

## Safety data sheet according to 1907/2006/EC, Article 31

Date Prepared: 20.03.2014

Revision: 14.03.2014

### 1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** BD ProbeTec Qx Collection Kit for Endocervical and Lesion Specimens
- **Article number:** 441357
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Sector of Use**
  - SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites
  - SU22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
  - SU20 Health services
  - SU24 Scientific research and development
- **Application of the substance / the mixture**
  - In-vitro Diagnostics
  - Preparation
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
  - BD Diagnostic Systems Europe
  - Regulatory Compliance Department
  - Becton Dickinson France
  - 11, rue Aristide Bergès
  - 38800 Le Pont de Claix
  - France
  - Telephone: 33 (0) 476 68 36 36
  - Email: [msds\\_europe@bd.com](mailto:msds_europe@bd.com)
- **Further information obtainable from:** Technical Service Representative
- **Emergency telephone number:** Tel: 33 (0) 476 68 36 36

### 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**

GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

- 
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**

Xn; Harmful

R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.

- **Information concerning particular hazards for human and environment:**
  - The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
  - The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

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· **Label elements**

· **Labelling according to EU guidelines:**

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials

· **Code letter and hazard designation of product:**

Xn Harmful

· **Hazard-determining components of labelling:**

potassium hydroxide  
dimethyl sulfoxide

· **Risk phrases:**

20/21/22 Harmful by inhalation, in contact with skin and if swallowed.

· **Safety phrases:**

- 23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).  
25 Avoid contact with eyes.  
26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
28 After contact with skin, wash immediately with plenty of water.  
36/37 Wear suitable protective clothing and gloves.  
60 This material and its container must be disposed of as hazardous waste.

· **Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.  
· **vPvB:** Not applicable.

### 3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture consisting of the following components.

· **Dangerous components:**

CAS: 67-68-5 EINECS: 200-664-3	dimethyl sulfoxide Xn R22; Xi R36/37/38 Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	12,0%
CAS: 56-81-5 EINECS: 200-289-5	glycerol Xi R36/38 Skin Irrit. 2, H315; Eye Irrit. 2, H319	10,82%
CAS: 1310-58-3 EINECS: 215-181-3	potassium hydroxide C R35; Xn R22 Skin Corr. 1A, H314; Acute Tox. 4, H302	1,65%

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· **Additional information** For the wording of the listed risk phrases refer to section 15.

### 4 First aid measures

· **Description of first aid measures**· **General information**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **After inhalation**

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

In case of unconsciousness place patient in side position for transportation.

· **After skin contact** Immediately wash with water and soap and rinse thoroughly.· **After eye contact**

Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing** If symptoms persist consult doctor.· **Information for doctor**· **Most important symptoms and effects, both acute and delayed**

No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

### 5 Firefighting measures

· **Extinguishing media**· **Suitable extinguishing agents**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **Special hazards arising from the substance or mixture**

No further relevant information available.

· **Advice for firefighters**· **Protective equipment:** No special measures required.

### 6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.· **Environmental precautions:** Wipe up with damp sponge or mop.· **Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· **Reference to other sections**

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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### 7 Handling and storage

- **Handling**
- **Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** 2 - 33C
- **Information about storage in one common storage facility:**  
Store away from oxidizing agents.
- **Further information about storage conditions:**  
Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Respiratory protection:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Protective gloves.

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**· Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

**· Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

**· Eye protection:** Safety glasses**· Body protection:** Protective work clothing.

### 9 Physical and chemical properties

**· Information on basic physical and chemical properties****· General Information****· Appearance:**

<b>Form:</b>	Liquid
<b>Colour:</b>	Clear
<b>Odour:</b>	Characteristic

**· pH-value:** 11,5 +/- 0,25**· Change in condition****Melting point/Melting range:** Not determined**Boiling point/Boiling range:** Not determined**· Flash point:** Not applicable**· Self-igniting:** Product is not selfigniting.**· Danger of explosion:** Product does not present an explosion hazard.**· Density:** Not determined**· Solubility in / Miscibility with****Water:** Soluble**· Other information** No further relevant information available.

### 10 Stability and reactivity

**· Reactivity****· Chemical stability****· Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

**· Possibility of hazardous reactions** No dangerous reactions known**· Conditions to avoid** No further relevant information available.**· Incompatible materials:** No further relevant information available.

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- **Hazardous decomposition products:**  
Sulphur oxides (SO<sub>x</sub>)  
Carbon monoxide (CO) and carbon dioxide (CO<sub>2</sub>)

**11 Toxicological information**

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values relevant for classification:**

**67-68-5 dimethyl sulfoxide**

Oral LD50 14500 mg/kg (rat)

**1310-58-3 potassium hydroxide**

Oral LD50 273 mg/kg (mou)

365 mg/kg (rat)

- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.  
Harmful

**12 Ecological information**

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Other information:**  
The ecological effects have not been thoroughly investigated, but currently none have been identified.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Must be specially treated adhering to official regulations.  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>UN proper shipping name</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  | Void            |
| · <b>Transport hazard class(es)</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  |                 |
| · <b>Class</b>   | Void            |
| · <b>Packing group</b>   |                 |
| · <b>ADR, IMDG, IATA</b>   | Void            |
| · <b>Environmental hazards:</b>  |                 |
| · <b>Marine pollutant:</b>   | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | -               |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Labelling according to EU guidelines:**  
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials

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**· Code letter and hazard designation of product:***Xn Harmful***· Hazard-determining components of labeling:***potassium hydroxide**dimethyl sulfoxide***· Risk phrases:***20/21/22 Harmful by inhalation, in contact with skin and if swallowed.***· Safety phrases:***23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).**25 Avoid contact with eyes.**26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.**28 After contact with skin, wash immediately with plenty of water.**36/37 Wear suitable protective clothing and gloves.**60 This material and its container must be disposed of as hazardous waste.***· National regulations****· Technical instructions (air):**

<b>Class</b>	<b>Share in %</b>
Water	74,2
NK	22,8

**· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.****16 Other information****Disclaimer:**

*To the best of our knowledge, the information contained herein is accurate. However, neither BD or any of its subsidiaries assumes any liabilities 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 described herein, we cannot guarantee that these are the only hazards that exist.*

**· Relevant phrases***H302 Harmful if swallowed.**H314 Causes severe skin burns and eye damage.**H315 Causes skin irritation.**H319 Causes serious eye irritation.**H335 May cause respiratory irritation.**R22 Harmful if swallowed.*

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R35 Causes severe burns.

R36/37/38 Irritating to eyes, respiratory system and skin.

R36/38 Irritating to eyes and skin.

· **Department issuing MSDS:**

Environmental, Health & Safety

Created by Michael J. Spinazzola

· **Contact:** Technical Service Representative

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Acute Tox. 4: Acute toxicity, Hazard Category 4

Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

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