



# Corsano CardioWatch 287-2

## Safety Data Sheet



	Corsano CardioWatch 287-2 Safety Data Sheet	
	Corsano CardioWatch 287-2 SDS v1.0.docx	
	Author: P. Fraboulet	Date: 21-Feb-24


<b>1 Product and Company Identification</b>	
1.1 Product identifier	Corsano CardioWatch 287-2 Bracelet Basic UDI-DI: 8720256776CW287-1C8
1.2 Relevant identified uses	Continuous monitoring of physiological parameters Remote Patient monitoring
1.3 Details of the supplier	Corsano Health B.V. Wilhelmina van Pruisenweg 35 2595 AN The Hague, The Netherlands <a href="https://corsano.com/contact-us/">https://corsano.com/contact-us/</a>
<b>2 Hazards identification</b>	
2.1 Classification	May be harmful if swallowed May cause allergic skin reaction
<b>3 Composition/information on ingredients</b>	
3.1 Substances	ABS (Acrylonitrile Butadiene Styrene) Polymethyl methacrylate Stainless Steel 316L Contains rechargeable Lithium-Ion Polymer battery
<b>4 First aid measures</b>	
4.1 Description of first aid measures	<u>Skin contact:</u> In case of skin irritation, immediately stop wearing the device and consult a health practitioner. <u>Inhalation:</u> In case of gases evolving from melted resin, move subject to fresh air, Treat symptomatically. <u>Ingestion:</u> Do not induce vomiting. Get medical attention.
4.2 Most important symptoms and effects, both acute and delayed	Skin bruising, skin irritation
4.3 Indication of any immediate medical attention and special treatment needed	In case of skin irritation or damage, consult a health practitioner. In case of inhalation of fumes or vapors, in case of ingestion, get immediate medical attention.
5 Firefighting measures	Water. Foam. Dry chemical powder, Carbon Dioxide-based fire extinguishers.
<b>6 Accidental release measure</b>	

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6.1	Personal precautions, protective equipment and emergency procedures	For safe handling, inspect that the enclosure of the device is not damaged. If the enclosure is damaged and leaks or smokes are observed, wear protective equipment (gloves, glasses) and use ventilation.
6.2	Environmental precautions	Dispose the device at your local disposal service.
6.3	Methods and material for containment and cleaning up	Do not use the device if the enclosure is damaged. In case of battery leak, handle the device with gloves. Cover liquid spill with sand, earth or other non-combustible absorbent material. Pick up and transfer to properly labeled containers. Clean contaminated surface thoroughly.
<b>7 Handling and storage</b>		
7.1	Precautions for safe handling	Operational Temperature +10 to +40 °C Ambient Temperature when charging +10 to +35 °C Operational Humidity 20% to 80% In case of acid leak, dust or smoke, wear protection gloves, protection glasses.
7.2	Conditions for safe storage, including any incompatibilities	Transport and storage Temperature -20 to +60 °C Transport and storage Humidity 20% to 90%
7.3	Specific end use(s)	No specific end uses.
<b>8 Exposure controls/personal protection</b>		
8.1	Control parameters	No threshold limit value. Stop wearing the device in case of skin bruising or irritation. Contains Lithium-Ion Polymer battery.
8.2	Exposure controls	No control for exposure is needed under normal use conditions. In case of acid leak, dust or smoke, wear protection gloves, protection glasses and ventilation.
<b>9 Physical and chemical properties</b>		

9.1 Information on basic physical and chemical properties	The device enclosure is made of black ABS material, Plexiglas transparent optical lenses and stainless steel 316L skin electrodes.
9.2 Other information	Softening above 100 °C (Enclosure) Insoluble in water.
<b>10 Stability and reactivity</b>	
10.1 Flammability	Low flammability. Flash Point: 404 °C (Enclosure)
10.2 Reactivity	No reactivity with water.
10.3 Chemical stability	Stable and non-reactive in normal conditions of handling.
10.4 Possibility of hazardous reactions	None under normal condition. Thermal decomposition or combustion of the contained Lithium-Ion Polymer battery may produce: carbon oxides, metal oxides, hydrogen fluoride.
10.5 Conditions to avoid	High temperature, fire
10.6 Incompatible materials	Strong oxidizing agents, strong acids, base materials.
10.7 Hazardous decomposition products	CO, HCN, AN, SM and NO.
<b>11 Toxicological information</b>	

<p>11.1 Information on toxicological effects (Enclosure)</p>	<p><u>Irritation:</u>  Tetrabromobisphenol A:  Slightly irritant to eyes and skin  Acrylonitrile-butadiene-styrene:  fumes or vapors from decomposing resin might be irritant to eyes  Stainless steel 316L:  May cause allergic skin reaction</p> <p><u>Acute oral toxicity:</u>  Tetrabromobisphenol A:  Weak  Acrylonitrile-butadiene-styrene:  Not determined  Stainless steel 316L:  May be harmful if swallowed</p> <p><u>Mutagenicity:</u>  Tetrabromobisphenol A:  Not determined  Acrylonitrile-butadiene-styrene:  Not determined  Stainless steel 316L:  Not applicable</p>
<p>11.2 Biocompatibility according to ISO 10993-1 :2018</p>	<p>Non-cytotoxicity to L929 cells: 86.55%  Skin irritation: Negligible  Skin sensitization: None</p>
<p>12 Ecological information</p>	
<p>12.1 Toxicity</p>	<p>Internal materials may be toxic for aquatic life.</p>
<p>12.2 Persistence and degradability</p>	<p>No information available.</p>
<p>12.3 Bioaccumulative potential</p>	<p>No information available.</p>
<p>12.4 Mobility in soil</p>	<p>No information available.</p>
<p>12.5 Results of PBT and vPvB assessment</p>	<p>No information available.</p>
<p>12.6 Other adverse effects</p>	<p>No information available.</p>

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13 Disposal considerations	Dispose at your local disposal service or in properly labelled containers. Do not dispose in common waste.
13.1 Waste treatment methods	Electronic devices and Lithium-Ion polymer batteries.
14 Transport information	<p>UN 3481 Lithium-Ion batteries contained in equipment.</p> <p>Each device contains a Lithium-Ion Polymer battery, rated 140 mAh (510 mWh).</p> <p><u>Test Report UN 38.3</u> The Lithium-Ion Polymer battery is tested according to UNITED NATIONS "Recommendations on the TRANSPORT OF DANGEROUS GOODS Manual of Tests and Criteria" Seventh revised edition (ST/SG/AC.10/11/Rev.7) for Altitude Simulation, Thermal Test, Vibration, Shock, External Short-Circuit, Crush, Overcharge, Forced Discharge.</p>
15 Regulatory information	<p>DIRECTIVE (EU) 2017/2102 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).</p> <p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).</p> <p>Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators.</p>
16 Other information	
16.1 Date of issue	21-Feb-2024
16.2 Revision	Rev 1.0

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16.3 Disclaimer	<p>Corsano Health B.V., Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available</p>
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