

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

Printing date 27.10.2020

Version number 1

Revision: 20.04.2020

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name: R5 - Positive Control (1 mL)****Article number: 7270E****1.2 Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

**Application of the substance / the mixture** In vitro diagnostic medical device or component.**1.3 Details of the supplier of the safety data sheet****Manufacturer/Supplier:**Bio-Rad  
3, Boulevard Raymond Poincaré  
F-92430 Marnes-la-Coquette  
Tel.: +33 (0)1 47 95 60 00  
Fax: +33 (0)1 47 41 91 33  
e-mail: fds-msds.fr@bio-rad.com**Further information obtainable from:** Customer Support.**1.4 Emergency telephone number:** See item 16**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

GHS07

Skin Sens. 1      H317 May cause an allergic skin reaction.

Aquatic Chronic 3      H412 Harmful to aquatic life with long lasting effects.

**2.2 Label elements****Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

**Hazard pictograms** GHS07**Signal word** Warning**Hazard-determining components of labelling:**

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

**Hazard statements**

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

**Precautionary statements**

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of water and soap.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Preparation containing hazardous components.

- **Dangerous components:**

CAS: 56-81-5 EINECS: 200-289-5	glycerol substance with a Community workplace exposure limit	25-50%
CAS: 55965-84-9 Index number: 613-167-00-5	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1) Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330 Skin Corr. 1C, H314; Eye Dam. 1, H318 Aquatic Acute 1, H400; Aquatic Chronic 1, H410 Skin Sens. 1A, H317	<0.01%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
  - **After inhalation:**  
Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably 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.
  - **After swallowing:** Call for a doctor immediately.
- **4.2 Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
  - **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray.  
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

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

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective clothing.  
Wear disposable gloves.
- **6.2 Environmental precautions:**  
Do not allow product to reach sewage system or any water course.  
Inform respective authorities in case of seepage into water course or sewage system.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 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.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**  
Keep receptacles tightly sealed.  
Follow good laboratory practices.
  - **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
  - **Storage:**
    - **Requirements to be met by storerooms and receptacles:** No special requirements.
    - **Information about storage in one common storage facility:** Not required.
    - **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

**56-81-5 glycerol**

WEL	Long-term value: 10 mg/m <sup>3</sup>
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- **Additional information:** The lists valid during the making were used as basis.

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- **Personal protective equipment:**
  - **General protective and hygienic measures:**
    - Immediately remove all soiled and contaminated clothing
    - Wash hands before breaks and at the end of work.
  - **Respiratory protection:** Suitable respiratory protective device recommended.
  - **Protection of hands:** Protective gloves
  - **Eye protection:** Safety glasses

**SECTION 9: Physical and chemical properties**

 · **9.1 Information on basic physical and chemical properties**

 · **General Information**

 · **Appearance:**

- **Form:** In water
- **Colour:** Orange
- **Odour:** Odourless
- **Odour threshold:** Not determined.

 · **pH-value:** 8.0 ± 0.1

 · **Change in condition**

- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** Undetermined.

 · **Flash point:** Not applicable.

 · **Flammability (solid, gas):** Not applicable.

 · **Ignition temperature:** 400 °C

 · **Decomposition temperature:** Not determined.

 · **Auto-ignition temperature:** Product is not selfigniting.

 · **Explosive properties:** Product does not present an explosion hazard.

 · **Explosion limits:**

- **Lower:** Not determined.
- **Upper:** Not determined.

 · **Vapour pressure at 20 °C:** 23 hPa

 · **Density:** Not determined.

- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.

 · **Solubility in / Miscibility with**

 · **water:** Fully miscible.

 · **Partition coefficient: n-octanol/water:** Not determined.

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· <b>Viscosity:</b>	
· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
· <b>Organic solvents:</b>	25.2 %
· <b>Water:</b>	71.0 %
· <b>9.2 Other information</b>	No further relevant information available.

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
  - **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

**SECTION 11: Toxicological information**

- **11.1 Information on toxicological effects**
  - **Acute toxicity** Based on available data, the classification criteria are not met.
    - **Primary irritant effect:**
      - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
      - **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
  - **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
  - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
    - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
    - **Carcinogenicity** Based on available data, the classification criteria are not met.
    - **Reproductive toxicity** Based on available data, the classification criteria are not met.
  - **STOT-single exposure** Based on available data, the classification criteria are not met.
  - **STOT-repeated exposure** Based on available data, the classification criteria are not met.
  - **Aspiration hazard** Based on available data, the classification criteria are not met.

**SECTION 12: Ecological information**

- **12.1 Toxicity**
  - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.

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- **Ecotoxicological effects:**
  - **Remark:** Harmful to fish
- **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.  
Avoid transfer into the environment.  
Harmful to aquatic organisms
- **12.5 Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

**SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**
  - **Recommendation** Must be specially treated adhering to official regulations.
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.

**SECTION 14: Transport information**

· <b>14.1 UN-Number</b> · ADR, ADN, IMDG, IATA	Void
· <b>14.2 UN proper shipping name</b> · ADR, ADN, IMDG, IATA	Void
· <b>14.3 Transport hazard class(es)</b> · ADR, ADN, IMDG, IATA · Class	Void
· <b>14.4 Packing group</b> · ADR, IMDG, IATA	Void
· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	Void

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**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

**National regulations:**

Class	Share in %
NK	25.2

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

**Relevant phrases**

- H301 Toxic if swallowed.
- H310 Fatal in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H330 Fatal if inhaled.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

**Department issuing SDS:**

MSDS / FDS Administr.  
Bio-Rad  
Marnes-la-Coquette, France

**Contact:**

Customer Support  
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**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 Harmonised System of Classification and Labelling of Chemicals

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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)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Acute Tox. 3: Acute toxicity - oral – Category 3  
Acute Tox. 2: Acute toxicity - dermal – Category 2  
Skin Corr. 1C: Skin corrosion/irritation – Category 1C  
Eye Dam. 1: Serious eye damage/eye irritation – Category 1  
Skin Sens. 1: Skin sensitisation – Category 1  
Skin Sens. 1A: Skin sensitisation – Category 1A  
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1  
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1  
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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