

SAFETY DATA SHEET



SAFETY DATA SHEET according to Regulation (EC) 2020/878

Issue date: 14/06/21

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Version 1

UK

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

1.1 Product identifier

Trade name: Buffered sodium citrate 3.8% tubes.
Safety cap: different colours.
Dimension in mm: 13x75, 13x75 IN, 13x75 GR, 13x100.
Predetermined vacuum in ml: 2.0, 2.5, 3.5, 4.0, 4.5, 5.0.
Catalog codes: 14010, 140100, 14020, 140200, 14315, 143150, 14520, 145200, 14521, 14530, 6145210

1.2 Relevant identified uses of the substance or mixture

In-Vitro Diagnostic device (directive CEE 98/79/CE)
Use intended by experienced personnel and professional operators

1.3 Details of the supplier of the safety data sheet

Company name: Vacutest Kima SRL.
Address: Via Dell'Industria 12
35020 Arzergrande (PD) – Italy
Telephone: 0039- 049-9720624
E-mail: info@vacutestkima.it

2. Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008 as amended

The product has not been classified as hazardous according to the legislation in force.

Classification according to Regulation (EC) No 1272/2008 as amended.

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

Hazard pictogram(s): Not applicable

Signal word(s): Not applicable

Hazard statement(s): Not applicable

Precautionary statement(s)	Not applicable
Other hazards:	No data available.
3. Composition/information on ingredients	
<i>3.1 Substances</i>	
Not applicable	
<i>3.2 Hazardous components</i>	
In accordance with Regulation (EC) no. 2020/878 it is not necessary to include any substance.	
4. First aid measures	
<i>4.1. Description of first aid measures</i>	
Inhalation: Due to the small packaging the risk of inhalation is minimal. In case of risk of inhalation of vapor/aerosols: Move person to fresh air.	
Skin contact: Wash skin with soap and water. Get medical attention if irritation persists after washing.	
Eye contact: Flush eyes with water as a precaution. If irritation occurs, get medical assistance.	
Ingestion: Rinse mouth. Get medical attention if any discomfort occurs.	
<i>4.2. Most important symptoms and effects, both acute and delayed</i>	
Direct contact with eyes may cause temporary irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.	
<i>4.3. Indication of any immediate medical attention and special treatment needed</i>	
Treat symptomatically.	
5. Firefighting measures	
<i>5.1 Extinguishing media</i>	
Suitable extinguishing media	
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.	
<i>5.2 Special hazards arising from the substance or mixture</i>	
Borane/boron oxides	
<i>5.3 Advice for firefighters</i>	
Wear self-contained breathing apparatus for firefighting if necessary.	
<i>5.4 Further information</i>	

No data available

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear suitable protective clothing.

6.2 Environmental precautions

Avoid discharge into drains, water courses or onto the ground unless authorised by permit.

6.3 Methods and material for containment and cleaning up

No special measures required.

6.4 Reference to other sections

For disposal see section 13.

7. Handling and storage

7.1 Handling

Handling according to GLP (Good Laboratory Practice) as indicated by OMS;
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

7.2 Storage

Store in original packaging. Keep away from direct sunlight, heat, sparks and open flame. Store at temperatures indicated on the packaging (between +5°C and +25°C)

7.3 Particular risks

None.

7.4 Specific end use(s)

Urine collection.

8. Exposure controls/personal protection

8.1 Exposure limits

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures

Follow standard monitoring procedures.

Derived no-effect level (DNEL)

Not available.

Predicted no effect concentrations (PNECs)

Not available.

Exposure guidelines

No exposure limits noted for ingredient(s).

*8.2 Exposure controls**8.2.1 Appropriate engineering controls*

General ventilation normally adequate.

Individual protection measures, such as personal protective equipment**General information**

Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection

Risk of contact: Wear dust goggles. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

*Skin protection**Hand protection*

For prolonged or repeated skin contact use suitable protective gloves. Nitrile gloves are recommended. Suitable gloves can be recommended by the glove supplier.

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested:KCL 741 Dermatril® L

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested:KCL 741 Dermatril® L

Other

Body Protection protective clothing

Respiratory protection

Under normal conditions, respirator is not normally required. In case of inadequate ventilation and work of brief duration, use suitable respiratory equipment. Where risk assessment shows air-purifying respirators are appropriate use a fullface particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Thermal hazards

None.

Hygiene measures

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Environmental exposure controls

Environmental manager must be informed of all major spillages.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance Physical state:	Liquid
Form:	Liquid
Color:	Clear
Odor:	Odorless
Odor Threshold:	No data available.
pH:	No data available.
Freezing point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Upper (%)	No data available.
Flammability Limit - Lower (%)	No data available.
Vapor pressure:	No data available.
Vapor density (air=1):	No data available.
Relative density:	No data available.
Solubility(ies)	
Solubility in Water:	No data available.
Solubility (other):	No data available.
Partition coefficient (n-octanol/water):	No data available.
Autoignition Temperature:	No data available.
Decomposition Temperature:	No data available.
SADT:	No data available.
Viscosity:	No data available.
Explosive properties:	No data available.
Oxidizing properties:	No data available.

10. Stability and reactivity

<i>10.1 Reactivity</i>	The product is stable and non-reactive under standard ambient conditions
<i>10.2 Chemical stability</i>	The product is stable under standard ambient condition
<i>10.3 Possibility of hazardous reactions</i>	No dangerous reaction known
<i>10.4 Incompatible materials</i>	None
<i>10.5 Hazardous decomposition products</i>	No data available

11. Toxicological information*11.1 Information on toxicological effects*

<i>11.1.1 Acute toxicity</i>	no data available
<i>11.1.2 Skin corrosion/irritation</i>	no data available
<i>11.1.3 Serious eye damage/eye irritation</i>	no data available
<i>11.1.4 Respiratory or skin sensitisation</i>	no data available
<i>11.1.5 Germ cell mutagenicity</i>	no data available
<i>11.1.6 Carcinogenicity IARC</i>	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. Ecological information

<i>12.1 Toxicity</i>	no data available
<i>12.2 Persistence and degradability</i>	No data available
<i>12.3 Bioaccumulative potential</i>	No data available
<i>12.4 Mobility in soil</i>	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
<i>12.5 Results of PBT and vPvB assessment</i>	
<i>12.6 Other adverse effects</i>	No data available

13. Disposal considerations*13.1. Waste treatment methods***Residual waste**

Dispose of waste and residues in accordance with local authority requirements.

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal.

EU waste code

Before using CER 18 01 07 chemicals other than those mentioned in 18 01 06

After use CER 18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection

14. Transport information

Not regulated as dangerous goods.

ADR

Not regulated as dangerous goods.

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

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.

RID

Not regulated as dangerous goods.

ADN

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

15. Regulatory information*15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**EU regulations*

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 on persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and

mutagens at work, as amended

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are

breastfeeding, as amended

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations

This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. The product does not need to be labelled in accordance with EC directives or respective national laws.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

16. Other information*List of abbreviations*

DNEL: Derived No-Effect Level.

PNEC: Predicted No-Effect Concentration.

ACGIH: American Conference of Governmental

References

ACGIH: American Conference of Governmental and Industrial Hygienists.

US. IARC Monographs on Occupational Exposures to Chemical Agents

National Toxicology Program (NTP) Report on Carcinogens

Information on evaluation method leading to the classification of mixture

The mixture is classified based on test data for physical hazards. The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available. For details, refer to Sections 9, 11 and 12.

Full text of H-Statements referred to under sections 2 and 15.

none

Training information

Follow training instructions when handling this material.

Date : 14/06/2021 Date of version: 14/06/2021

Changes from previous version: none

Disclaimer

To the best of our knowledge, the information contained herein is accurate. However, neither this company nor any of its subsidiaries assumes any liability whatsoever for 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 are described herein, we cannot guarantee that these are the only hazards that exist.

Further information

The data contained in this MSDS are based on the state of knowledge at the time of review and provides information for the sole purpose of use, transportation, storage and disposal.

They should not be considered as a technical specification of the product and its quality. For such information please refer to the technical data sheet and quality sheet prepared by this company which can be provided on specific customer request.