

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: R4 - Cut Off Control (1 mL)****Article number: 7270D****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.
 - **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:**
CO₂, 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.
- **5.3 Advice for firefighters**
 - **Protective equipment:** No special measures required.

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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.
- **6.3 Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
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** 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/m³

- **Additional information:** The lists valid during the making were used as basis.
- **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

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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

· **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.

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

· **Density:** Not determined.

· Solubility in / Miscibility with

- **water:** Fully miscible.

· Solvent content:

- **Organic solvents:** 25.2 %

· **9.2 Other information** 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.

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- **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.
 - **Ecotoxicological effects:**
 - **Remark:** Harmful to fish
 - **Additional ecological information:**
 - **General notes:**
 - 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

- | | |
|---------------------------------------|------|
| · 14.1 UN-Number | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |

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· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	
	Not applicable.
· Transport/Additional information:	Not dangerous according to the above specifications.
· UN "Model Regulation":	Void

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.

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· Department issuing SDS:

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

· Contact:

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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
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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