

Material Safety Data Sheet

According to 91/155/EC

Reviewed on 3.23.2007

1 Identification of substance:

- **Trade name:** Determine HBsAg Test Card
- **Article number:** 7D25
- **Application of the substance / the preparation** For In Vitro Diagnostic Use
- **Supplier:**
Inverness Medical Japan co., Ltd
357 Matsuhidai, Matudo City, Chiba
270-2214
Japan
Tel: 81-47-311-5750
- **Informing department:** Quality & Regulatory Affairs

2 Composition/Data on components:

- **Chemical characterization; Mixture of chemical and/or biological substances for diagnostic use.**
- **Hazardous ingredients per OSHA Criteria:** None

3 Hazards identification

- **Routes of Exposure:** None anticipated, when used as directed
- **Classification system**
The classification was made according to OSHA 29 CFR 1910.1200 and 1910.1030 and applicable European Community Directives, and is expanded upon from company and/or literature data.
- **National Fire Protection Association (NFPA) ratings (scale 0-4)**
Health =0
Fire = 0
Reactivity=0
- **Hazard Overview**
- **Health: Minimal risk if used as directed**
- **Fire: Noncombustible**
- **Reactivity; Minimal Risk**
- **Special Hazards; None**
- **Carcinogenicity information**
- **OSHA (Occupational Safety and Health Administration)**
None of the ingredients is listed.
- **NTP (National Toxicology Program)**
None of the ingredients is listed
- **IARC (International Agency for Research on Cancer)**
None of the ingredients listed

4 First aid measures

- **After inhalation ;** Remove from source of exposure.
- **After skin contact:** Wash effected area with soap and water.
- **After eye contact:** Flush with copious amounts of water.
- **After swallowing:** Seek immediate medical advice.

5 Fire fighting measures

- **Suitable extinguishing agents:**
Dry Chemical, CO2, water spray or regular form. Fight larger fires with water spray, fog or regular form.
- **Protective equipment:** No special measures required.

6 Accidental release measures:

- **Safe work practices:** No special work practices required.
- **Measures for environmental protection:** No special measures required.
- **Measures for cleaning/collecting:** Collect mechanically.
- **Additional information:** No dangerous substances are released.

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7 Handling and storage

- **Information for safe handling:** Practice general safety precautions.
- **Information about protection against explosions and fires:** No special measures required.
- **Requirements to be met by storerooms and containers:**
Refer to the package insert or product label for additional information on storage conditions.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Protect from heat and direct sunlight.

8 Exposure controls and personal protection

- **Components with Occupational Exposure Limits:**
25322-68-3 Polyethylene glycol (0.10%)
ACGIH TLV (average molecular weight 200-600)
57-50-1-sucrose, pure (0.10%)
ACGIH TLV 10 mg/m³;A4
NOISH REL 10mg/m³*, 5mg/m³**
*total dust **respirable fraction
OSHA PEL 15 mg/m³* mg/m³, 4mg/m³** ppm
*total dust **respirable fraction
- **General protective and hygienic measures:**
The usual precautionary measures should be adhered to general rules for handling chemicals.
- **Breathing equipment:**
Not necessary, if room is well-ventilated.
Take precautions, if chemical concentrations exceed the exposure limits (if any) listed above.
- **Protection of hands:**
The gloves serve to protect the user against splashes. For safety reasons they should be changed immediately after wetting.
Since the product is in fact a preparation out of several substances, no specific information can be given on the permeation breakthrough time. The choice of suitable gloves depends not only on the material, but also on other quality features and must, therefore, be checked with the respective manufacturer. As far as we know, disposable gloves, among other things out of nitriles, are suitable. Nevertheless, this recommendation is not intended to replace a suitability test, which is essential and must be carried out under the respective conditions of use.
- **Eye protection:** Wear safety glasses or other protective eyewear.
- **Body protection:** Wear laboratory coat or appropriate protective clothing when working with material.

9 Physical and chemical properties

• General Information

Form:	Solid
Colour:	White
Odour:	Characteristic

• Change in condition

Melting point/Melting range:	Not determined
Boiling point/Boiling range:	Not determined
• Flash point:	Not applicable
• Self-inflammability:	Product is not selfigniting.
• Danger of explosion:	Product is not explosive.
• Density	Not determined
• Solubility in / Miscibility with	
Water:	Unsoluble

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Dangerous reactions** No dangerous reactions known.
- **Dangerous products of decomposition:** No dangerous decomposition products known.

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11 Toxicological information

- **LD/LC50 values that are relevant for classification:** No data available for this product.
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritant effect.
- **Sensitization:** No sensitizing effect known.
- **Target organs /systems;** Unknown:

12 Ecological information:

- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

13 Disposal considerations

- **General notes:**
In general laboratory waste is under the special supervision of the authorities. Refer to applicable local regulations.
- **Recommendation:** Non contaminated packagings can be used for recycling.

14 Transport information

• Road: DOT Class:	-
• Remarks:	not restricted
- Sea: IMDG Class	-
• Marine pollutant:	No
- Remarks;	not restricted
• Air ICAO/IATA Class:	-
• Remarks:	not restricted

15 Regulatory information

- **Designation according to EC guidelines:**
Observe the normal safety regulations when handling chemicals.
The product is not subject to identification regulations under EC Directives.

16 Other information:

- **These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.**
- **Contact supplier:**
Quality & Regulatory Affairs:
Inverness Medical Japan Co., Ltd
Tel.: +81-47-311-5750