Section 1: Identification of Company and Product

Company: Advanced Microdevices Pvt. Ltd.
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Product: Stericheck - Sterility Testing Devices

Catalog Numbers

- SXXV XXX XXX XXX XX (15 digit code starting with SXXV for PVDF Membrane)
- SXXC XXX XXX XXX XX (15 digit code starting with SXXC for Cellulose Ester Membrane)
- SXXN XXX XXX XXX XX (15 digit code starting with SXXN for Nylon-66 Membrane)

Trade Names/Synonyms:

Stericheck Closed Sterility Testing Devices
Stericheck Canisters
Stericheck Presterilized Closed Sterility Testing Device
Stericheck Presterilized Closed Sterility Testing Device with Membranes
Stericheck Presterilized Closed Sterility Testing Devices Type SVP1/SVP2/SVP3/ LVP/ PFS

Section 2: Composition, Information on Ingredients

Component:

- PVDF membrane/ Nylon-66 Membrane/ Cellulose Ester Membrane
- PTFE Membrane
- SAN Polymer
- PVC Polymer
- Stainless Steel
- Polypropylene Polymer
- Nylon Polymer
Section 3: Potential Hazard Identification

Colour:
1. SAN Polymer – Main Body: Colorless Transparent
   Base of Canister : Blue or Pink
   Vent of Canister : Blue or Pink
2. PVC – Transparent
3. Membrane – White
4. Stainless Steel Needle – Metallic
5. Polypropylene – Natural White
6. Nylon Polymer – Orange and Blue

Physical Form: Two canisters connected to stainless steel needle through double lumen PVC tube, packed in a presterilized blister pack.

Odour: Odorless

Major Health Hazards: Under normal operating temperature and pressure conditions, these devices do not present a health hazard. Caution need to be exercised while handling the stainless steel needles as they do pose an injection hazard.

Physical Hazards: Under normal operating temperature and pressure conditions, these devices do not present a physical hazard.

Potential Health Effects:
Inhalation
- Short term exposure: Non-volatile and so no inhalation hazard
- Long term exposure: no information is available

Eyes:
- Unlikely to cause any damage.

Skin contact:
- Short term exposure: No allergic reaction reported
- Long term exposure: no information is available

Ingestion:
- Unlikely to be ingested

Section 4: Fire and Explosion Hazard

Fire hazard: Minimal fire hazard.

Explosion hazard: The plastic components of these devices melt and/or decompose under fire conditions. Upon ignition, the plastic materials add to the intensity of the fire. These are likely to emit hazardous and toxic gases, vapors, fume and smoke particles.

Extinguishing media: Water and ABC chemical extinguishers

Large fires: Flood with water. Apply water from a protected location or from a safe distance.
Section 5: Occupational Release Measures

Spills and leaks: Being integral devices, they do not release materials to the environment when used within recommended operating temperature and pressure conditions.

Liquids being processed through these devices might be released to the surrounding upon failure of devices due to temperature and pressure condition outside of the recommended operating ranges. These releases should be dealt with according to the nature of the process liquids.

Section 6: Handling and Storage

Storage: Store in a cool dry location, away from heat radiators and organic solvents that may compromise the integrity of the housing.

Handle using good laboratory practices to preserve the sterility of the device.

Section 7: First Aid Measures

Inhalation: Stericheck devices do not present an inhalation hazard because of the non-volatile nature of the polymeric component materials.

Skin Contact: No allergic skin reaction from these devices has been reported. Puncture wounds and consequent injection of foreign substances are possible when handling the stainless steel needles.

Eye Contact: Owing to the size and solid nature of these devices they are not expected to present an eye injury hazard.

Ingestion: These devices do not present an ingestion hazard.

Section 8: Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Physical and Chemical Properties:</th>
<th>Components</th>
<th>Stericheck Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
<td></td>
</tr>
<tr>
<td>Colour</td>
<td>White/ Off White / Blue/ Pink</td>
<td></td>
</tr>
<tr>
<td>Physical form</td>
<td>Canister with Tubes and Needles</td>
<td></td>
</tr>
<tr>
<td>Odour</td>
<td>No sharp odour</td>
<td></td>
</tr>
<tr>
<td>Melting point</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Insoluble</td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Volatility</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>
Section 9: Stability and Reactivity

Chemical Stability: Stable at normal temperatures and pressure.

Conditions To Avoid: Temperature above 55°C and heat sources (dry and or direct heat), sparks and contact with incompatible materials to be avoided.

Hazardous Polymerisation: Hazardous polymerization will not occur.

Incompatible With: Strong oxidizing agents, organic solvents.

Hazardous Decomposition Products: The nature and concentration of various decomposition and combustion products that will result from heating of these polymers will vary depending upon variables such as temperature, oxygen and water vapor concentration, and the presence of other materials.

The possible products, include, but are not limited to those shown below:

<table>
<thead>
<tr>
<th>Polymer</th>
<th>Decomposition/ Combustion Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVDF, PTFE</td>
<td>Tetrafluoroethylene, fluorohydrocarbon fragments, carbon monoxide, carbon dioxide, hydrogen fluoride.</td>
</tr>
<tr>
<td>Cellulose Ester</td>
<td>Oxides of carbon and nitrogen</td>
</tr>
<tr>
<td>Nylon</td>
<td>Oxides of nitrogen</td>
</tr>
<tr>
<td>SAN</td>
<td>Hydrogen cyanide, nitrogen oxides, carbon monoxide, and carbon dioxide.</td>
</tr>
<tr>
<td>PVC</td>
<td>Phosgene, hydrogen chloride and oxides and other compounds of carbon and chlorine.</td>
</tr>
<tr>
<td>Polypropylene</td>
<td>Carbon monoxide and Carbon dioxide</td>
</tr>
</tbody>
</table>

Section 10: Toxicological Information

Carcinogenicity: None of components is known to be carcinogenic.

Chronic Effects: No adverse health effects are expected from prolonged or repeated exposure to this product.

Endocrine Disrupters: None of the components are suspected endocrine disrupters.

Toxicity Data: No toxicological data is available for this product as an entity.

Section 11: Ecological Information

Ecological Information: Owing to inert nature of the polymeric materials in these devices, it is expected that they will have very limited biodegradability in water or soils.

Section 12: Disposal Consideration

Disposal Consideration: When ready for disposal, this device should be considered according to local regulation.

It is recommended to separately collect the used device fractions. The liquid processed through these devices may leave residual materials, which are subject to hazardous waste regulations, and would, therefore, subject the used devices to local disposal regulation.
Section 13: Exposure Control/Personal Protection

**Exposure limits:** PTFE/PVDF/Cellulose Ester/Nylon membrane: No occupational exposure limits established. Other Parts: No occupational exposure limits established.

**Ventilation:** Based on available information, additional ventilation is not required. General ventilation is adequate. If the processing involves heat, additional ventilation is required. Ensure compliance with applicable exposure limits.

**Eye Protection:** Eye protection not required under normal conditions.

**Clothing:** Protective clothing is not required under normal conditions.

**Gloves:** Protective gloves are not required under normal conditions.

**Respirator:** No respirator is required under normal conditions of use.

Section 14: Transport Information

**Transport Information:** Owing to non-hazardous nature of these devices, the transport of these devices is not regulated. However, once used, these devices may contain residual materials that are regulated materials. The user should determine the applicability of current regulation prior to shipping used devices.

Section 15: Other Information

**DISCLAIMER**

The information contained herein is accurate to the best of the knowledge and experience of supplier. However, the supplier does not assume any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution.

Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.