

Section 1. Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier****Product Identity** Islet-Mate™**Alternate Names** Islet-Mate™**1.2. Relevant identified uses of the substance or mixture and uses advised against****Intended use** See Technical Data Sheet.**Application Method** See Technical Data Sheet.**1.3. Details of the supplier of the safety data sheet****Company Name** BRTI Life Sciences
Bioactive Regenerative Therapeutics, Inc.
North Shore Business Enterprise, Center-Bay 130
1313, Fairgrounds Road
Two Harbors, Minnesota 55616**Customer Service:** BRTI Life Sciences**1.4. Emergency telephone number****Emergency****24 hour Emergency Telephone No.** 888-868-9100**Section 2. Hazard identification of the product****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**Skin Irrit. 2;H315 Causes skin irritation.
Eye Irrit. 2;H319 Causes serious eye irritation.
STOT SE 3;H335 May cause respiratory irritation.**2.2. Label elements****According to Regulation (EC) No 1272/2008****Warning**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

[Prevention]:

- P261 Avoid breathing dust / fume / gas / mist / vapors / spray.
- P264 Wash thoroughly after handling.
- P271 Use only outdoors or in a well-ventilated area.
- P280 Wear protective gloves / eye protection / face protection.

[Response]:

- P302+352 IF on skin: Wash with plenty of soap and water.
- P304+312 If inhaled: Call a poison center or doctor / physician if you feel unwell.
- P305+351+338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
- P321 Specific treatment (see information on this label).
- P332+313 If skin irritation occurs: Get medical advice / attention.
- P337+313 If eye irritation persists: Get medical advice / attention.
- P362 Take off contaminated clothing and wash before reuse.

[Storage]:

- P403+233 Store in a well ventilated place. Keep container tightly closed.
- P405 Store locked up.

[Disposal]:

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

2.3. Other hazards

This product contains no PBT/vPvB chemicals.

Section 3. Composition/information on ingredients
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3.2. Mixtures

If the product contains substances that present a hazard according to Regulation (EC) No. 1272/2008 [CLP/GHS] (as amended by (EU) 2015/830), they are listed below.

Ingredient/Chemical Designations	Weight %	EC No. 1272/2008 Classification*	Notes
Chitosan CAS Number: 0009012-76-4 EC No. Index No.:	50 - 75	Not Classified	[1]
Dextran, hydrogen sulfate, sodium salt CAS Number: 0009011-18-1 EC No. Index No.:	25 - 50	Skin Irrit. 2;H315 Eye Irrit. 2;H319 STOT SE 3;H335	[1]

[^]CLP 31 Reference EC No. 1272/2008 1.1.3.1. Notes relating to the identification, classification and labelling of substances (Table 3.1).

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

- [1] Substance with a health or environmental hazard.
- [2] Substance with a workplace exposure limit.
- [3] PBT-substance or vPvB-substance.

*The full texts of the phrases are shown in Section 16.

Section 4. First aid measures

4.1. Description of first aid measures

General	In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.
Inhalation	If dry powder component is inhaled, remove to fresh air. If breathing is difficult, administer oxygen. If not breathing, provide artificial respiration. Immediately seek medical attention.
Eye	Do not let the victim rub his/her eye(s). Hold eyes apart and flush eyes with water for at least 1-5 minutes. Seek medical attention immediately.
Skin	Do not let the victim rub his/her eye(s). Hold eyes apart and flush eyes with water for at least 15 minutes. Seek medical attention immediately.
Ingestion	Immediately contact a Poison Center or doctor/physician. If swallowed, induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person.

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

Overview	Eye Contact: Contact with eyes may cause irritation. Skin Contact: May cause irritation or rash. Inhalation: In its final form, inhalation is not a likely route of exposure, but health effects may be similar to those from ingestion. Ingestion: Accidental ingestion in an occupational scenario is not a likely route of exposure. However, in the event of ingestion, health effects are expected to include nausea and gastrointestinal disturbance. Treat symptomatically. See section 2 for further details.
Inhalation	May cause respiratory irritation.
Eye	Causes serious eye irritation.
Skin	Causes skin irritation.

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

Notes to physician Treat symptomatically.

Section 5. Fire-fighting measures

5.1. Extinguishing media

Product is non-flammable. However, use an appropriate media including water spray, dry powder, foam, or carbon dioxide for the surrounding fire.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: No hazardous decomposition data available.

Avoid breathing dust / fume / gas / mist / vapors / spray.

5.3. Advice for fire-fighters

As with all fires, wear positive pressure, self-contained breathing apparatus, (SCBA) with a full face piece and protective clothing. Persons without respiratory protection should leave area. Wear SCBA during clean-up immediately after fire. No smoking.

Wear personal protective equipment to prevent contact with skin and eyes.

Product is non-flammable, but when heated to decomposition it may emit acrid smoke and irritating fumes.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up

The following spill response instructions only apply to bulk quantities of the material. Report emergency situations immediately. Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel and to the environment. Personnel involved in the clean up of spills should wear the appropriate gloves and eye protection. Clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

6.4 Reference to other sections

See Section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment.

See Section 13 for additional waste treatment information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle containers carefully to prevent damage and spillage.

In a manufacturing setting or other situation where exposure to the substance may occur wear appropriate personal protective equipment. Use good personal hygiene - wash hands and exposed skin thoroughly with soap and water after handling. Remove any contaminated clothing and clean before reuse. Properly dispose of contaminated belts and shoes and other items that cannot be decontaminated.

Keep away from heat and flame.

See section 2 for further details. - [Prevention]:

7.2. Conditions for safe storage, including any incompatibilities

Incompatible materials: No data available.

When not in use, store in a cool, dry, well-ventilated area. Store dry blend at -20 C and hydration fluid at 4 C in closed containers that are labeled in accordance with OSHA's Hazard Communication Standard [29 CFR 1910.1200]. Keep this drug out of the reach of children.

See section 2 for further details. - [Storage]:

7.3. Specific end use(s)

No data available.

Section 8. Exposure controls and personal protection

8.1. Control parameters

Exposure

CAS No.	Ingredient	Source	Value
0009011-18-1	Dextran, hydrogen sulfate, sodium salt	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
0009012-76-4	Chitosan	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit

8.2. Exposure controls

Respiratory

If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

Eyes

Wear appropriate chemical safety goggles, safety glasses or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

Skin

Avoid unintended skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of a face shield, boots, or coveralls. A safety shower should be located in the work area. Wear PVC or rubber gloves to keep skin contact to a minimum. Refer to the manufacturer's recommendations regarding the suitability of any gloves used.

Engineering Controls

Under normal conditions normally required. However in a manufacturing environment, the use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate aerosols, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Other Work Practices

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details.

Section 9. Physical and chemical properties

Appearance	Clear liquid, white powder, hydrogel when combined.
Odor	Not Provided.
Odor threshold	Not determined
pH	Not Measured
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured
Flash Point	Not Measured
Evaporation rate (Ether = 1)	Not Measured
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not Measured Upper Explosive Limit: Not Measured
Vapor pressure (Pa)	Not Measured
Vapor Density	Not Measured
Specific Gravity	Not Measured
Solubility in Water	Not Measured
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not Measured
Decomposition temperature	Not Measured
Viscosity (cSt)	Not Measured

9.2. Other information

No other relevant information.

Section 10. Stability and reactivity

10.1. Reactivity

Hazardous Polymerization will not occur.

10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

No hazardous decomposition data available.

Section 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapour LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Dextran, hydrogen sulfate, sodium salt - (9011-18-1)	No data available	No data available	No data available	No data available	No data available
Chitosan - (9012-76-4)	No data available	No data available	No data available	No data available	No data available

Carcinogen Data

CAS No.	Ingredient	Source	Value
0009011-18-1	Dextran, hydrogen sulfate, sodium salt	OSHA	Regulated Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0009012-76-4	Chitosan	OSHA	Regulated Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	2	Causes skin irritation.
Serious eye damage/irritation	2A	Causes serious eye irritation.
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	3	May cause respiratory irritation.
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

Section 12. Ecological information

12.1. Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l	3hr IC50 Bacteria mg/l	Biodegradability %
Dextran, hydrogen sulfate, sodium salt - (9011-18-1)	Not Available	Not Available	Not Available	---	---
Chitosan - (9012-76-4)	Not Available	Not Available	Not Available	---	---

12.2. Persistence and degradability

There is no data available on the preparation itself.

12.3. Bioaccumulative potential

Not Measured

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects

No data available.

Section 13. Disposal considerations

13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

Section 14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Regulated	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air class: Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable
14.5. Environmental hazards			
IMDG	Marine Pollutant: No;		

14.6. Special precautions for user

Not Applicable

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not Applicable

Section 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU Legislation**

REGULATION (EU) 2015/830 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

National Legislation

None noted.

15.2. Chemical Safety Assessment

No Chemical Safety Assessment has been carried out.

Section 16. Other information**SDS Revision Date** 04/05/2019

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Bioactive Regenerative Therapeutics, Inc. (BRTI, 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, express or implied. The information contained herein is designated only as guidance for safe handling and storage of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment, should handle all chemicals. Bioactive Regenerative Therapeutics, Inc. shall not be held liable for any loss, injury or damage from contact with the product.

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