

# Safety Data Sheet

acc. to OSHA HCS


Printing date 12/01/2015

Reviewed on 12/01/2015

## 1 Identification

- **Product identifier**
- **Trade name:** EQAS® Therapeutic Drug Monitoring Program
- **Catalog or product number:** BC10
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Sector of Use** SU20 Health services
- **Application of the substance / the mixture** In-vitro laboratory reagent or component
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Bio-Rad Laboratories, Diagnostic Group  
9500 Jeronimo Road  
Irvine, California 92618-2017 1(949) 598-1200
- **Information department:** Technical services, customer support
- **Emergency telephone number:**  
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

## 2 Hazard(s) identification

- **Classification of the substance or mixture**  
Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2A H319 Causes serious eye irritation.
  - **Label elements**
  - **GHS label elements** The product is classified and labeled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms**
- 

GHS07
- **Signal word** Warning
  - **Hazard statements**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.
  - **Precautionary statements**  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P363 Wash contaminated clothing before reuse.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P337+P313 If eye irritation persists: Get medical advice/attention.  
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
  - **Emergency overview:**
  - **Routes of exposure:**  
Ingestion  
Inhalation  
Skin

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- **Classification system**
- **NFPA ratings (scale 0-4)**  
Health = 1  
Fire = 0  
Reactivity = 0
- **Special Hazards** Contains human sourced and/or potentially infectious components.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**3 Composition/information on ingredients**

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**

EINECS: 268-338-3	Human Source Material		50-100%
CAS: 7647-14-5 EINECS: 231-598-3	sodium chloride	Skin Irrit. 2, H315; Eye Irrit. 2A, H319	5-10%
	Proprietary Reagent KT	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335	5-10%

- **Additional information**  
Contains human sourced and/or potentially infectious components.  
Contains added constituents of animal origin.

**4 First-aid measures**

- **Description of first aid measures**
- **General information** No special measures required.
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **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** Rinse mouth with water. Seek medical attention and appropriate follow-up.
- **Information for doctor**
- **Most important symptoms and effects, both acute and delayed**  
Eye irritation  
Skin irritation
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

**5 Fire-fighting measures**

- **Extinguishing media**
- **Suitable extinguishing agents**  
CO2, extinguishing 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.

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

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
- **Environmental precautions:**  
Do not allow to enter sewers/ surface or ground water.  
Keep contaminated washing water and dispose of appropriately.
- **Methods and material for containment and cleaning up:**  
Absorb liquid components with liquid-binding material.  
Pick up mechanically.  
Clean the affected area carefully; suitable cleaners are:  
Disinfectant
- **Reference to other sections** See Section 13 for disposal information.

### 7 Handling and storage

- **Handling**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** According to product specification
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Refer to package insert for additional information regarding storage conditions.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components 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 that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**  
The usual precautionary measures for handling chemicals should be followed.  
Follow the usual biosafety practices for handling potentially infectious materials.
- **Breathing equipment:** Not required.
- **Protection of hands:** 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.

Synthetic gloves

· **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>	Solid
<b>Color:</b>	Yellowish
<b>Odor:</b>	Light

· **pH-value at 20 °C:** 7.30-7.90

· **Change in condition**

**Melting point/Melting range:** undetermined  
**Boiling point/Boiling range:** undetermined

· **Flash point:** Not applicable

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Density:** Not determined

· **Solubility in / Miscibility with Water:**

Soluble

· **Solvent content:**

**Organic solvents:** 0.0 %

**Solids content:** 100.0 %

· **Other information** No further relevant information available.

**10 Stability and reactivity**

· **Reactivity** No further relevant information available.

· **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:** No dangerous decomposition products known

**11 Toxicological information**

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritant effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
- **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

103-90-2	paracetamol	3
50-06-6	phenobarbital	2B
58-55-9	theophylline	3
58-08-2	caffeine	3
59-05-2	methotrexate	3

· **NTP (National Toxicology Program)**

630-93-3	Phenytoin Sodium	R
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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

**12 Ecological information**

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

**13 Disposal considerations**

- **Waste treatment methods**
- **Recommendation** Dispose of waste in accordance to applicable national, regional, or local regulations.

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- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

**14 Transport information**

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

**15 Regulatory information**

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA (Superfund Amendments and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

20830-75-5 | digoxin

· **Section 313 (40CFR372.65):**

554-13-2 | lithium carbonate

· **TSCA (Toxic Substances Control Act):**

7647-14-5 | sodium chloride

69-72-7 | Salicylic acid

Proprietary Reagent BS 9

103-90-2 | paracetamol

554-13-2 | lithium carbonate

630-93-3 | Phenytoin Sodium

58-55-9 | theophylline

58-08-2 | caffeine

59-05-2 | methotrexate

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20830-75-5	digoxin
549-18-8	amitriptyline hydrochloride

· **California Proposition 65:**

· **Chemicals known to cause cancer:**

50-06-6	phenobarbital
630-93-3	Phenytoin Sodium

· **Developmental Toxicity**

554-13-2	lithium carbonate
298-46-4	Carbamazepin
1405-41-0	Gentamicin Sulfate
32986-56-4	tobramycin
59-05-2	methotrexate

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **MAK (German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **National regulations**

· **Technical instructions (air):**

Class	Share in %
I	0.1-1.0

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**16 Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environmental Health and Safety.

· **Contact:**

Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000

· **Date of preparation / last revision** 12/01/2015 / -

· **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

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DOT: US Department of Transportation  
IATA: International Air Transport Association  
ACGIH: American Conference of Governmental Industrial Hygienists  
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)  
NFPA: National Fire Protection Association (USA)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2  
Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A  
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

**\* Data compared to the previous version altered.**

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