Device Safety Data Sheet – Liquid Reagents

1. Product and company identification

Product name: Sexual Health Device - liquid components	**Product numbers:** PS-001402, PS-000175
Company identification: Visby Medical, Inc. 3010 North 1st Street San Jose, CA 95134 Tel: +1-833-468-4729	**Emergency Contact:** CHEMTREC (24-hour availability): +1 (800) 424-9300 (USA and Canada; Toll-Free)
Relevant identified uses of the substance or mixture and uses advised against: Bulk formulated pharmaceutical product/mixture for use in diagnostic kit.	**Note:** This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product/mixture. The toxicological and ecological properties of this mixture and/or its ingredients have not been fully characterized. This SDS will be revisited as more data become available.

2. Hazards identification

Classification of the substance or mixture:	
Globally Harmonized System [GHS]:	Skin sensitizer - Category 1.
Other/Supplemental:	Mixture not yet fully tested
Label Elements	
GHS hazard pictogram:	
GHS signal word:	Warning
GHS hazard statements:	H317 - May cause allergic skin reaction.
GHS precautionary statements:	P261 - Avoid breathing vapor/mist/spray. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/eye protection/face protection. P302 + P352 - IF ON SKIN: Wash with plenty of soap and water. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Other hazards:	The potential health hazards associated with exposure/ handling of this mixture are unknown; no data specific for the mixture were identified. The following data describe the hazards of individual ingredients, where applicable. Product/mixture contains Proclin 300, which is an ingredient that contains a 3:1 mixture of 5-chloro-2-methyl-4-isothiazolin-3-one: 2-methyl-4-isothiazolin-3-one and which is reported to be a skin sensitizer at levels as low as 0.0015%. Product also contains Streptavidin-HRP conjugate, which contains the same 3:1 mixture of 5-chloro-2-methyl-4-isothiazolin-3-one: 2-methyl-4-isothiazolin-3-one at low levels of ≤15 ppm.
Note:	This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

3. Composition/Information On Ingredients

Hazardous Components:

Ingredient	CAS #	EINECS/ ELINCS#	Amount	GHS Classification
3:1 Mixture: 5-chloro-2-methyl-4-isothiazolin-3-one: 2-methyl-4-isothiazolin-3-one	55965-84-9	613-167-00-5	≤0.002%	ATO3: H301; ATD3: H311; ATI3: H331; SC1B: H314; SS1: H317; AA1: H400; CA1: H410

Note: The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 or full text of GHS classifications.

4. First Aid Measures

Immediate Medical Attention Needed:	Yes
Eye Contact:	In the event of a chemical exposure, immediately irrigate eyes with copious quantities of water for at least 15 minutes. Remove contact lenses as soon as practical. Do not delay irrigation while waiting for contact lens removal. If irritation occurs or persists, notify medical personnel and supervisor.
Skin Contact:	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation:	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Ingestion:	If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Protection of first aid responders:	See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed:	See Sections 2 and 11

Indication of immediate medical attention and special treatment needed, if necessary:	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.
5. Firefighting Measures	
Extinguishing media:	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture:	No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, magnesium-containing compounds, phosphorus-containing compounds, potassium- containing compounds, and chlorine-containing compounds.
Flammability/Explosivity:	No explosivity or flammability data identified. As product is primarily an aqueous solution, it is not expected to be flammable or explosive.
Advice for firefighters:	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.
6. Accidental Release Measures	
Personal precautions, protective equipment, and emergency procedures:	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
Environmental precautions:	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up:	DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent.
Reference to other sections:	See Sections 8 and 13 for more information.
7. Handling And Storage	
Precautions for safe handling:	Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin, and other mucous membranes. Wash thoroughly after handling. Avoid breathing vapor/mist/spray.
Conditions for safe storage including any incompatibilities:	Store according to product labeling. Keep away from in-compatible materials. Keep container/package tightly closed in a cool, well-ventilated place.
Specific end use(s):	No information identified.
8. Exposure Controls/Personal Protection	

Note:	Wash hands, face, and other potentially exposed areas immediately in the event of physical contact.
Control Parameters/Occupational Exposure Limit Values:	<table><tr><th>Compound</th><th>Issuer</th><th>Type</th><th>OEL</th></tr><tr><td>3:1 Mixture: 5-chloro-2methyl-4-isothiazolin3-one: 2-methyl-4-isothiazolin-3-one</td><td>--</td><td>--</td><td>--</td></tr></table>
Exposure/Engineering controls:	Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/ or enclosure at aerosol/mist-generating points. Use engineered local exhaust ventilation (LEV) and/ or enclosure for procedures where aerosolization may occur such as opened transfers, pumping, and spraying. Solutions can be handled outside a containment system or without LEV during procedures with no potential for aerosolization. All containers for solutions and slurries must be covered while being transferred.
Respiratory protection:	Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. At a minimum, a tight-fitting full-face respirator with HEPA filters is required when performing aerosol generating operations. A powered air-purifying respirator (PAPR) with HEPA filters and head cover is required for spill cleanup.
Hand protection:	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Skin protection:	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
Eye/face protection:	Wear safety glasses with side shields, chemical splash goggles, or full-face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Environmental Exposure Controls:	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
Other protective measures:	Wash hands in the event of contact with this product/ mixture, especially before eating, drinking, or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.
9. Physical And Chemical Properties	
Appearance:	Clear Liquid

Color:	Colorless
Odor:	No information identified.
Odor threshold:	No information identified.
pH:	8.4-8.8
Melting point/freezing point:	No information identified.
Initial boiling point and boiling range:	No information identified.
Flash point:	No information identified.
Evaporation rate:	No information identified.
Flammability (solid, gas):	Not applicable.
Upper/lower flammability or explosive limits:	Not applicable.
Vapor pressure:	No information identified.
Vapor density:	No information identified.
Relative density:	No information identified.
Water solubility:	Miscible in water.
Solvent solubility:	No information identified.
Partition coefficient (n-octanol/water):	No information identified.
Auto-ignition temperature:	No information identified.
Decomposition temperature:	No information identified.
Viscosity:	No information identified.
Explosive properties:	No information identified.
Oxidizing properties:	No information identified.
Molecular formula:	Not applicable (Mixture)
Molecular weight:	Not applicable (Mixture)
10. Stability And Reactivity	
Reactivity:	No information identified.

Chemical stability:	No information identified.
Possibility of hazardous reactions:	Not expected to occur.
Conditions to avoid:	No information identified.
Incompatible materials:	No information identified.
Hazardous decomposition products:	No information identified.

11. Toxicological Information

Route of entry:	May be absorbed by inhalation, skin contact, and ingestion.
Acute toxicity:	

Compound	Type	Route	Species	Dose
3:1 Mixture: 5-chloro-2-methyl-4-isothiazolin-3-one: 2-methyl-4isothiazolin-3one LD50	Oral	Rat	64 mg/ kg	
	LD_{50}	Dermal	Rat	>141 mg/kg
	LD_{50}	Dermal	Rabbit	87.12 mg/kg
	LD_{50}	Inhalation	Rat	0.171 mg/L/4h

Irritation/Corrosion:	Proclin 300 contains an ingredient which was corrosive to rabbit skin at ≥0.75%.
Sensitization:	Proclin 300 contains an ingredient which was positive for skin sensitization at concentrations >0.0015%.
STOT-single exposure:	No studies identified.
STOT-repeated exposure/Repeat-dose toxicity:	No studies identified.
Reproductive toxicity	No studies identified.
Developmental toxicity	No studies identified.
Genotoxicity	No studies identified.
Carcinogenicity	No studies identified. None of the components of the mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
Aspiration hazard	No data available.
Human health data	See “Section 2 - Other Hazards”
Additional information	The toxicological properties of this mixture have not been fully characterized.

12. Ecological Information

Toxicity:

Compound	Type	Species	Concentration
3:1 Mixture: 5-chloro2-methyl4-isothiazolin-3-one: 2-methyl-4isothiazolin3-one	EC_{50}/120h (5-chloro2-methyl-4isothiazolin3-one)	*Anabaena flos-aquae*	0.31 mg/L
	EC ($5-_{50}$chloro/72h - 2-methyl-4isothiazolin3-one)	*Pseudokirchneriella subcapitata (alga)*	0.11-0.16 mg/L
	EC_{50}/96h (5-chloro2-methyl-4isothiazolin3-one)	*Pseudokirchneriella subcapitata (alga)*	0.03-0.13 mg/L
	LC_{50}/96h (5-chloro2-methyl-4isothiazolin3-one)	*Oncorhynchus mykiss*	1.6 mg/L
	EC ($5-_{50}$chloro/48h - 2-methyl-4isothiazolin3-one)	*Daphnia magna*	4.71 mg/L

Persistence and Degradability:	No data available.
Bioaccumulative potential:	No data available.
Mobility in soil:	No data available.
Results of PBT and vPvB assessment:	No data available.
Other adverse effects:	No data available.
Note:	The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided.

13. Disposal Considerations

Waste treatment methods:	Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.
14. Transport Information	
Transport:	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number:	None assigned.
UN proper shipping name:	None assigned.
Transport hazard classes and packing group:	None assigned.
Environmental hazards:	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users:	Due to lack of data, avoid release to the environment.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:	Not applicable.
15. Regulatory Information	
Safety, health and environmental regulations/ legislation specific for the substance or mixture:	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
Chemical safety assessment:	Not conducted.
TSCA status:	Medical devices are exempt from TSCA.
SARA section 313:	Not listed.
California proposition 65:	Not listed.
Additional information:	No other information identified.
16. Other Information	

Full text of H phrases and GHS classifications:	ATO3 - Acute Toxicity (Oral) Category 3. H301 - Toxic if swallowed. ATD3 - Acute Toxicity (Dermal) Category 3. H311 - Toxic in contact with skin. ATI3 - Acute Toxicity (Inhalation) Category 3. H331 - Toxic if inhaled. SC1B Skin corrosion Category 1. H314 - Causes severe skin burns and eye damage. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction. AA1- Aquatic toxicity (acute) - Category 1. H400 - Very toxic to aquatic life. CA1 - Aquatic toxicity (chronic) - Category 1. H410 - Very toxic to aquatic life with long lasting effects.
Sources of data:	Information from published literature and internal company data.
Abbreviations:	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
Issue Date:	03 March 2023
Disclaimer:	The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical/ diagnostic product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

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