

Safety Data Sheet

acc. to OSHA HCS



Printing date 07/27/2017

Reviewed on 07/27/2017

1 Identification

- **Product identifier**
- **Trade name: qUAntify® Plus Control, Level 2**
- **Catalog or product number:** 964
- **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 Sens. 1 H317 May cause an allergic skin reaction.
Repr. 1 H360 May damage fertility or the unborn child.
 - **Label elements**
 - **GHS label elements** The product is classified and labeled according to the Globally Harmonized System (GHS).
 - **Hazard pictograms**
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- GHS07 GHS08
- **Signal word** Danger
 - **Hazard-determining components of labeling:**
5-chloro-2-methyl-2H-isothiazol-3-one
 - **Hazard statements**
H317 May cause an allergic skin reaction.
H360 May damage fertility or the unborn child.
 - **Precautionary statements**
P261 Avoid breathing dust/fume/gas/mist/vapors/spray
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.
 - **Emergency overview:**
 - **Routes of exposure:**
Ingestion
Skin
Inhalation

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- **Classification system**
- **NFPA ratings (scale 0-4)**
Health = 0
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:**

CAS: 1330-43-4 EINECS: 215-540-4	boric acid, disodium salt Repr. 1B, H360	0.1-1%
CAS: 57-13-6 EINECS: 200-315-5	urea	0.1-1%
CAS: 100-51-6 EINECS: 202-859-9	Benzyl alcohol Acute Tox. 4, H302; Acute Tox. 4, H332	0.01-0.1%
CAS: 26172-55-4 EINECS: 247-500-7	5-chloro-2-methyl-2H-isothiazol-3-one Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331 Skin Corr. 1B, H314 Skin Sens. 1, H317	0.001-0.01%

· **SVHC**

1330-43-4 | boric acid, disodium salt

- **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 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. 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**
Skin irritation
Eye irritation

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· **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

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.

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· **Control parameters**

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

1330-43-4 boric acid, disodium salt

REL (United States)	Long-term value: 1 mg/m ³ anhydrous
TLV (United States)	Short-term value: 6* mg/m ³ Long-term value: 2* mg/m ³ *as inhalable fraction

67-64-1 acetone

PEL (United States)	Long-term value: 2400 mg/m ³ , 1000 ppm
REL (United States)	Long-term value: 590 mg/m ³ , 250 ppm
TLV (United States)	Short-term value: 1187 mg/m ³ , 500 ppm Long-term value: 594 mg/m ³ , 250 ppm BEI

7647-01-0 hydrochloric acid

PEL (United States)	Ceiling limit value: 7 mg/m ³ , 5 ppm
REL (United States)	Ceiling limit value: 7 mg/m ³ , 5 ppm
TLV (United States)	Ceiling limit value: 2.98 mg/m ³ , 2 ppm

57-13-6 urea

WEEL (United States)	Long-term value: 10 mg/m ³
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100-51-6 Benzyl alcohol

WEEL (United States)	Long-term value: 10 ppm
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· **Ingredients with biological limit values:**

67-64-1 acetone

BEI (United States)	50 mg/L Medium: urine Time: end of shift Parameter: Acetone (nonspecific)
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· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Follow the usual biosafety practices for handling potentially infectious materials.
The usual precautionary measures for handling chemicals should be followed.

· **Breathing equipment:** Not required.

· **Protection of hands:** Protective gloves.

· **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

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· **Body protection:** Protective work clothing.

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form: Liquid

Color: Yellow

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value at 20°C:** 7.0-9.0

· **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: Fully miscible

· **Viscosity:**

dynamic: Not determined.

· **Solvent content:**

Organic solvents: 0.5 %

Water: 50-100 %

Solids content: 2.1 %

· **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.

· **Hazardous decomposition products:** No dangerous decomposition products known

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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:** Sensitization possible through skin contact.
- **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:
Irritant
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)**

7647-01-0	hydrochloric acid	3
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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **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**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Dispose of waste in accordance to applicable national, regional, or local regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

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· **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)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR, IMDG, IATA	Void
· Environmental hazards:	Not applicable.
· 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):

7647-01-0 hydrochloric acid

· Section 313 (40CFR372.65):

7647-01-0 hydrochloric acid

7632-00-0 sodium nitrite

· TSCA (Toxic Substances Control Act):

1330-43-4 boric acid, disodium salt

50-99-7 glucose

67-64-1 acetone

7647-01-0 hydrochloric acid

57-13-6 urea

60-27-5 Creatinine

9048-46-8 Bovine Serum Albumin

100-51-6 Benzyl alcohol

Proprietary Reagent J2

1310-73-2 sodium hydroxide

Proprietary Reagent XX

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26172-55-4	5-chloro-2-methyl-2H-isothiazol-3-one
2682-20-4	2-methyl-2H-isothiazol-3-one
7632-00-0	sodium nitrite
554-73-4	Orange IV
7732-18-5	water

· **California Proposition 65:**

· **Developmental Toxicity**

1405-41-0	Gentamicin Sulfate
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· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

1330-43-4	boric acid, disodium salt	I (oral)
67-64-1	acetone	I
57-13-6	urea	II

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

1330-43-4	boric acid, disodium salt	A4
67-64-1	acetone	A4
7647-01-0	hydrochloric acid	A4

· **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 %
NK	0.1-1

· **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** 07/27/2017 / -

· **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
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Sens. 1: Skin sensitisation – Category 1
Repr. 1: Reproductive toxicity – Category 1
Repr. 1B: Reproductive toxicity – Category 1B

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