

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
 Product Name : BCR-ABL IS AmpliTaq® Gold
 Product Reference # : 145259

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : CE-IVD

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Company

Asuragen, Inc.
 2150 Woodward Ave Suite 100
 Austin, TX 78744
 T: +1 512-681-5200
 USA, Toll-free T: +1 877-777-1874
 E-mail: support@asuragen.com
 Web address: www.asuragen.com

1.4. Emergency telephone number

Emergency number : Tel: +1 -512-681-5200 US, Toll-free Tel: 1-877-777-1874

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

Other hazards not contributing to the classification : Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Glycerin	(CAS No) 56-81-5 (EC no) 200-289-5	45 - 55	Not classified
Potassium chloride	(CAS No) 7447-40-7 (EC no) 231-211-8	< 1	Not classified
Nonylphenol ethoxylates	(CAS No) 9016-45-9 (EC no) 500-024-6	< 1	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Chronic 2, H411

Full text of H-statements: see section 16

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According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.
- First-aid measures after skin contact : Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.
- First-aid measures after eye contact : Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.
- Symptoms/injuries after inhalation : Prolonged exposure may cause irritation.
- Symptoms/injuries after skin contact : Prolonged exposure may cause skin irritation.
- Symptoms/injuries after eye contact : May cause slight irritation to eyes.
- Symptoms/injuries after ingestion : Ingestion may cause adverse effects.
- Chronic symptoms : None expected under normal conditions of use.

4.3. Indication of any immediate medical attention and special treatment needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray, dry chemical, foam, carbon dioxide.
- Unsuitable extinguishing media : Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Not considered flammable but may burn at high temperatures.
- Explosion hazard : Product is not explosive.
- Reactivity : Hazardous reactions will not occur under normal conditions.

5.3. Advice for firefighters

- Precautionary measures fire : Exercise caution when fighting any chemical fire.
- Firefighting instructions : Use water spray or fog for cooling exposed containers.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For non-emergency personnel

- Protective equipment : Use appropriate personal protection equipment (PPE).
- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.
- Methods for cleaning up : Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection. See Section 13, Disposal Considerations.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.

Storage conditions : Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible products : Strong acids, strong bases, strong oxidizers.

Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

CE-IVD

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Potassium chloride (7447-40-7)		
Bulgaria	OEL TWA (mg/m ³)	5,0 mg/m ³
Latvia	OEL TWA (mg/m ³)	5 mg/m ³
Lithuania	IPRV (mg/m ³)	5 mg/m ³
Glycerin (56-81-5)		
Belgium	Limit value (mg/m ³)	10 mg/m ³ (mist)
Croatia	GVI (granična vrijednost izloženosti) (mg/m ³)	10 mg/m ³
France	VME (mg/m ³)	10 mg/m ³ (aerosol)
Greece	OEL TWA (mg/m ³)	10 mg/m ³
Spain	VLA-ED (mg/m ³)	10 mg/m ³ (mist)
Switzerland	VLE (mg/m ³)	100 mg/m ³ (inhalable dust)
Switzerland	VME (mg/m ³)	50 mg/m ³ (inhalable dust)
United Kingdom	WEL TWA (mg/m ³)	10 mg/m ³ (mist)
United Kingdom	WEL STEL (mg/m ³)	30 mg/m ³ (calculated-mist)
Czech Republic	Expoziční limity (PEL) (mg/m ³)	10 mg/m ³
Estonia	OEL TWA (mg/m ³)	10 mg/m ³
Finland	HTP-arvo (8h) (mg/m ³)	20 mg/m ³
Ireland	OEL (8 hours ref) (mg/m ³)	10 mg/m ³ (mist)
Ireland	OEL (15 min ref) (mg/m ³)	30 mg/m ³ (calculated-mist)
Poland	NDS (mg/m ³)	10 mg/m ³ (inhalable fraction)
Portugal	OEL TWA (mg/m ³)	10 mg/m ³ (mist)

8.2. Exposure controls

Appropriate engineering controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal protective equipment : Gloves. Protective clothing. Protective goggles.



Materials for protective clothing : Chemically resistant materials and fabrics.

Hand protection : Wear protective gloves.

Eye protection : Chemical safety goggles.

Skin and body protection : Wear suitable protective clothing.

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- Respiratory protection : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
- Other information : When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Evaporation rate	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Glycerin decomposes to produce corrosive fumes of Acrolein.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Potassium chloride (7447-40-7)

LD50 oral rat	2600 mg/kg
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Glycerin (56-81-5)

LD50 oral rat	23000 mg/kg
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LD50 dermal rabbit	> 10 g/kg
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LC50 inhalation rat (mg/l)	> 570 mg/m ³ (Exposure time: 1 h)
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Nonylphenol ethoxylates (9016-45-9)	
LD50 oral rat	1310 mg/kg HSDB
LD50 dermal rabbit	1780 ml/kg
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Not classified.

Potassium chloride (7447-40-7)	
LC50 fish 1	1060 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 1	825 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	750 (750 - 1020) mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 2	880 mg/l (Exposure time: 24 h - Species: Daphnia magna)

Glycerin (56-81-5)	
LC50 fish 1	54000 (51000 - 57000) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

Nonylphenol ethoxylates (9016-45-9)	
EC50 Daphnia 1	1,821 mg/l

12.2. Persistence and degradability

BCR-ABL IS AmpliTaq® Gold	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

BCR-ABL IS AmpliTaq® Gold	
Bioaccumulative potential	Not established.

Glycerin (56-81-5)	
BCF fish 1	(no bioaccumulation)
Log Pow	-1,76

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local, regional, national, and international regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

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According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated for transport				
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No

14.6. Special precautions for user

No additional information available

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3.b. Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	Nonylphenol ethoxylates
3.c. Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1	Nonylphenol ethoxylates

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Potassium chloride (7447-40-7)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Revision date: : 11/08/2016

Data sources : According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Full text of H- and EUH-statements:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2

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STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H302	Harmful if swallowed
H312	Harmful in contact with skin
H315	Causes skin irritation
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H411	Toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

EU GHS SDS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.