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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Testosterone Cypionate Injection (Hospira, Inc.)

Product Code(s) PZ03047
Trade Name: Not applicable
Chemical Family: Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used for hormone replacement therapy

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company

275 North Field Drive

Hospira UK Limited
Horizon

Lake Forest, Illinois 60045

1-800-879-3477

Honey Lane
Hurley

Maidenhead, SL6 6RJ United Kingdom

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Acute toxicity - OralCategory 4 - (H302)CarcinogenicityCategory 1B - (H350)Reproductive toxicityCategory 1A - (H360FD)Acute aquatic toxicityCategory 2 - (H401)Chronic aquatic toxicityCategory 3 - (H412)

2.2. Label elements

Signal word Danger

Hazard statements H302 - Harmful if swallowed

H360FD - May damage fertility. May damage the unborn child

H350 - May cause cancer H401 - Toxic to aquatic life

H412 - Harmful to aquatic life with long lasting effects

Precautionary Statements P202 - Do not handle until all safety precautions have been read and understood

P264 - Wash hands thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

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P273 - Avoid release to the environment

P280 - Wear protective gloves and protective clothing

P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell

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P330 - Rinse mouth

P308 + P313 - IF exposed or concerned: Get medical attention/advice

P405 - Store locked up

P501 - Dispose of contents/container in accordance with all local and national regulations



2.3. Other hazards
Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH	EC No	Classification	Specific	M-Factor	M-Factor
		Registration		according to	concentration		(long-term)
		Number		Regulation	limit (SCL)		
				(EC) No.			
				1272/2008			
				[CLP]			
Testosterone	20		200-368-4	Repr. 1A	Not Listed	1	No data
Cypionate				(H360FD)			available
(CAS #: 58-20-8)				Carc. 1B			
				(H350)Acute 1			
				(H400)Chronic			
				3 (H412)			
BENZYL BENZOATE	10 - 20		204-402-9	Acute Tox. 4	Not Listed	No data	No data
(CAS #: 120-51-4)				(H302)		available	available
				Aquatic			
				Chronic 2			
				(H411)			
BENZYL ALCOHOL	<1.0		202-859-9	Acute Tox. 4	Not Listed	No data	No data
(CAS #: 100-51-6)				(H302)		available	available
				Acute Tox. 4			
				(H332)			
NonHazardous	NonHazardous						
Chemical name	Weight-%	REACH	EC No	Classification	Specific	M-Factor	M-Factor

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		Registration Number		according to Regulation (EC) No. 1272/2008 [CLP]	concentration limit (SCL)		(long-term)
Cottonseed Oil (CAS #: 8001-29-4)	*		232-280-7	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

Chemical name	Oral LD50	Dermal LD50	hour - dust/mist -	Inhalation LC50 - 4 hour - vapor - mg/L	
0.11	00700	N. 1.4 '1.1.1	mg/L	N. 1.6 9.11	N. 1.6 71.1.1
Cottonseed Oil 8001-29-4	89730	No data available	No data available	No data available	No data available
BENZYL BENZOATE 120-51-4	500	4000	No data available	No data available	No data available
BENZYL ALCOHOL 100-51-6	1230	2000	4.178	No data available	No data available

Additional information * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation Remove to fresh air. Seek immediate medical attention/advice.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

Skin contact Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek

medical attention.

Ingestion Never give anything by mouth to an unconscious person. Wash out mouth with water. Do

not induce vomiting unless directed by medical personnel. Seek medical attention

immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and For info

effects

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

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Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

Fine particles (such as dust and mists) may fuel fires/explosions.

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chemical

Carbon dioxide, carbon monoxide **Hazardous combustion products**

5.3. Advice for firefighters

Special protective equipment for

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. fire-fighters

Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Personal precautions

Section 8). Minimize exposure.

Use personal protection recommended in Section 8. For emergency responders

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be

taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Prevent further leakage or spillage if safe to do so. **Methods for containment**

Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean

spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

See section 8 for more information. See section 13 for more information. Reference to other sections

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

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Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Testosterone Cypionate

Pfizer OEL TWA-8 Hr: 4 µg/m³, Skin

BENZYL ALCOHOL

Pfizer OEL TWA-8 Hr: 10 ppm

BENZYL BENZOATE

Russia MAC: 5 mg/m³

BENZYL ALCOHOL

Bulgaria 5.0 mg/m³ Czech Republic 40 mg/m³

Ceiling: 80 mg/m³

Finland 10 ppm 45 mg/m³

Germany 22 mg/m³ can occur as vapor and aerosol at the same time

5 ppm can occur as vapor and aerosol at the same time

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Ceiling / Peak: 44 mg/m³ Ceiling / Peak: 10 ppm

Skin

Germany 5 ppm

22 mg/m³ H*

 Ceiling Limit Value
 25 mg/m³

 Latvia
 5 mg/m³

 Poland
 240 mg/m³

 Russia
 MAC: 5 mg/m³

Skin 5 ppm

22 mg/m³ H*

8.2. Exposure controls

Switzerland

Engineering controls Engineering controls should be used as the primary means to control exposures. General

room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental exposure controls No information available.

Personal protective equipment Refer to applicable national standards and regulations in the selection and use of personal

protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in

the workplace and specific operational processes.

Eye/face protection Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the

standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with

drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

the standards in accordance with Energy, North 1700 of international equivalent.).

Skin and body protection Wear impervious protective clothing to prevent skin contact – consider use of disposable

clothing where appropriate. (Protective clothing must meet the standards in accordance

with EN13982, ANSI 103 or international equivalent.).

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Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

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General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state Liquid Color Clear

OdorNo information available.Odor thresholdNo information available

Molecular formulaMixtureMolecular weightMixture

<u>Property</u> <u>Values</u>

pHNo data availableMelting point / freezing pointNo data available

Boiling point / boiling range

Flash point No information available

Evaporation rate No data available Flammability (solid, gas) No data available

Flammability Limit in Air

Upper flammability limit: No data available

Lower flammability limit: No data available

No data available Vapor pressure Vapor density No data available Relative density No data available Water solubility No data available Solubility(ies) No data available No data available Partition coefficient No data available **Autoignition temperature** No data available **Decomposition temperature** No data available Kinematic viscosity Dynamic viscosity No data available

Particle characteristics
Particle Size
Particle Size Distribution
No information available
No information available
Explosive properties
No information available

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

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Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available. **Sensitivity to Static Discharge** No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information: The information in this section describes the hazards of various forms of the active

ingredient.

Long Term: Adverse reproductive effects seen in repeat-dose animal studies are consistent with the

pharmacologic action of this drug and are expected to be relevant to humans.

Known Clinical Effects: Clinical use has caused effects on reproductive system, including prolonged erection

(priapism), breast development in males (gynecomastia); loss of libido; decreased sperm count, impairment of male fertility, development of male characteristics (masculinization), development of male characteristics in the female fetus, impairment of female fertility. Clinical use of this drug has caused prostate cancer, liver cancer, kidney cancer.

Acute toxicity

Classification is based on mixture calculation methods based on component data

Serious eve damage/eve irritation

Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation
Skin corrosion/irritation
Respiratory or skin sensitization
STOT - single exposure
STOT - repeated exposure
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.

Reproductive toxicity Classification is based on mixture calculation methods based on component data.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Classification is based on mixture calculation methods based on component data.

Aspiration hazardBased on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

Cottonseed Oil

Rat Oral LD50 > 90 ml/kg

BENZYL BENZOATE

Rat Oral LD50 1680 mg/kg

Testosterone Cypionate

Mouse Para-periosteal LD 50 > 1000 mg/kg

BENZYL ALCOHOL

Rat Oral LD 50 1230 mg/kg Mouse Oral LD 50 1360 mg/kg Rabbit Dermal LD 50 2 gm/kg

Testosterone propionate

Rat Oral LD 50 1000 mg/kg Mouse Oral LD 50 1350 mg/kg

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Testosterone

Rat (F) Para-periosteal LD50 325 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Cottonseed Oil	> 90 mL/kg (Rat)	-	-
BENZYL BENZOATE	= 500 mg/kg (Rat)	= 4000 mg/kg(Rabbit)	-
BENZYL ALCOHOL	= 1230 mg/kg (Rat)	= 2 g/kg(Rabbit)	> 4178 mg/m³ (Rat) 4 h

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not

achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

BENZYL ALCOHOL

Eye Irritation Rabbit Severe Skin Irritation Rabbit Minimal Skin Irritation Guinea Pig Moderate

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Testosterone Cypionate

5 Day(s) Mouse Oral 200 mg/kg LOAEL Liver

Testosterone propionate

28 Day(s) Monkey Subcutaneous 2.7 mg/kg LOAEL None identified 5 Day(s) Mouse Oral 1000 mg/kg/day NOAEL None identified

28 Day(s) Monkey Subcutaneous 2.7 mg/kg/day LOAEL Endocrine system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Testosterone propionate

Embryo / Fetal Development Monkey Subcutaneous 1.25 mg/kg/day LOEL Teratogenic

Embryo / Fetal Development Rat Subcutaneous 0.4 mg/kg NOEL Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Testosterone Cypionate

Bacterial Mutagenicity (Ames) Negative

Testosterone
In Vivo Micronucleus Mouse Negative
In Vivo Mouse Spermatogonal Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Testosterone propionate

Not specified Rat Subcutaneous 80-100 mg LOEL Tumors, Male reproductive system

Carcinogenicity Androgenic (anabolic) steroids are classified as probable human carcinogens (IARC 2A) by

the International Agency for Research on Cancer (IARC).

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Toxic to aquatic organisms. Harmful to aquatic life with long lasting effects. Releases to the

environment should be avoided. The information included in this section describes the

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potential hazards of various forms of the active ingredient.

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12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

BENZYL BENZOATE

Brachydanio rerio (Zebra fish) LC50 96 hours 1.34 mg/L

Algae EC50 72 0.475 mg/L

Shrimp LC50 96 hours 4.8 mg/L

BENZYL ALCOHOL

Pimephales promelas (Fathead Minnow) EPA LC50 96 hours 460 - 770 mg/L

Daphnia magna (Water Flea) NPDES OECD EC50 48 Hours 230 mg/L

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 hours 500 mg/L

Testosterone

Daphnia magna (Water Flea) OECD NOEC 48 Hours > 6.2 mg/L

Scenedesmus subspicatus (Green Alga) OECD ErC50 72 hours 0.7 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Testosterone

Daphnia magna (Water Flea) OECD 21 Day(s) LOEC 0.31 mg/L

Daphnia magna (Water Flea) OECD 21 Day(s) NOEC 0.15 mg/L

12.2. Persistence and degradability

Persistence and degradability

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

BENZYL ALCOHOL

OECD Activated sludge Ready 92 % After 28 Day(s) Ready

Testosterone

Activated sludge Mineralization (CO2 Evolution) 68 % After 72 Hour(s) Ready

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
BENZYL BENZOATE	The substance is not PBT / vPvB
BENZYL ALCOHOL	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

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13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):
Not applicable
Not applicable
Not applicable

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

U.S. - DEA (Drug Enforcement Administration)

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Cottonseed Oil

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS 232-280-7
AICS Present

Testosterone Cypionate

CERCLA/SARA Section 313 de minimus % Not Listed

California Proposition 65 developmental toxicity 10/1/1991

female reproductive toxicity 4/1/90 male reproductive toxicity 4/1/90 Schedule III Controlled Substance

EINECS 200-368-4

Standard for Uniform Scheduling of Medicines and Schedule 4

Poisons (SUSMP)

BENZYL BENZOATE

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS 204-402-9
AICS Present

BENZYL ALCOHOL

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
TSCA Present
EINECS 202-859-9
AICS Present

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Chemical name	French RG number	Title
BENZYL ALCOHOL	RG 84	-
100-51-6		

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage the unborn child Carcinogenicity-Cat.1B; H350 - May cause cancer Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on

Ingredients. Updated Section 6 - Accidental Release Measures. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 -

Other Information.

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Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.