score	Persistence Score	Toxicity Score	Overall Hazard Score
Fumaric acid	1.6	1.0	2.0	1.5
Disodium fumarate	1.3	1.0	1.0	1.1

Based on the toxicity assessment, both fumaric acid and disodium fumarate have been given an overall hazard score of 1.5 or lower (1 = lowest, 3 = highest), indicating that they are expected to pose a low hazard to the aquatic environment.





3.3.3 Terrestrial

The chemical information sheets (Appendix B) present the physical and chemical information for fumaric acid and disodium fumarate in addition to available ecotoxicological data for terrestrial organisms.

For both surrogates terrestrial toxicity data were available for mammals and earthworms. Additionally QSARs were used to predict toxicity to plants (lettuce) and earthworms.

Table 4 below summarises the terrestrial toxicity for fumaric acid and disodium fumarate.

Table 4: Terrestrial toxicity data for surrogates for monosodium fumarate

	Mammalian LD50	ECOSAR earthworm LC50	QSAR lettuce EC50	QSAR earthworm LC50
	mg/kg	mg/L	mg/L	mg/kg
Fumaric acid	9,300	3,212	127	1.88
Disodium fumarate	8,000	3,212	175	411

Soil half-life, Henry's Law Constant and Log K_{ow} were collated to assess persistence and bioaccumulation in terrestrial ecosystems. Both surrogates are organic solids with low volatility, short half-lives and have 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 both surrogates (fumaric acid and disodium fumarate) was assessed to be low to moderate. The hazard range from low to moderate was assigned following consideration of the lower effects concentrations predicted for lettuce (fumaric acid and disodium fumarate) and earthworm (fumaric acid) using the Hulzebos and van Gestel QSAR models. However the balance of the remaining data is consistent with low hazard.

4.0 DIUTAN GUM

4.1 Overview

Diutan gum is a polysaccharide produced through the fermentation of the sugar source, using *Sphingomonas* bacteria. Diutan gum is composed of D-glucopyranosyl, 6-deoxy-L-mannopyranosyl, and D-glucuronyl units, acetate modified and Na, K, Ca, and Mg mixed salts (ChemID*plus*, 2016). Diutan gum is a white to tan powder (at 20°C and 101.3 kPa), with a water solubility of > 40 g/L (at pH range 7 and 10 at 20°C) (NICNAS, 2010).

Diutan gum in used in a wide variety of thickening and suspending applications, including in cementitious packaged products, Oilfield space fluids, drilling fluids and drilling cement applications, fire-fighting foam applications, tyre/pneumatic application sealants, cleaning products and coating products (NICNAS, 2010).

4.2 Human health hazard assessment

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) concluded in 2010 that, diutan gum is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NICNAS, 2010). However, adverse lung effects (e.g. congestion) are possible if solid particles of the polymer are inhaled. Diutan gum is categorized in Hazard Band 2, based on the potential for congestion of the lungs if respirable particulates are inhaled.





4.3 Environmental hazard assessment

4.3.1 Fate and behaviour in the Environment

Diutan gum is highly water soluble and has a low K_{oc} value, therefore, if released to the environment, diutan gum will most likely partition into water (NICNAS, 2010). Diutan gum is highly biodegradable, via biotic and abiotic processes (NICNAS, 2010). In the environmental pH range of 4 to 9, biodegradation is expected to be the primary degradation pathway (instead of degradation by hydrolysis). Based on the molecular weight, water solubility and K_{ow} value, diutan gum is not expected to bioaccumulate (NICNAS, 2010).

4.3.2 Aquatic

An environmental hazard assessment was undertaken on diutan gum, based on PBT. The chemical information sheets are provided in Appendix B.

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

Table 5: Hazard score for diutan gum

Chemical	Bioaccumulation Score	Persistence Score	Toxicity Score	Overall Hazard Score
Diutan gum	1.0	1.0	1.0	1.0

Based on the toxicity assessment, diutan gum has been given an overall hazard score of 1 (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 diutan gum for terrestrial organisms.

For diutan gum terrestrial toxicity data were available only for mammals. Consistent with the approach adopted for chemicals with few or no data, QSARs have been used to predict toxicity to plants (lettuce) and earthworms.

Table 6: Terrestrial toxicity data for diutan gum

	Mammalian LD50	QSAR lettuce EC50	QSAR earthworm LC50
	mg/kg bw	mg/L	mg/kg
Diutan gum	> 5,000	228,000,000	0.24

Soil half-life and a Henry's Law Constant were not found for diutan gum, however a value for Log K_{ow} was available. Based on the limited data, diutan gum is highly solubility, readily biodegradable, and is not expected to bioaccumulate.

Based on the review of the available physico-chemical and terrestrial ecotoxicological data, the weight of evidence suggests the potential hazard to the terrestrial environment posed by diutan gum is likely be low.

5.0 MASS BALANCE

The FDR provides the total volume of the fluid, a list of individual chemical names/CAS numbers and estimations of volume fractions (%), mass (lb) and volume (gal) of each component.



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These fluid components were divided into chemical additives, proppants and water, and the estimated mass of each fluid is summarised in Table 7. While there are variations in preparation methods and injection protocols, it is assumed that the concentrations reported in Table 7 lie within a range of possible concentrations.

The FDR indicates that the components listed are based on 0.4 megalitres (ML) of fluid. However, QGC indicated that the injected total volumes per well could range from 0.5 to 0.7 ML of fluid (Kearney 2015, pers. comm C. Brumley: S. Kearney). Therefore, the mass of additives, proppants and water added per stimulation have also been calculated using an upper (0.7 ML) and lower (0.5 ML) range of injected total volumes (Table 7).

Table 7: Indicative Component Mass per Stimulation Stage

Fluid System	Stimulation Fluid ²	Mass calculated using a range of injected total volumes per well ²		
Typical fluid Volume ¹	446 900 L (~0.4 ML)	0.5 ML of fluid	0.7 ML of fluid	
Additives	16 600 kg (~ 3%)	~ 20 800 kg	~ 29 100 kg	
Proppant	215 200 kg (~ 32%)	~ 269 000 kg	~376 600 kg	
Water	437 500 kg (~ 65%)	~ 546 800 kg	~ 765 600 kg	

- 1. Fluid volume for stimulation, as indicated in the service provider's disclosure statement.
- 2. Numbers are estimates. Fluid name has been redacted to maintain the confidentiality of commercially sensitive information.

The hydraulic stimulation fluid comprises predominantly water (\sim 65%), with a secondary component consisting of proppant (\sim 32%) and a minor fraction which consists of additives (\sim 3%).

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 a mass of approximately 3 320 kg of chemical additives, excluding proppant, remaining in each well, based on 0.4 ML of stimulation fluid. Based on the varying stimulation fluid volumes of 0.5 ML to 0.7 ML, this mass could range from 4 160 kg to 5 820 kg of chemical additives.

6.0 RECOMMEDATIONS FOR MONITORING

Golder assessed three chemicals (boronatrocalcite, monosodium fumarate, diutan gum) based on exposure hazards to humans, aquatic and terrestrial ecology and mass balance concentrations. Based on a low to moderate hazard for ecology and human health, monosodium fumarate and diutan gum are considered to present insufficient hazard for inclusion in the analytical suite. Further assessment of the mass fraction in the FDR, indicated low potential concentrations of monosodium fumarate and diutan gum in the stimulation fluid.

Boronatrocalcite was categorized as a human health Hazard Band 4, due to its potential to cause reproductive toxicity (infertility) and its potential for damaging the unborn child. The reproductive toxicity of boric acid and its salts occurs at high doses via the oral route. It is unlikely to present a reproductive toxicity hazard via skin contact and when inhaled as dust below the occupational exposure limit. However, based on the hazard band rating Golder recommends consideration of boronatrocalcite on the EA list. As a standard analysis for boronatrocalcite is not available, Golder recommends assessment of boron, as a tracer element for the boronatrocalcite compound.





7.0 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.

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. It is noted that boronatrocalcite was assigned a Hazard Band category of 4.

8.0 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.

9.0 CONCLUSIONS

Table 8 and Table 9 summarise the outcomes of the human health and ecological toxicity reviews, respectively.

Table 8: Summary of Human Health Toxicity Hazard Band Ranking

Compound	Human Health Hazard Band ¹	Comment
Boronatrocalcite	4	Based on its potential to cause reproductive toxicity (infertility) and its potential for damaging the unborn child. However, the reproductive toxicity of boric acid and its salts occurs at high doses via the oral route. It is unlikely to present a reproductive toxicity hazard via skin contact and when inhaled as dust below the occupational exposure limit.
Monosodium fumarate	2	Based on reversible but serious (moderate) eye irritation.
Diutan gum	2	Based on the potential for congestion of the lungs if respirable particulates are inhaled.

Note: 1. A ranking of 0 represents the lowest toxicity and 4 represents the highest toxicity.





Table 9: Summary of Ecotoxicology Ranking

Compound	Aquatic Hazard	Aquatic Hazard Comment	Terrestrial Hazard	Terrestrial Hazard Comment
Boronatrocalcite	Moderate	The moderate hazard classification was based on acute toxicological effects in freshwater and fish for the surrogate – sodium metaborate.	Low to moderate	Based on review of limited chemical and environmental fate information (the surrogate chemical is highly water soluble, binds to clay and accumulates in plants) and acute rat toxicity data.
Monosodium fumarate	Low	Based on low persistence bioaccumulation and toxicity potential for two surrogate chemicals – fumaric acid and disodium fumarate.	Low to Moderate	Based on the QSAR results for earthworms and lettuce for both surrogates.
Diutan gum	Low	Based on low persistence, bioaccumulation and toxicity.	Low	Based on the QSAR earthworm results.

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.

10.0 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.





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11.0 REFERENCES

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Report Signature Page

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APPENDIX A

Human Health Chemical Profiles





Name	Boronatrocalcite
Synonyms	Ulexite, sodium calcium borate
CAS number	1319-33-1
Molecular formula	(NaCaB ₅ O ₆ (OH) ₆ •5(H ₂ O))
Molecular Structure	H ₂ O H ₂ O H ₂ O H ₂ O
	Ca ²⁺ O- O B O- Na ⁺
	H ₂ O H ₂ O H ₂ O H ₂ O

Overview	References
Boronatrocalcite is the mineral ulexite. Ulexite is a hydrated sodium calcium borate hydroxide mineral. Ulexite is slightly soluble, decomposes and contains approximately 13% boron.	WHO 1998; ECHA
Ulexite is mined to produce borate products for uses such as insulation, textile grade fiberglass, bleach, fire retardants, agricultural fertilisers and herbicides (as a trace element),and enamels. A study of the thermal degradation of ulexite has shown under increased temperature (around 600°C) the crystalline structure will break down to eventually release NaB ₃ O ₅ and NaCaBO ₃ .	2015; Stoch & Waclawska, 1990
Limited toxicology data are available for ulexite; however, the assessment of boron salts was undertaken by WHO (1998) and ECHA (2015). Disodium octaborate tetrahydrate is converted to boric acid (B(OH) ₃) and disodium borate (2NaB(OH) ₄) upon dissolution in water. Low concentrations of simple inorganic borates (e.g. boric acid, disodium tetraborate pentahydrate, boric oxide and disodium octaborate tetrahydrate) will predominately exist as undissociated boric acid in aqueous solutions at physiological and acidic pH. At about pH 11 the metaborate anion (B(OH) ₄ -) becomes the main species in solution. In between pH 7 and 11, both un-dissociated boric acid and metaborate ions will be present. This leads to the conclusion that the main species in the plasma of mammals and in the environment is un-dissociated boric acid. Since other borates (such as potassium borate) dissociate to form boric acid in aqueous solutions, they too can be considered to exist as un-dissociated boric acid under the same conditions. Boron oxide /boric acid salts are used in this profile to describe the toxicity of ulexite.	WHO 1998; ECHA 2015
Boric acid and borax are absorbed from the gastrointestinal tract and the respiratory tract, as indicated by increased levels of boron in the blood, tissues, or urine or by systemic toxic effects of exposed individuals or laboratory animals. Clearance of boron compounds is similar in humans and animals. Elimination of borates from the blood is largely by excretion; 90% or more of the administered dose is eliminated via the urine, regardless of the route of administration. Excretion is relatively rapid, occurring over a period of a few, or possibly several, days.	

Human Health Toxicity Summary	Reference
Carcinogenicity Ulexite has not been classified as carcinogenic. The data that the classification is based on is categorised as 'conclusive'.	ECHA 2015



No treatment related increase in tumour incidence was reported for a dietary, lifetime carcinogenicity study in B6C3F1 mice (test conducted according to OECD guidelines 451) with concentrations of boric acid up to 5000 ppm.	
Ulexite has not been evaluated by the International Agency for Research on Cancer (IARC) as to its carcinogenicity.	IARC, 2016
Mutagenicity/Genotoxicity	,
Ulexite is not classified as a germ cell mutagen (the data that the classification is based on is categorised as 'conclusive').	ECHA 2015
Reproductive Toxicity Suspected of damaging fertility or the unborn child (via oral route). ECHA lists disodium octaborate as having a GHS group of 1B and a class of H360.	ECHA 2015
In a multigenerational study with rats, boric acid was administered via the oral route at 336 mg/kg/d (boron equivalent of 58.5 mg/kg/d). The authors reported that male rats were sterile and evidence of decreased ovulation in about half of the ovaries examined from the females exposed to boric acid at 336 mg/kg/d. In addition 1/16 high dose females produced a litter when mated with control male animals. The authors concluded that the boric acid LOAEL for reproductive effects was 336 mg/kg/d.	
Short- and long-term oral exposures to boric acid or borax in laboratory animals have demonstrated that the male reproductive tract is a consistent target of toxicity. Testicular lesions have been observed in rats, mice, and dogs given boric acid or borax in food or drinking-water.	WHO 1998
Developmental Toxicity/Teratogenicity Evidence of developmental toxicity in offspring of rats fed boric acid (dose of 76 mg/kg) in their diet throughout gestation. The clinical observations included reduced foetal body mass, short and wavy ribs. These effects disappeared during the postnatal period. Similar but more marked effects were observed at the highest dose of 143 mg/kg and apart from a short 13th rib, they also disappeared during the postnatal period. The boric acid NOAEL for developmental effects was 55 mg/kg bw/d.	ECHA 2015
Endocrine Disruption Ulexite is not 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.	EC 2000
Acute Toxicity (oral, dermal, inhalation) Not classified as acutely toxic via oral, dermal or inhalation exposure. The data that the classification is based on is categorised as 'conclusive'	ECHA 2015
Oral The oral LD₅₀ of boric acid in male albino rats was 3690 mg/kg with 95 % confidence limits of 2710 - 5010 mg/kg (exposure by gavage). There were no control subjects in this experiment.	WHO 1998
The oral LD₅₀ of boric acid in rats ranged from 2 660 mg/kg to 5140 mg/kg (Boron equivalent of 465 mg/kg to 899 mg/kg).	ECHA 2015
Dermal Acute dermal limit study of sodium tetraborate pentahydrate was carried out on New Zealand	



White rabbits (US EPA-FIFRA guidelines at the time, 1985). The exposure duration was 24 h. There were no control animals. The LD $_{50}$ was > 2 000 mg/kg. Clinical changes included anorexia and decreased activity in four rabbits, diarrhoea and soft stools in 3 rabbits and nasal discharge in three rabbits, indicating low acute dermal toxicity. Inhalation The inhalation a LC $_{50}$ of disodium tetraborate pentahydrate in rats was > 2.04 mg/L (2.04 g/m 3) after exposure to dust for 4 h. During the first hour of exposure, ocular discharge, hypoactivity and hunched posture were noted. A few animals exhibited nasal discharge and/or hunched position. All animals recovered by day six after removal from chamber.	
Chronic/repeat dose toxicity (oral, dermal, inhalation) Male and female rats were exposed to oral doses to boric acid of 5.9 mg/kg/d, 17.5 mg/kg/d and 58.5 mg/kg/d in a two year dietary study. The NOAEL for boron was 5 mg/kg/d and the LOAEL 58.5 mg/kg/d. Testicular atrophy and seminiferous tubule degeneration were observed at (6, 12 and 24) months at the high boron dose of 58.5 mg/kg/d (body weight)	ECHA 2015
Sensitisation of the skin or respiratory system Not classified as a skin or respiratory system sensitiser by ECHA. The data that the classification is based on is categorised as 'conclusive'. The exposure period was 0, 7 and 21 days. No irritation was observed in guinea pigs exposed to 95 % w/w (0.4 g) disodium tetraborate pentahydrate moistened with distilled water to enhance skin contact (OECD Guideline 406 "Skin Sensitisation" method [Buehler] test). ECHA interpretation of the results was not sensitising.	ECHA 2015
Corrosion (irreversible)/irritation (reversible) effects on the skin or eye Not classified as corrosive to skin or eyes. The data that the classification is based on is categorised as 'conclusive'. An in vivo skin corrosion test was carried out on rabbits exposed to potassium tetraborate powder for 4 h. No control animals were included. Potassium tetraborate was not corrosive. Potassium tetraborate was not irritating to the eyes of New Zealand White Rabbits in an OECD compliant study.	ECHA 2015



Physical Hazards	Reference
Flammable Potential Not classified as flammable. The data that the classification is based on is categorised as 'conclusive'.	ECHA 2015
Explosive Potential Not classified as explosive. The data that the classification is based on is categorised as 'conclusive'.	ECHA 2015

Toxicity Values	Value	Reference	
Animal Toxicity Data			
Acute Toxicity			
LD ₅₀			
Rat, oral	2 660 to 5 140 mg/kg	WHO 1998, ECHA 2015	
Rabbit, dermal	> 2 000 mg/kg	ECHA 2015	
LC ₅₀			
Rat	> 2040 mg/m ³	ECHA 2015	
High Chronic/Repeat Dose Toxicity			
LOAEL, rat, oral	58.5 mg B/kg/d	ECHA 2015	
NOAEL, rat, oral	17.5 mg B/kg/d	ECHA 2015	
_			

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*		
Trainal Health Toxicity Ranking	Hazard data	Comment
Hazard Band 4		
Carcinogenicity (IARC Group 1 or 2A)	No	IARC 2016
	No	Not classified as a
		germ cell mutagen by
Mutagenicity/Genotoxicity (GHS Category 1A and 1B)		ECHA 2015
	Yes	Suspected of
		damaging fertility or the unborn child by
Reproductive Toxicity/Developmental toxicity (GHS Category 1,		ECHA 2015 - GHS
1A and 1B)		Category 1B
	No	Not listed as an
		endocrine disruptor by
		European
Endocrine Disruption ¹		Commission.
Hazard Band 3		
Carcinogenicity (IARC Group 2B)	No	IARC 2016
	No	Not classified as a
Mutaganiaity/Canatoviaity (CHS Catagany 2)		germ cell mutagen by
Mutagenicity/Genotoxicity (GHS Category 2) Reproductive Toxicity/Developmental toxicity (GHS Category 2)	No	ECHA 2015 GHS Category 1B
Acute Toxicity (oral, dermal or inhalation)	No	See below.
Very Toxic/Toxic	NO	See below.
• oral LD ₅₀ ≤ 300 mg/kg ²		
 dermal LD₅₀ ≤ 1000 mg/kg 		
 inhalation LC₅₀ ≤ 10 mg/L³ (or mg/m³) (vapour) 		
High Chronic/repeat dose toxicity	No	See below.
 oral LOAEL ≤ 10 mg/kg/d²; 		
 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	Not classified as
Oamasina (imanasilala affast)		corrosive to skin or
Corrosive (irreversible effect)	Na	eyes by ECHA 2015
	No	Not classified as a respiratory system
		sensitiser by ECHA
Respiratory sensitiser		2015
Hazard Band 2		
Harmful chronic/repeat dose toxicity	Yes	LOAEL, rat, oral of
oral LOAEL > 10 mg/kg and		58.5 mg/kg/d
≤ 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,		
$> 0.2 \text{ mg/L} \le 1.0 \text{ mg/L/d for vapours or}$		
> 0.02 mg/L ≤ 0.2 mg/L/d for dust/mists/fumes ³		Nich de la colonia de la colon
	No	Not classified as a skin
Skin Sensitiser		sensitiser by ECHA 2015
Hazard Band 1		2010
I IMENIA BUIN I		L



Project name: Chemical Hazard Assessment, Southwest Queensland

Client name: QGC

Acute Toxicity-Harmful	No	LD50, Rat oral of 2660
 oral LD₅₀ > 300 mg/kg ≤ 2000 mg/kg 		to 5 140 mg/kg
 dermal LD₅₀ >1 000 mg/kg ≤ 2000 mg/kg; 		(ECHA 2015)
 inhalation LC₅₀ (6 h/d) > 10 mg/L ≤ 20 mg/L for vapours)³ 		
	No	Potassium tetraborate is classified as a non-irritant to the eyes of New Zealand White rabbits
Irritant (reversible effect)		ECHA (2013)
Hazard Band 0		<u> </u>
All indicators outside criteria listed in Hazards 1-4		
Physical Hazards		
Flammable potential	No	
Explosive potential	No	
	4	Based on Reproductive
Hazard Evaluation (highest band) not including physical hazards		Toxicity/Developmental toxicity
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).



Project name: Chemical Hazard Assessment, Southwest Queensland

Client name: QGC

Human Health Guidelines		
Media	Concentration (mg/m³; mg/L; mg/kg)	Reference
Occupational Exposure Limits		
Air (OEL)		
	1 mg/m ³	Exposure Standard for
		Disodium tetraborate
8-h TWA		pentahydrate, HSIS 2016
STEL	NDF	
Peak Limitation	NDF	
Environmental Exposure		
Air, ambient	NDF	
Air, indoor	NDF	
Water metable	4 mg /L (boron)	Australian Drinking Water
Water, potable		Guidelines 6, 2011
Water, recreational		
Soil, residential	4 500 mg/kg (boron)	NEPM, 2013
Soil, commercial/industrial	300 000 mg/kg (boron)	NEPM, 2013

Footnotes:

OEL = Occupational Exposure Limit

TWA = 8 h Time-Weighted Average

STEL = (15 min) Short-term Exposure Limit

Qualifying Summary Comments

Ulexite has been assigned to Hazard Band 4 because of its potential to cause reproductive toxicity (infertility) and its potential for damaging the unborn child.

Ulexite is a hydrated sodium calcium borate hydroxide mineral. Ulexite is slightly soluble, decomposes and contains approximately 13% boron. Ulexite is mined to produce borate products. A study of the thermal degradation of ulexite has shown under increased temperature (around 600° C) the crystalline structure will break down to eventually release NaB₃O₅ and NaCaBO₃. In aqueous solutions sodium borates are likely to convert to boric acid/borate and at physiological and acidic pH, predominately exist as un-dissociated boric acid. Based on this, the potential human toxicity of ulexite can be based on boric acid.

The reproductive toxicity of boric acid and its salts occurs at high doses via the oral route. It is unlikely to present a reproductive toxicity hazard via skin contact and when inhaled as dust below the occupational exposure limit.



Project name: Chemical Hazard Assessment, Southwest Queensland

Client name: QGC

References

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Created by:	MGT	Date: 01/03/2016
Reviewed by:	JF	Date: 08/03/2016



Name	Diutan gum
Synonyms	D-Glucose, polymer with 6-deoxy L-mannose and D- glucuronic acid, acetate, calcium magnesium potassium sodium salt
	D-Glucurono-6-deoxy-L-manno-D-glucan, acetate, calcium magnesium potassium sodium salt D-Glucurono-D-gluco-6-deoxy-L-mannan, acetate, calcium magnesium potassium sodium salt
CAS number	595585-15-2 (also known under 125005-87-0)
Molecular formula	(C ₆ H ₁₂ O ₆ . C ₆ H ₁₂ O ₅ . C ₆ H ₁₀ O ₇)x.xC ₂ H ₄ O ₂ . xCa.xK.xMg.xNa
Molecular Structure	Not available

Overview	References
Diutan gum is a polysaccharide produced through the fermentation of the sugar source, using Sphingomonas bacteria. Diutan gum is composed of D-glucopyranosyl, 6-deoxy-L-mannopyranosyl, and D-glucuronyl units, acetate modified and Na, K, Ca, and Mg mixed salts.	ChemID <i>plus</i> , 2016
Diutan gum is a white to tan powder (at 20°C and 101.3 kPa), with a water solubility of > 40 g/L (at pH range 7 and 10 at 20°C). It is highly biodegradable and hydrolysis is not expected to constitute a significant degradation pathway. Based on the molecular weight, water solubility and K _{ow} value diutan gum is not expected to bioaccumulate.	NICNAS, 2010
Diutan gum in used in a wide variety of thickening and suspending applications, including in cementitious packaged products, Oilfield space fluids, drilling fluids and drilling cement applications, fire-fighting foam applications, tyre/pneumatic application sealants, cleaning products and coating products.	NICNAS, 2010
NICNAS conclude that based on the available data, diutan gum is not classified as hazardous under the NOHSC <i>Approved Criteria for Classifying Hazardous Substances</i> . However, adverse lung effects (e.g. congestion) are possibly if solid particles of the polymer are inhaled. The polymer is also not classifiable according to Global Harmonised System (GHS) classification criteria.	NICNAS, 2010

Human Health Toxicity Summary	Reference
Carcinogenicity Diutan gum has not been evaluated by the International Agency for Research on Cancer (IARC) as to its carcinogenicity.	IARC, 2015
Mutagenicity/Genotoxicity NICNAS report that diutan gum is not mutagenic to bacteria and not clastogenic to human lymphocyte treated in vitro.	NICNAS, 2010
Reproductive Toxicity	
No data available	
Developmental Toxicity/Teratogenicity	
No data available	



Endocrine Disruption Diutan gum is not 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.	EC, 2000
Acute Toxicity (oral, dermal, inhalation) NICNAS report that diutan gum is of low acute toxicity via the oral route. The report presents an acute toxicity study in rats, where the LD ₅₀ ¹ was reported as > 5 000 mg/kg bw.	NICNAS, 2010
Studies of exposure via the dermal route were not available.	2010
NICNAS report that limited information was available to assess exposure via the inhalation route, with one study presented where effects were similar in both the test and control animals and therefore, cannot be attributed to the diutan gum. NICNAS do report that the U.S. Environmental Protection Agency (USEPA) have identified concerns relating to lung effects from inhalation exposure to diutan gum, based on structural analogues and data submitted when the polymer was assessed as a new chemical in the U.S. The concern was raised by the notifier of the polymer in the U.S., and is based on the understanding that fine respirable particles of high molecular weight substance, when inhaled deep into the lungs, would absorb water and cause congestions. While the USEPA does not expect water-soluble polymers to exhibit lung toxicity because they are expected to rapidly clear the respiratory tract and therefore not cause an overloading effect, they require testing on new chemicals of this type (USEPA, 2015).	NICNAS, 2010/ USEPA, 2015
Chronic/repeat dose toxicity (oral, dermal, inhalation) Diutan gum is not classified as a repeat dose toxicant via the oral route. The NICNAS review notes that in a 28-day oral repeat dose study in rats the no observed effect level (NOEL) was reported as 1000 mg/kg bw/day, based on the absence of treatment related effects.	NICNAS, 2010
Sensitisation of the skin or respiratory system Diutan gum was not classifiable as a skin or respiratory sensitiser. There was no evidence of sensitisation potential when diutan gum was tested in a guinea pig maximisation test.	NICNAS, 2010
Corrosion (irreversible)/irritation (reversible) effects on the skin or eye Based on a study in rabbits, diutan gum was categorised by NICNAS as a slight irritant to the eyes (i.e. not classifiable as an eye irritant).	NICNAS, 2010
NICNAS reviewed two dermal irritation studies and concluded that based on the results, diutan gum is not classified as a skin irritant.	NICNAS, 2010
The first study was carried out on an analogue chemical containing the same monosaccharide units, but with a different molecular weight and branching structure. Under the conditions of the test, the analogue polymer was moderately irritating, with mild erythema (skin redness) and slightly to moderate oedema (skin swelling). However, it was noted that the test protocol for this study was more severe than the OECD test method. A second study reports on the irritation effects of a 50% solution of diutan gum in a guinea pig sensitation study (24 hour exposure time). This study reported mild to moderate erythema, but oedema was absent.	

¹ LD50 – lethal dose for 50% of experimental population



Physical Hazards	Reference
Flammable Potential NICNAS report diutan gum as being not highly flammable.	NICNAS, 2010
Explosive Potential NICNAS report diutan gum as not expected to show any explosive tendencies from the structure.	NICNAS, 2010

Toxicity Values	Value	Reference	
Animal Toxicity Data			
Acute Toxicity			
LD ₅₀			
Rat, oral	> 5000 mg/kg bw	NICNAS, 2010	
LC ₅₀			
	NDF		
High Chronic/Repeat Dose Toxicity			
NOAEL, rat, oral	1000 mg/kg bw/day	NICNAS, 2010	

 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	IARC, 2015
Mutagenicity/Genotoxicity (GHS Category 1A and 1B)	No	NICNAS, 2010
Reproductive Toxicity/Developmental toxicity (GHS Category 1,		
1A and 1B)	NDF	
Endocrine Disruption ¹	No	EC, 2000
Hazard Band 3		1170 0017
Carcinogenicity (IARC Group 2B)	No	IARC, 2015
Mutagenicity/Genotoxicity (GHS Category 2)	No	NICNAS, 2010
Reproductive Toxicity/Developmental toxicity (GHS Category 2)	NDF	
Acute Toxicity (oral, dermal or inhalation)		
Very Toxic/Toxic		
 oral LD₅₀ ≤ 300 mg/kg² 		
• dermal LD ₅₀ ≤ 1000 mg/kg	NI.	0
• inhalation LC ₅₀ ≤ 10 mg/L ³ (or mg/m ³) (vapour)	No	See below
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	Na	Coo bolow
Corrosive (irreversible effect)	No No	See below
Respiratory sensitiser	No NDF	NICNAS, 2010
Hazard Band 2	INDI	
Harmful chronic/repeat dose toxicity		
oral LOAEL > 10 mg/kg and		
≤ 100 mg/kg/d		Oral Rat NOAEL of
 dermal LOAEL > 20 mg/kg/d and ≤ 200 		1 000 mg/kg bw/day
mg/kg/d		5
		Potential for
 inhalation (6-h/d) LOAEC > 50 mg/L ≤ 250 mg/L/d for gases, 		congestion of the lungs if respirable
> 0.2 mg/L ≤ 1.0 mg/L/d for vapours or		particulates are
> 0.2 mg/L \leq 1.0 mg/L/d for dust/mists/fumes ³	Yes	inhaled.
Skin Sensitiser	No	NICNAS, 2010
Hazard Band 1		,
Acute Toxicity-Harmful		
 oral LD₅₀ > 300 mg/kg ≤ 2000 mg/kg 		
 dermal LD₅₀ >1 000 mg/kg ≤ 2000 mg/kg; 		
 inhalation LC₅₀ (6 h/d) > 10 mg/L ≤ 20 mg/L for 		Oral Rat LD ₅₀ >
vapours) ³	No	5 000 mg/kg
Irritant (reversible effect)		
Hazard Band 0		
All indicators outside criteria listed in Hazards 1-4		
Physical Hazards		
Flammable potential	No	NICNAS, 2010
Explosive potential	No	NICNAS, 2010
		Potential for
		congestion of the
Hozord Evaluation (highest hand) not including physical		lungs if respirable
Hazard Evaluation (highest band) not including physical hazards	2	particulates are inhaled.
Data confidence (out of 12 parameters)	10/12	83%
Data confluence (out of 12 parameters)	10/12	03 /0



Project name: Chemical Hazard Assessment, Southwest Queensland

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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).

Media	Concentration (mg/m³; mg/L; mg/kg)	Reference
Occupational Exposure Limits		
Air (OEL)		
8-h TWA	Not available	
STEL	Not available	
Peak Limitation	Not available	
Environmental Exposure		
Air, ambient	Not available	
Air, indoor	Not available	
Water, potable	Not available	
Water, recreational	Not available	
Soil, residential	Not available	
Soil, commercial/industrial	Not available	

Footnotes:

OEL = Occupational Exposure Limit

TWA = 8 h Time-Weighted Average

STEL = (15 min) Short-term Exposure Limit

Qualifying Summary Comments

Diutan gum is a polysaccharide produced through the fermentation of a sugar source. It is a white to tan powder (at 20°C and 101.3 kPa), which has solubility of > 40 g//L in water (pH 7 and 10 at 20°C) and is highly biodegradable. Diutan gum is used in a wide variety of thickening and suspending applications.

NICNAS conclude that based on the available data, diutan gum is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. However, adverse lung effects (e.g. congestion) are possibly if solid respirable particles of diutan gum are inhaled. Diutan gum is categorized in Hazard Band 2, based on the potential for congestion of the lungs if respirable particulates are inhaled.

^{*} 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].

¹Based 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)



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Client name: QGC

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Created by:	MGT	Date: 2/3/2016
Reviewed by:	JF	Date: 08/03/2016



Name	Monosodium fumarate
Synonyms	Sodium fumarate; sodium hydrogen fumarate; 2- butenedioic acid, monosodium salt; fumaric acid, monosodium salt; sodium hydrogen but-2-enedioate
CAS number	7704-73-6 (also listed as 5873-57-4 sodium hydrogen fumarate)
Molecular formula	C ₄ H ₃ O ₄ Na
Molecular Structure	HO Na*

Overview	References
Monosodium fumarate (referred to as sodium fumarate) is the mono-sodium salt of fumaric acid. Fumaric acid is an intermediate in the citric acid cycle used by cells to produce energy in the form of ATP from food. The solubility and pH is likely to increase in the order of fumeric acid, sodium fumerate and disodium fumarate due to increasing polarity and dissociation. The solubility of fumeric acid is 7 g/L (at 25°C).	CIR, 2009; ECHA, 2016b
Sodium fumarate is used in cosmetic ingredients as a buffering agent (pH adjuster). The Cosmetic Ingredient Review (CIR) completed a review of fumaric acid and related salts and esters used in cosmetics in 2009. The CIR Expert Panel concluded that on the basis of the data available, fumaric acid, disodium fumarate, sodium fumerate, dibehenyl fumarate, Di-C12-15 alky fumarate, diethylhexyl fumarate, diisostearyl fumarate, sodium stearyl fumarate, and ferrous fumarate are safe as used in cosmetic formulations in the practices of use given in the report (at concentrations up to 20%).	CIR, 2009
 The U.S Food and Drug Administration (FDA) established by regulation (21CFR172.350) that fumaric acid and its salts may be safely used as food additives, in accordance with the following conditions: a) The additives meet the following specifications: Fumaric Acid contains a minimum of 99.5 percent by weight of fumaric acid, calculated on the anhydrous basis. The calcium, magnesium, potassium, and sodium salts contain a minimum of 99 percent by weight of the respective salt, calculated on the anhydrous basis. Ferrous Fumarate contains a minimum of 31.3 percent total iron and not more than 2 percent ferric iron. (b) with the exception of ferrous fumarate, fumaric acid and the named salts are used singly or in combination in food at a level not in excess of the amount reasonably required to accomplish the intended effect (c) Ferrous fumarate is used as a source of iron in foods for special dietary use, when the use is consistent with good nutrition practice. This review focuses primarily on sodium fumarate. However, where information is available for fumaric acid and disodium fumarate, this has been provided to fill data gaps. 	FDA, 2016



Human Health Toxicity Summary	Reference
Carcinogenicity Sodium fumarate, fumaric acid or disodium fumarate have not been evaluated by the International Agency for Research on Cancer (IARC) as to their carcinogenicity.	IARC, 2016
Mutagenicity/Genotoxicity Fumaric acid is not classified as a germ cell mutagen. The data that the classification is based on is categorised as 'conclusive'.	ECHA, 2016b
Reproductive Toxicity Fumaric acid is not classified as a reproductive toxicant. The data that the classification is based on is categorised as 'conclusive'.	ECHA, 2016b
Developmental Toxicity/Teratogenicity Fumaric acid is not classified as a developmental toxicant. The data that the classification is based on is categorised as 'conclusive'.	ECHA, 2016b
Endocrine Disruption Sodium fumarate, fumaric acid or disodium fumarate are not 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.	EC, 2000
Acute Toxicity (oral, dermal, inhalation) CIR cite a study by Levey et al. (1946) which reports an oral LD ₅₀ in rats of ~8,000 mg/kg bw (milligrams/ kilograms body weight). Fumaric acid is not classified as acutely toxic via the oral, dermal or inhalation route. The data that the classification is based on is categorised as 'conclusive'.	CIR, 2009 ECHA, 2016b
Chronic/repeat dose toxicity (oral, dermal, inhalation) CIR cite a study by Packman et al. (1963), where 4 groups of 15 rabbits were fed diets containing 0 or 6.9% sodium fumarate (equating to 5% fumaric acid) for 150 days. CIR report that no significant differences from controls in body weight gain, feed consumption, mortality rate, blood counts, blood sugar, non-protein nitrogen level and urine. Organ weights were not significantly different between the groups and histologic examination showed no adverse findings attributable to the diet. In particular, spermatogenesis and testicular structure were unaffected.	CIR, 2009
Sensitisation of the skin or respiratory system Fumaric acid is not classified as a skin or respiratory sensitiser. Although the skin sensitisation data that the classification is based on is categorised as 'conclusive', the data was categorised as 'data lacking' for respiratory sensitisation potential.	ECHA, 2016b
Corrosion (irreversible)/irritation (reversible) effects on the skin or eye Fumaric acid is classified as an eye irritant (GHS Eye Irrigation group of 2, H319 ('Causes serious eye irritation). The data that the classification is based on is categorised as 'conclusive' Fumaric acid is classified as a skin irritant (conclusive data). The data that the classification is	ECHA, 2016b/ ECHA, 2016a
based on is categorised as 'conclusive' Fumaric acid is a slight skin irritant when tested in an acute dermal irritation/corrosion test in rabbits. Fumaric acid is also likely to be a slight to mild respiratory irritant.	



Physical Hazards	Reference
Flammable Potential Fumaric acid is not classified as a flammable solid.	ECHA, 2016b
Explosive Potential Fumaric acid is not classified as an explosive substance.	ECHA, 2016b

Toxicity Values	Value	Reference			
Animal Toxicity Data					
Acute Toxicity					
LD ₅₀					
Rat, oral, sodium fumarate	~8 000 mg/kg bw	CIR, 2009			
Rat, oral, fumaric acid, female	9 300 mg/kg bw	CIR, 2009			
Rat, oral, fumaric acid, male	10 700 mg/kg bw	CIR, 2009			
Rat, oral, fumaric acid	10 700 mg/kg bw	CIR, 2009			
Rabbit, oral, disodium fumaric	~3 600 mg/kg bw	CIR, 2009			
Rabbit, dermal, fumaric acid	>20 000 mg/kg bw	CIR, 2009			
Rabbit, oral, fumaric acid	5 000 mg/kg bw	CIR, 2009			
LC ₅₀					
Rat, fumaric acid	> 1.31 mg/L air	ECHA, 2016b			

Footnotes:
LD₅₀ – lethal dose for 50% of experimental population
LC₅₀ – 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	IARC, 2016
Mutagenicity/Genotoxicity (GHS Category 1A and 1B)	No	ECHA, 2016b
Reproductive Toxicity/Developmental toxicity (GHS Category 1,		
1A and 1B)	No	ECHA, 2016b
Endocrine Disruption ¹	No	EC, 2000
Hazard Band 3		
Carcinogenicity (IARC Group 2B)	No	IARC, 2016
Mutagenicity/Genotoxicity (GHS Category 2)	No	ECHA, 2016b
Reproductive Toxicity/Developmental toxicity (GHS Category 2)	No	ECHA, 2016b
Acute Toxicity (oral, dermal or inhalation)		
Very Toxic/Toxic		
 oral LD₅₀ ≤ 300 mg/kg² 		
 dermal LD₅₀ ≤ 1000 mg/kg 		
 inhalation LC₅₀ ≤ 10 mg/L³ (or mg/m³) (vapour) 	No	See below
High Chronic/repeat dose toxicity		
 oral LOAEL ≤ 10 mg/kg/d²; 		
 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	See below
Corrosive (irreversible effect)	No	ECHA, 2016a
Respiratory sensitiser	NDF	·
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 \leq 1.0 mg/L/d for vapours or		
> 0.02 mg/L ≤ 0.2 mg/L/d for dust/mists/fumes ³	No	CIR, 2009
Skin Sensitiser	No	ECHA, 2016b
Hazard Band 1		
Acute Toxicity-Harmful		
 oral LD₅₀ > 300 mg/kg ≤ 2000 mg/kg 		
 dermal LD₅₀ >1 000 mg/kg ≤ 2000 mg/kg; 		Oral LD ₅₀
 inhalation LC₅₀ (6 h/d) > 10 mg/L ≤ 20 mg/L for 		~8 000 mg/kg bw
vapours) ³	No	CIR, 2009
Irritant (reversible effect)	Yes	ECHA, 2016a
Hazard Band 0		·
All indicators outside criteria listed in Hazards 1-4		
Physical Hazards		
Flammable potential	No	ECHA, 2016b
Explosive potential	No	ECHA, 2016b
Hazard Evaluation (highest band) not including physical		
hazards	2	Eye Irritant
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].



Project name: Chemical Hazard Assessment, Southwest Queensland

Client name: QGC

NDF - No data found within the limits of the search strategy

Media	Concentration (mg/m³; mg/L; mg/kg)	Reference
Occupational Exposure Limits		
Air (OEL)		
8-h TWA	NDF	
STEL	NDF	
Peak Limitation	NDF	
Environmental Exposure		
Air, ambient	NDF	
Air, indoor	NDF	
Water, potable	NDF	
Water, recreational	NDF	
Soil, residential	NDF	
Soil, commercial/industrial	NDF	

Footnotes:

OEL = Occupational Exposure Limit

TWA = 8 h Time-Weighted Average

STEL = (15 min) Short-term Exposure Limit

NDF - No data found within the limits of the search strategy

Qualifying Summary Comments

Monosodium fumarate (referred to as sodium fumarate) is the mono-sodium salt of fumaric acid. Fumaric acid is an intermediate in the citric acid cycle used by cells to produce energy in the form of ATP from food.

Sodium fumarate is used in cosmetic ingredients as a buffering agent (pH adjuster). The CIR completed a review of fumaric acid and related salts and esters used in cosmetics in 2009 and concluded that they were safe for use, as described in the review. Fumaric acid and its salts are also approved by the FDA for use as food additives.

Sodium fumarate is categorised in Hazard Band 2 on the basis of its reversible but serious (moderate) eye irritation.

References

Cosmetic Ingredient Review (CIR), 2009. Final Report of the Cosmetic Ingredient Review Expert Panel: Safety Assessment of Fumaric Acid and Related Salts and Esters as Used in Cosmetics, dated 23 March 2009. Available at http://www.cir-safety.org/ingredients, accessed March 2016.

European Commission (EC), 2000. Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption, preparation of a candidate list of substances as a basis for priority setting, *Final Report* (Incorporating corrigenda to final report dated 21 June 2000).

^{"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).



Project name: Chemical Hazard Assessment, Southwest Queensland

Client name: QGC

European Chemicals Agency (ECHA), 2016a. *Pre-Registration Substance Information: Sodium hydrogen fumarate (CAS no.: 5873-57-4).* Available at http://echa.europa.eu/substance-information/-/substanceinfo/100.025.032, accessed March 2016.

European Chemicals Agency (ECHA), 2016b. *Registered Substances List Dossier for Fumaric acid.* Available at http://echa.europa.eu/registration-dossier/-/registered-dossier/15099/2/, last updated 3 February 2016, Accessed March 2016.

International Program on Chemical Safety (IPCS), 2011. Fumaric acid summary. Available at http://www.inchem.org/documents/icsc/icsc/eics1173.htm, Accessed March 2016.

U.S. Food and Drug Administration (FDA), 2016. Code of Federal Regulations (CFR) Title 2- Food and Drugs, Chapter I-Food and Drug Administration, Department of Health and Human Services, Subchapter B-Food for Human Consumption, U.S Food and Drug Administration, Part 172 – Food Additives Permitted For Direct Addition to Food for Human Consumption, Subpart D – Special Dietary and Nutritional Additives, 350 Fumaric acid and salts of fumaric acid (21CFR172.350). Available at http://www.ecfr.gov/cgi-bin/text-idx?SID=dd32c9752b3b6132d9e0df485707c04a&mc=true&node=pt21.3.172&rgn=div5#se21.3.172_1350, accessed March 2016.

International Agency for Research on Cancer (IARC), 2015. Agents Classified by the *IARC Monographs*, Volumes 1–114, last updated 26 October, 2015. Available at http://monographs.iarc.fr/ENG/Classification/index.php, accessed March 2016.

Created by:	MGT	Date: 4/03/2016
Reviewed by:	JF	Date: 10/03/2016





APPENDIX B

Ecotoxicology Profiles





Project number: 127635006 ORGANIC

Name	Diutan gum
Synonyms	
CAS Number	595585-15-2
Molecular Formula	(C6H1206.C6H12O5.C6H10O7)x.xC2H4O2.xCaxKxMgxNa

Value	Reference
White to tan powder	NICNAS 2010
100000	NICNAS 2010
1,427.00	NICNAS 2010
40,000.00	NICNAS 2010
-0.42	NICNAS 2010
-2.76E+00	NICNAS 2010
	White to tan powder 100000 1,427.00 40,000.00

Persistance / Bioaccumulation	Value	Reference
Biowin 3 (Ultimate Survey Biodegradation):		
Biowin 4 (Primary Biodegradation):		
EPISUITE Ready Biodegradability:		
Biowin 7 (Anaerobic Model Prediction):		
Fugacity_Air: (%)		
Fugacity_Water: (%)		
Fugacity_Soil: (%)		
Fugacity_Sediment: (%)		
Bioconcentration factor (BCF):		
Biotransformation half - life (Days):		





Aquatic Ecotoxicological Data

Acute toxicity data	a						
SpeciesName	Common Name	Endpoint	Effect	Effect Measure	Test Time (Days)	Conc mg/L	Reference
Oncorhynchus mykiss	Rainbow trout	Fish LC50	MOR	Mortality	4	100	NICNAS 2010
Daphnia magna	Waterflea	Invertebrate LC50	MOR	Mortality	2	100	NICNAS 2010
	Green algae	Plant EC50	GRO	Growth	3	100	NICNAS 2010

Terrestrial Ecotoxicological Data

Common Name	Endpoint	Effect	Effect Measure	Test Time (Days)	Conc	Reference	Units
Rat	Mammalian LD50	MOR	Mortality		5000	NICNAS 2010	mg/kg
Lettuce	QSAR lettuce	GRO	Growth		2280000 00	Calculated	mg/L
Worms	QSAR worms	MOR	Mortality		0.24	Calculated	mg/kg

Created By: Naomi Cooper Date: 7/03/2016

Checked By: Kirsten Broadgate Date: 7/03/2016



Project number: 127635006 ORGANIC

Name	Fumaric acid (Surrogate for)
Synonyms	
CAS Number	110-17-8
one number	110 17 0
Molecular Formula	C4H4O4

Physical Properties	Value	Reference
PhaseState:	Crystals	HSDB 2010
Molecular Weight (g/mol):	116.07	EPISUITE 2011 v4.1
Melting Point (°C):	287.00	HSDB 2010
Boiling Point (°C):	285.25	EPISUITE 2011 v4.1
Density / Specific Gravity (g/L):	1.64	HSDB 2010
Vapour Pressure (mm Hg at 25°C):	0.000154	HSDB 2010
Solubility (mg/L):	0.01	HSDB 2010
Henry's Law Constant (atm m³/mole):	0.0000000000135	EPISUITE 2011 v4.1
Organic carbon partition coefficient (Koc):	7.33	EPISUITE 2011 v4.1
Log organic carbon partition coefficient (log Koc):	0.87	EPISUITE 2011 v4.1
Log octanol - water partition coefficient (log Kow):	4.60E-01	EPISUITE 2011 v4.1

Persistance / Bioaccumulation	Value	Reference
Biowin 3 (Ultimate Survey Biodegradation):	3.6719	EPISUITE 2011 v4.1
Biowin 4 (Primary Biodegradation):	4.4514	EPISUITE 2011 v4.1
EPISUITE Ready Biodegradability:	Biodegrades fast	EPISUITE 2011 v4.1
Biowin 7 (Anaerobic Model Prediction):	1.0626	EPISUITE 2011 v4.1
Fugacity_Air: (%)	0.0673	EPISUITE 2011 v4.1
Fugacity_Water: (%)	29	EPISUITE 2011 v4.1
Fugacity_Soil: (%)	70	EPISUITE 2011 v4.1
Fugacity_Sediment: (%)	0.059	EPISUITE 2011 v4.1
Bioconcentration factor (BCF):	3.162	EPISUITE 2011 v4.1
Biotransformation half - life (Days):	0.1841	EPISUITE 2011 v4.1





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	245	ECOSAR 2012
	Waterflea	Invertebrate LC50	MOR	Mortality	2	212	ECOSAR 2012
	Green algae	Plant EC50	MOR	Mortality	3	41	ECOSAR 2012

Terrestrial Ecotoxicological Data

Common Name	Endpoint	Effect	Effect Measure	Test Time (Days)	Conc	Reference	Units
Rat	Mammalian LD50	MOR	Mortality		9300	HSDB 2010	mg/kg
Lettuce	QSAR lettuce	GRO	Growth		127	Calculated	mg/L
Worm	QSAR worms	MOR	Mortality		1.88	Calculated	mg/kg

Common Name	Endpoint	Effect	Effect Measure	Test Time (Days)	Conc	Reference	Units
Earthworm	1	MOR	Mortality		3212	ECOSAR 2012	mg/L

Created By: Naomi Cooper Date: 7/03/2016

Checked By: Kirsten Broadgate Date: 7/03/2016



Project number: 127635006 ORGANIC

Name	Sodium fumarate (Surrogate for)
Synonyms	
CAS Number	17013-01-3
Molecular Formula	C4H2O4Na2
IVIOIECUIAI FOITIUIA	04Π2 04Nd2

Physical Properties	Value	Reference
PhaseState:	White crystalline powder	
Molecular Weight (g/mol):	160.04	EPISUITE 2011 v4.1
Melting Point (°C):	156.12	EPISUITE 2011 v4.1
Boiling Point (°C):	429.61	EPISUITE 2011 v4.1
Density / Specific Gravity (Enter Unit):		
Vapour Pressure (mm Hg at 25°C):	0.000000716	EPISUITE 2011 v4.1
Solubility (mg/L):	228,000.00	EPISUITE 2011 v4.1
Henry's Law Constant (atm m³/mole):	0.0000000000136	EPISUITE 2011 v4.1
Organic carbon partition coefficient (Koc):	7.33	EPISUITE 2011 v4.1
Log organic carbon partition coefficient (log Koc):	0.87	EPISUITE 2011 v4.1
Log octanol - water partition coefficient (log Kow):	4.60E-01	ECOSAR 2012

Persistance / Bioaccumulation	Value	Reference
Biowin 3 (Ultimate Survey Biodegradation):	3.6719	EPISUITE 2011 v4.1
Biowin 4 (Primary Biodegradation):	4.4514	EPISUITE 2011 v4.1
EPISUITE Ready Biodegradability:	Biodegrades fast	EPISUITE 2011 v4.1
Biowin 7 (Anaerobic Model Prediction):	1.0626	EPISUITE 2011 v4.1
Fugacity_Air: (%)	0.0000741	EPISUITE 2011 v4.1
Fugacity_Water: (%)	29	EPISUITE 2011 v4.1
Fugacity_Soil: (%)	71	EPISUITE 2011 v4.1
Fugacity_Sediment: (%)	0.0587	EPISUITE 2011 v4.1
Bioconcentration factor (BCF):	3.162	EPISUITE 2011 v4.1
Biotransformation half - life (Days):	0.02464	EPISUITE 2011 v4.1





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	53316	ECOSAR 2012	
		Invertebrate LC50	MOR	Mortality	2	25295	ECOSAR 2012	
	Green algae	Plant EC50	GRO	Growth	3	8964	ECOSAR 2012	

Terrestrial Ecotoxicological Data

Common Name	Endpoint	Effect	Effect Measure	Test Time (Days)	Conc	Reference	Units
Rat	Mammalian LD50	MOR	Mortality		8000	ACRON Organic	mg/kg
Lettuce	QSAR lettuce	GRO	Growth		127	Calculated	mg/L
Worms	QSAR worms	MOR	Mortality		411	Calculated	mg/kg

Common Name	Endpoint	Effect	Effect Measure	Test Time (Days)	Conc	Reference	Units
Earthworm	1	MOR	Mortality		3212	ECOSAR 2012	mg/L

Created By: Naomi Cooper Date: 7/03/2016

Checked By: Kirsten Broadgate Date: 7/03/2016



Project number: 127635006 INORGANIC

Name	Sodium metaborate
Synonyms	Boric acid, monosodium salt;
CAS Number	7775-19-1
Molecular Formula	BHO2Na

Physical Properties	Value	Reference
PhaseState:	White hexagonal crystals	HSDB 2006
Molecular Weight (g/mol):	65.8	HSDB 2006
Melting Point (°C):	966.00	HSDB 2006
Boiling Point (°C):	1434	HSDB 2006
Solubility (mg/L):	200,000.00	HSDB 2006

Other Relevant Factors	Value	Reference
Reactivity		'
Species:		
Reaction type:		
pH / Acidity		
acid / alkaline		
pH (10% solution)		

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	Mortality	Mortality	4	79.7	OECD 2012	
Ceriodaphnia dubia	Waterflea	Invertebrate LC50	Mortality	Mortality	2	91	OECD 2012	

Chronic toxicity data								
SpeciesName	Common Name	Endpoint	Effect	Effect Measure		Conc mg/L	Reference	
Pimephales promelas	Fathead minnow	Fish LOEC			32	16	OECD 2012	
Oncorhynchus mykiss	Rainbow trout	Fish NOEC			14	0.1	OECD 2012	
Daphnia magna		Invertebrate NOEC			14	2.4	OECD 2012	





Terrestrial Ecotoxicological Data

Common Name	Endpoint	Effect	Effect Measure	Test Time (Days)	Conc	Reference	Units
Rat	Mammalian LD50	Mortality	Mortality		2330	HSDB 2006	

Created By: Naomi Cooper Date: 7/03/2016

Checked By: Kirsten Broadgate Date: 7/03/2016



APPENDIX C

Important Information Relating To This Report





IMPORTANT INFORMATION RELATING TO THIS REPORT

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