


## Media Safety Data Sheet

1. Product and company identification	
<b>Product name:</b> Visby Vaginal Specimen Collection Media	<b>Product numbers:</b> PS-300602
<b>Company identification:</b> Visby Medical, Inc. 3010 North 1st Street San Jose, CA 95134  Tel: +1-833-468-4729	<b>Emergency Contact:</b> CHEMTREC (24-hour availability): +1 (800) 424-9300 (USA and Canada; Toll-Free)
<b>Relevant identified uses of the substance or mixture and uses advised against:</b> Mixture for use as swab specimen collection or specimen dilution media; not intended for human consumption.	<b>Note:</b> This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product/mixture.
2. Hazards identification	
Classification of the substance or mixture:	
<b>Globally Harmonized System [GHS]:</b>	Skin sensitizer - Category 1
Label Elements	
<b>GHS hazard pictogram:</b>	
<b>GHS signal word:</b>	Warning
<b>GHS precautionary statements:</b>	P261 - Avoid breathing mist or vapor. 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. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.
<b>Other Hazards:</b>	No data were available for the mixture. Proclin 300 (3:1 mixture 5-chloro-2- methyl-4-isothiazolin-3-one: 2-methyl-4-isothiazolin-3-one) is reported to be a skin sensitizer at levels as low as 0.015%. The mixture contains small amounts of trizma hydrochloride, trizma base, and Tween 80, and may be an eye irritant.
<b>Note:</b>	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

<b>Description:</b>	Liquid Mixture								
<b>Hazardous Components:</b>	<p><u>3:1 Mixture: 5-chloro-2- methyl-4-isothiazolin-3-one; 2-methyl-4-isothiazolin-3-one</u></p> <table border="1"> <tr> <td>CAS#</td> <td>55965-84-9</td> </tr> <tr> <td>EINECS/ELINCS#</td> <td>613-167-00-5</td> </tr> <tr> <td>Amount</td> <td>0.03%</td> </tr> <tr> <td>GHS Classification</td> <td>ATO3: H301; ATD3: H311; ATI3: H331; SC1B: H314; SS1: H317; AA1: H400; CA1: H410</td> </tr> </table>	CAS#	55965-84-9	EINECS/ELINCS#	613-167-00-5	Amount	0.03%	GHS Classification	ATO3: H301; ATD3: H311; ATI3: H331; SC1B: H314; SS1: H317; AA1: H400; CA1: H410
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<b>Note:</b>	The substance listed above is considered dangerous/ hazardous. The primary ingredient is water (>97%). The remaining components are not hazardous and/or are present at amounts below reportable limits. See Section 16 for full text of GHS classifications.								

### 4. First-aid measures

<b>Immediate Medical Attention Needed</b>	Yes
<b>Eye contact:</b>	If easy to do, remove contact lenses, if worn. Immediately flush out eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Skin Contact:</b>	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Inhalation:</b>	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.
<b>Ingestion:</b>	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. If signs/ symptoms occur, get medical attention.
<b>Protection of first aid responders:</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed:</b>	See Sections 2 and 11.
<b>Indication of immediate medical attention and special treatment needed, if necessary:</b>	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

5. Fire-fighting measures	
<b>Suitable extinguishing media:</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
<b>Specific hazards arising from the substance or mixture:</b>	No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, and sulfur- and chlorine-containing compounds.
<b>Flammability/Explosivity:</b>	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.
<b>Advice for firefighters:</b>	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.
6. Accidental release measures	
<b>Personal precautions, protective equipment, and emergency procedures:</b>	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.
<b>Environmental precautions:</b>	Do not empty into drains. Avoid release to the environment.
<b>Methods and material for containment and cleaning up:</b>	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.
<b>Reference to other sections</b>	See Sections 8 and 13 for more information.
7. Handling & Storage	
<b>Precautions for safe handling:</b>	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 clothing. Wash thoroughly after handling. Avoid breathing vapor/mist/spray.
<b>Conditions for safe storage including any incompatibilities:</b>	Store in a tightly sealed container.
<b>Specific end use(s)</b>	No information identified.
8. Exposure controls/personal protection	
<b>Note:</b>	Wash hands, face, and other potentially exposed areas immediately in the event of physical contact.

<p><b>Control Parameters/ Occupational Exposure Limit Values:</b></p>	<table border="1"> <thead> <tr> <th data-bbox="673 199 966 279">Compound</th> <th data-bbox="966 199 1089 279">Issuer</th> <th data-bbox="1089 199 1208 279">Type</th> <th data-bbox="1208 199 1320 279">OEL</th> </tr> </thead> <tbody> <tr> <td data-bbox="673 279 966 426">3:1 Mixture: 5-chloro-2-methyl-4-isothiazolin-3-one: 2-methyl-4-isothiazolin-3-one</td> <td data-bbox="966 279 1089 426">--</td> <td data-bbox="1089 279 1208 426">--</td> <td data-bbox="1208 279 1320 426">--</td> </tr> </tbody> </table>	Compound	Issuer	Type	OEL	3:1 Mixture: 5-chloro-2-methyl-4-isothiazolin-3-one: 2-methyl-4-isothiazolin-3-one	--	--	--
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<p><b>Exposure/ Engineering controls:</b></p>	<p>Control exposures to below the OEL (for the active ingredient(s) if available). 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.</p>								
<p><b>Respiratory protection:</b></p>	<p>Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. 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.</p>								
<p><b>Hand protection:</b></p>	<p>Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered.</p>								
<p><b>Skin protection:</b></p>	<p>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.</p>								
<p><b>Eye/face protection:</b></p>	<p>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.</p>								
<p><b>Environmental exposure controls:</b></p>	<p>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.</p>								
<p><b>Other protective measures:</b></p>	<p>Wash hands in the event of contact with this substance, 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).</p>								
<p><b>9. Physical and chemical properties</b></p>									
<p><b>Appearance:</b></p>	<p>Clear Liquid</p>								
<p><b>Color</b></p>	<p>Colorless</p>								

<b>Odor:</b>	No information identified.
<b>Odor threshold:</b>	N/A
<b>pH</b>	8.4-8.8
<b>Melting point, freezing point:</b>	No information identified.
<b>Initial boiling point and boiling range:</b>	No information identified.
<b>Flash point:</b>	Not identified. As an aqueous solution, product/mixture is not likely to be flammable.
<b>Evaporation rate:</b>	No information identified.
<b>Flammability:</b>	N/A
<b>Upper/lower flammability or explosive limits:</b>	N/A
<b>Vapor pressure:</b>	No information identified.
<b>Vapor density:</b>	No information identified.
<b>Relative density:</b>	No information identified.
<b>Water solubility:</b>	Soluble in water.
<b>Solvent solubility:</b>	No information identified.
<b>Partition coefficient:</b>	No information identified.
<b>Auto-ignition temperature:</b>	No information identified.
<b>Decomposition temperature:</b>	No information identified.
<b>Viscosity:</b>	No information identified.
<b>Explosive properties:</b>	N/A
<b>Oxidizing properties:</b>	N/A
<b>Molecular formula:</b>	N/A (Mixture)
<b>Molecular weight:</b>	N/A (Mixture)
<b>10. Stability and reactivity</b>	
<b>Reactivity:</b>	No information identified.
<b>Chemical stability:</b>	Stable under normal handling and storage conditions.

<b>Possibility of hazardous reactions:</b>	Not expected to occur.
<b>Conditions to avoid:</b>	No information identified.
<b>Incompatible materials:</b>	No information identified.
<b>Hazardous decomposition products:</b>	No information identified.

## 11. Toxicology information

<b>Route of entry:</b>	May be absorbed by inhalation, skin contact and ingestion.																						
<b>Acute toxicity:</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Compound</th> <th style="width: 10%;">Type</th> <th style="width: 15%;">Route</th> <th style="width: 15%;">Species</th> <th style="width: 30%;">Dose</th> </tr> </thead> <tbody> <tr> <td rowspan="4">3:1 Mixture: 5-chloro-2-methyl-4-isothiazolin-3-one: 2-methyl-4-isothiazolin-3-one</td> <td>LD<sub>50</sub></td> <td>Oral</td> <td>Rat</td> <td>64 mg/kg</td> </tr> <tr> <td>LD<sub>50</sub></td> <td>Dermal</td> <td>Rat</td> <td>&gt;141 mg/kg</td> </tr> <tr> <td>LD<sub>50</sub></td> <td>Dermal</td> <td>Rabbit</td> <td>87.12 mg/kg</td> </tr> <tr> <td>LD<sub>50</sub></td> <td>Inhalation</td> <td>Rat</td> <td>0.171 mg/L/4h</td> </tr> </tbody> </table>	Compound	Type	Route	Species	Dose	3:1 Mixture: 5-chloro-2-methyl-4-isothiazolin-3-one: 2-methyl-4-isothiazolin-3-one	LD <sub>50</sub>	Oral	Rat	64 mg/kg	LD <sub>50</sub>	Dermal	Rat	>141 mg/kg	LD <sub>50</sub>	Dermal	Rabbit	87.12 mg/kg	LD <sub>50</sub>	Inhalation	Rat	0.171 mg/L/4h
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<b>Irritation/Corrosion:</b>	Proclin 300 was corrosive to rabbit skin at ≥0.75%.																						
<b>Sensitization:</b>	Proclin 300 was positive for skin sensitization at concentrations >0.0015%																						
<b>STOT- single exposure:</b>	No data on product information.																						
<b>STOT- repeated exposure/ Repeat dose toxicity:</b>	No data on product information.																						
<b>Reproductive toxicity:</b>	No data on product information.																						
<b>Developmental toxicity:</b>	No data on product information.																						
<b>Genotoxicity:</b>	No data on product information.																						
<b>Carcinogenicity:</b>	No data on product formulation. 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.																						
<b>Aspiration hazard:</b>	No data on product information.																						
<b>Human health data:</b>	See "Section 2- Other Hazards"																						

## 12. Ecological Information

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<p><b>Persistence and Degradability:</b></p>	<p>No data available.</p>																							
<p><b>Bioaccumulative potential:</b></p>	<p>No data available. Not expected to bioaccumulate.</p>																							
<p><b>Mobility in soil:</b></p>	<p>No data available.</p>																							
<p><b>Results of PBT and vPvB assessment:</b></p>	<p>Not performed.</p>																							
<p><b>Other adverse effects:</b></p>	<p>No data available.</p>																							
<p><b>Note:</b></p>	<p>The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided.</p>																							
<p><b>13. Disposal considerations</b></p>																								
<p><b>Waste treatment methods:</b></p>	<p>Used product should be disposed of according to local, state, and federal regulations. 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 onsite wastewater treatment facility.</p>																							
<p><b>14. Transport information</b></p>																								
<p><b>Transport:</b></p>	<p>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.</p>																							
<p><b>UN Number:</b></p>	<p>None assigned.</p>																							
<p><b>UN proper shipping name:</b></p>	<p>None assigned.</p>																							
<p><b>Transport hazard classes and packing group:</b></p>	<p>None assigned.</p>																							

<b>Environmental hazards:</b>	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
<b>Special precautions for users:</b>	Due to lack of data, avoid release to the environment.
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
<b>15. Regulatory information</b>	
<b>Safety, health and environmental regulations/ legislation specific for the substance or mixture</b>	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.
<b>Chemical safety assessment:</b>	Not conducted.
<b>TSCA status:</b>	Not listed.
<b>SARA Section 313:</b>	Not listed.
<b>California Proposition 65:</b>	Not listed.
<b>Additional information:</b>	No other information identified.
<b>16. Other information</b>	
<b>Full text of H phrases and GHS classifications</b>	H301 – Toxic if swallowed. H311 – Toxic in contact with skin. H314 – Causes severe skin burns and eye damage. H317 – May cause an allergic skin reaction. H331 – Toxic if inhaled. H400 – Very toxic to aquatic life. H410 – Very toxic to aquatic life with long lasting effects. ATO3 – Acute Toxicity (Oral) Category 3. ATD3 – Acute Toxicity (Dermal) Category 3. SC1 – Skin corrosion Category 1. SS1 – Skin sensitizer Category 1. AT13 Acute Toxicity (Inhalation) Category 3. AA1- Acute aquatic toxicity Category 1. CA1 – Chronic Aquatic Toxicity Category 1.
<b>Sources of data:</b>	Information from published literature and internal company data.



<p><b>Abbreviations:</b></p>	<p>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</p>
<p><b>Issue date:</b></p>	<p>03 March 2023</p>
<p><b>Disclaimer:</b></p>	<p>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 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.</p> <p>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.</p>



Visby Medical, Inc  
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