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Material Safety Data Sheet

1. PRODUCT & COMPANY IDENTIFICATION

Product Name: SmarHBV

Description: *In vitro* Diagnostic Reagent

Code Numbers: XSQHBV-100N-032 (71001264)

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| <p>MANUFACTURER</p> <p>Cepheid AB</p> <p>P.O.Box 20045, SE-161 02 Bromma, Sweden</p> <p>Visiting address: Bällstavägen 34-36, Bromma-Sthlm, Sweden</p> <p>Phone: +46-8-555 20 400</p> | <p>EMERGENCY PHONE</p> <p>Phone 1: 112 Phone 2: Dial local emergency number!</p> |
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2. COMPOSITION / INFORMATION ON INGREDIENTS

This Material Safety Data Sheet covers the SmarHBV kit. This product consists of two sub-kits; SmarHBV Detection Kit and SmarHBV Control Kit. The Detection Kit contains two solutions and the Control Kit contains four solutions.

SUB kit: SmarHBV Detection kit

Sub-kit code/Article nr: 710001262

Component 1: SmarHBV Mastermix; Code: 71001275

| <u>Chemical Name</u> | <u>Wt.%</u> | <u>CAS#</u> | <u>Classification</u> |
|----------------------|---------------|-------------|------------------------------------------------------------|
| Uracil-deglycosylase | 1 % ≤ C < 5 % | N/A | This biological constituent is known to be non-infectious. |
| Taq DNA polymerase | 1 % ≤ C < 5 % | N/A | This biological constituent is known to be non-infectious. |
| Potassium chloride | 1 % ≤ C < 5 % | 7447-40-7 | This constituent is not classified as dangerous according |

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| | | | to EC Directive 1999/45/EC (preparations). |
| Water and other constituents. Each of the other constituents are present in less than 1% concentration or less than 0,1% for potential carcinogens, reproductive toxins, respiratory tract sensitizers and mutagens. | Balance | N/A | None of the other constituents in this mixture contribute significantly to the hazards associated with this component. All hazard information pertinent to this product has been provided in this MSDS per the requirements and in compliance with EC Directive 91/155/EEC and EC Directive 1999/45/EC (preparations). |

Component 2: SmartRgt Mg 18X; Code: 71001278

| <u>Chemical Name</u> | <u>Wt. %</u> | <u>CAS#</u> | <u>Classification</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| D-(+)- Trehalose dehydrate | 41,6% | 6138-23-4 | This constituent is not classified as dangerous according to EC Directive 1999/45/EC (preparations). |
| Tween-20 | 1,6% | 9005-64-5 | This constituent is not classified as dangerous according to EC Directive 1999/45/EC (preparations). |
| Water and other constituents. Each of the other constituents are present in less than 1% concentration or less than 0,1% for potential carcinogens, reproductive toxins, respiratory tract | < 1% | N/A | None of the other constituents in this mixture contribute significantly to the hazards associated with this component. All hazard information pertinent to this product has been provided in this MSDS, per the |

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| sensitizers and mutagens. | | | requirements and in compliance with EC Directive 91/155/EEC and EC Directive 1999/45/EC (preparations). |
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Sub-kit: SmartHBV Control kit

Sub-kit code/Article nr: 710011263

Component 3: SmartRgt DNA NTC; Code: 71001211

| <u>Chemical Name</u> | <u>Wt. %</u> | <u>CAS#</u> | <u>Classification</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Water and other constituents. Each of the other constituents are present in less than 1% concentration or less than 0,1% for potential carcinogens, reproductive toxins, respiratory tract sensitizers and mutagens. | Balance | N/A | None of the other constituents in this mixture contribute significantly to the hazards associated with this component. All hazard information pertinent to this pro-duct has been provided in this MSDS, per the requirements and in compliance with EC Directive 91/155/EEC and EC Directive 1999/45/EC (preparations). |

Component 4: SmartHBV Low; Code: 71001265

| <u>Chemical Name</u> | <u>Wt. %</u> | <u>CAS#</u> | <u>Classification</u> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Water and other constituents. Each of the other constituents are present in less than 1% concentration or less than 0,1% for potential carcinogens, reproductive toxins, respiratory tract | Balance | N/A | None of the other constituents in this mixture contribute significantly to the hazards associated with this component. All hazard information pertinent to this pro-duct has been provided in this MSDS, per the |

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| sensitizers and mutagens. | | | requirements and in compliance with EC Directive 91/155/EEC and EC Directive 1999/45/EC (preparations). |
|---------------------------|--|--|---------------------------------------------------------------------------------------------------------|

Component 5: SmartHBV High; Code: 71001261

| <u>Chemical Name</u> | <u>Wt. %</u> | <u>CAS#</u> | <u>Classification</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Water and other constituents. Each of the other constituents are present in less than 1% concentration or less than 0,1% for potential carcinogens, reproductive toxins, respiratory tract sensitizers and mutagens. | Balance | N/A | None of the other constituents in this mixture contribute significantly to the hazards associated with this component. All hazard information pertinent to this pro-duct has been provided in this MSDS, per the requirements and in compliance with EC Directive 91/155/EEC and EC Directive 1999/45/EC (preparations). |

Component 6: SmartRgt DNA IC-C; Code: 71001210

| <u>Chemical Name</u> | <u>Wt. %</u> | <u>CAS#</u> | <u>Classification</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Water and other constituents. Each of the other constituents are present in less than 1% concentration or less than 0,1% for potential carcinogens, reproductive toxins, respiratory tract sensitizers and mutagens. | Balance | N/A | None of the other constituents in this mixture contribute significantly to the hazards associated with this component. All hazard information pertinent to this pro-duct has been provided in this MSDS, per the requirements and in compliance with EC Directive |

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| | | | 91/155/EEC and EC Directive 1999/45/EC (preparations). |
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3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

PHYSICAL APPEARANCE:

All components are colourless and odourless liquids.

POTENTIAL HEALTH EFFECTS

All components are considered to be non hazardous products as specified in EC Directive 1999/45/EC (preparations)

COMMENTS ON HEALTH

All work should apply to Good Laboratory Practice (GLP) and as such any potential risks involved in using the kit are at a minimum.

4. FIRST AID MEASURES

EYES: Rinse out with plenty of water with the eye-lid open. Call ophthalmologist if needed.

SKIN: Wash off with plenty of water. Remove contaminated clothing.

INGESTION: Make victim drink plenty of water. Call in physician or consult with doctor if feeling unwell.

INHALATION: Fresh air

5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

CO₂, powder, foam, (water)

FIRE FIGHTING PROCEDURES

Due to the relatively small amounts of the preparations present, fire fighting is primarily to be focused and adapted towards materials stored in close proximity.

SPECIAL RISKS

Possible development of hazardous gases and vapours in the event of fire. Possible formation of explosive mixtures with air. The following gases and vapours may form in small amounts in the event of fire: HCN, nitrous gases.

SPECIAL PROTECTIVE EQUIPMENT

Do not stay in dangerous zone without suitable chemical protection clothing and self-contained breathing apparatus.

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6. ACCIDENTAL RELEASE MEASURES

GENERAL PROCEDURES

Do not inhale gases/vapours and aerosols. Avoid contact with substances. Ensure supply of fresh air in enclosed rooms.

ENVIRONMENTAL-PROTECTION MEASURES

Do not allow to enter sewerage system. All solutions **except** Components 1 contains maximum 0,09% Sodium azide which may react with copper, lead and heavy metals to form highly explosive metal azides. In case of spills in sewerage, flush with large volumes of water to prevent azide build-ups.

PROCEDURES FOR CLEANING / ABSORPTION

Take up with liquid-absorbent material (e.g. Chemisorb®). Forward for disposal. Clean up affected area.

7. HANDLING AND STORAGE

HANDLING

Always apply Good Laboratory Practice (GLP).

STORAGE

Store all components in box, dry below 8°C. Component 1 **must** be stored below -20°C . Accessible for authorized personnel only.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

PERSONAL PROTECTION

Due to the nature of the components in the assembled kit and its intended use we recommend wearing protective lab-coats and disposable laboratory gloves, with frequent changes, at all times.

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

EYES: Not required for most components.

RESPIRATORY: Not required unless aerosols and/or vapours are generated.

SKIN: Required

In full contact:

Glove material: Nitrile rubber Layer thickness: 0.11 mm Breakthrough time: >480 min

In splash contact:

Glove material: Nitrile rubber Layer thickness: 0.11 mm Breakthrough time: >480 min

The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC and the resultant standard EN374, for example Best® NitriSolve® 727 series (full and splash contact), Best® N-DEX Plus® 8005 (full and splash contact). The

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breakthrough times stated above were determined by Best in laboratory tests acc. to EN374 with samples of the recommended glove types.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE & APPEARANCE:

FORM: All components are liquids. All other components are clear and colourless.

ODOUR: All components are virtually odourless.

pH: For all other components pH is between 6 to 8 or not available.

SOLUBILITY: Soluble (in water) Soluble (in ethanol)

SPECIFIC GRAVITY: Not available

VISCOSITY: Not available

10. STABILITY AND REACTIVITY

CONDITIONS TO BE AVOIDED:

Strong heating

SUBSTANCES TO BE AVOIDED:

All Components **except** 1 contains maximum 0,09% Sodium azide which may react with copper, lead, heavy metals and metallic salts to form highly explosive metal azides.

Sodium azide may react with the following substances bromine, sulphuric acid, dimethyl sulphate/acid, dichloromethane and carbon disulfide and toxic fumes or gases.

HAZARDOUS DECOMPOSITION PRODUCTS:

In the event of fire: See chapter 5.

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY Quantitative data on the toxicity of this product are not available.

FURTHER TOXICOLOGICAL INFORMATION : Property that must be anticipated on the basis from the components of the preparation: After skin contact: Irritations. Danger of skin absorption. After eye contact: Irritations. Risk of damage to eyes. After swallowing: Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

FURTHER DATA: The product should be handled with the care usual when dealing with chemicals. As most components contain sodium azide, a substance suspected to be hazardous although not fully investigated, further hazardous properties cannot be excluded.

12. ECOLOGICAL INFORMATION

ECOTOXIC EFFECTS:

Quantitative data on the ecological effect of this product are not available.

BIOLOGICAL EFFECTS:

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Toxic for aquatic organisms. May cause long-term adverse effects in the aquatic environment.

FURTHER ECOLOGIC DATA:

Harmful effects to aquatic organisms. Harmful effects due to pH shift. Herbicidal effects when accumulated.

No ecological problems are to be expected when the product is handled with due care and attention.

Do not allow to enter waters, waste water or soil!

13. DISPOSAL CONSIDERATIONS

PRODUCT DISPOSAL: Chemicals must be disposed of in compliance with the respective national regulations. *PACKAGING:* All packaging must be disposed of in compliance with country-specific regulations or must be passed to packaging return system.

14. TRANSPORT INFORMATION

Not subject to transport regulations.

15. REGULATORY INFORMATION

LABELLING ACCORDING TO EC DIRECTIVES:

Symbol: R-phrases: S-phrases: For classification of individual components, see chapter 2.

16. OTHER INFORMATION

REGIONAL REPRESENTATION: Cepheid AB, P.O.Box 20045, SE-161 02 Bromma, Sweden, Tel: +46-8-555 20 400 Fax: +46-8-555 20 499, e-mail: info@cepheid.se

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.