



BCR-ABL IS RT Enzyme Mix

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Revision Date: 05/18/2018

Date of Issue: 10/15/2015

Supersedes Date: 10/15/2015

Version: 2.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: BCR-ABL IS RT Enzyme Mix

Product Reference #: 145390

1.2. Intended Use of the Product

For in vitro diagnostic use

1.3. Name, Address, and Telephone of the Responsible Party

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

GHS-US/CA Classification

Not classified

2.2. Label Elements

GHS-US/CA Labeling

No labeling applicable

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

| Name | Product Identifier | % * | GHS Ingredient Classification |
|---|---------------------|-------|--|
| Glycerin | (CAS-No.) 56-81-5 | 50.00 | Not classified |
| Water | (CAS-No.) 7732-18-5 | 48.46 | Not classified |
| Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy- | (CAS-No.) 9002-93-1 | 0.50 | Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 2, H401 Aquatic Chronic 2, H411 |
| 1,3-Propanediol, 2-amino-2-(hydroxymethyl)- | (CAS-No.) 77-86-1 | 0.30 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Comb. Dust |
| Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate | (CAS-No.) 6381-92-6 | 0.01 | Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist), H332 Skin Irrit. 2, H315 |

BCR-ABL IS RT Enzyme Mix

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

| | | | |
|---|---------------------|------|---|
| | | | Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Acute 3, H402 Aquatic Chronic 3, H412 Comb. Dust |
| Sodium chloride | (CAS-No.) 7647-14-5 | 0.58 | Not classified |
| 2,3-Butanediol, 1,4-dimercapto-, (R*,R*)- | (CAS-No.) 3483-12-3 | 0.15 | Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Comb. Dust |

Full text of H-phrases: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of 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).

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

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: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

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.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Glycerin decomposes to produce corrosive fumes of Acrolein. Acrid smoke and irritating fumes.

BCR-ABL IS RT Enzyme Mix

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Reference to Other Sections

Refer to Section 9 for flammability properties.

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 protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: 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. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials 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 Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

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 Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

For in vitro diagnostic use

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established Exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), Canadian provincial governments, or the Mexican government.

| Glycerin (56-81-5) | | |
|-----------------------|-------------------------------------|---|
| Mexico | OEL TWA (mg/m ³) | 10 mg/m ³ (mist) |
| USA OSHA | OSHA PEL (TWA) (mg/m ³) | 15 mg/m ³ (mist, total particulate) 5 mg/m ³ (mist, respirable fraction) |
| Alberta | OEL TWA (mg/m ³) | 10 mg/m ³ (mist) |
| British Columbia | OEL TWA (mg/m ³) | 10 mg/m ³ (mist) 3 mg/m ³ (mist-respirable) |
| New Brunswick | OEL TWA (mg/m ³) | 10 mg/m ³ (mist) |
| Nunavut | OEL STEL (mg/m ³) | 20 mg/m ³ (mist) |
| Nunavut | OEL TWA (mg/m ³) | 10 mg/m ³ (mist) |
| Northwest Territories | OEL STEL (mg/m ³) | 20 mg/m ³ (mist) |
| Northwest Territories | OEL TWA (mg/m ³) | 10 mg/m ³ (mist) |
| Québec | VEMP (mg/m ³) | 10 mg/m ³ (mist) |

BCR-ABL IS RT Enzyme Mix

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

| | | |
|--------------|-------------------------------|--|
| Saskatchewan | OEL STEL (mg/m ³) | 20 mg/m ³ (mist) |
| Saskatchewan | OEL TWA (mg/m ³) | 10 mg/m ³ (mist) |
| Yukon | OEL TWA (mg/m ³) | 30 mppcf (mist) 10 mg/m ³ (mist) |

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the 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 and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

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 |
| Appearance | : Not available |
| Odor | : Not available |
| Odor Threshold | : Not available |
| pH | : Not available |
| Evaporation Rate | : Not available |
| Melting Point | : Not available |
| Freezing Point | : Not available |
| Boiling Point | : Not available |
| Flash Point | : Not available |
| Auto-ignition Temperature | : Not available |
| Decomposition Temperature | : Not available |
| Flammability (solid, gas) | : Not applicable |
| Lower Flammable Limit | : Not available |
| Upper Flammable Limit | : Not available |
| Vapor Pressure | : Not available |
| Relative Vapor Density at 20°C | : Not available |
| Relative Density | : Not available |
| Specific Gravity | : Not available |
| Solubility | : Not available |
| Partition Coefficient: N-Octanol/Water | : Not available |
| Viscosity | : Not 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.

BCR-ABL IS RT Enzyme Mix

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

10.6. Hazardous Decomposition Products: Carbon oxides (CO, CO₂). Nitrogen oxides. Glycerin decomposes to produce corrosive fumes of Acrolein.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

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.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

| | |
|--|--|
| Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy- (9002-93-1) | |
| LD50 Oral Rat | 1800 mg/kg |
| 1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1) | |
| LD50 Oral Rat | 5900 mg/kg |
| LD50 Dermal Rat | > 5000 mg/kg |
| Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6) | |
| LD50 Oral Rat | 2000 mg/kg |
| ATE US/CA (dermal) | 1,100.00 mg/kg body weight |
| ATE US/CA (dust, mist) | 1.50 mg/l/4h |
| Sodium chloride (7647-14-5) | |
| LD50 Oral Rat | 3 g/kg |
| LD50 Dermal Rabbit | > 10000 mg/kg (Species: New Zealand White) |
| LC50 Inhalation Rat | > 42 g/m ³ (Exposure time: 1 h) |
| 2,3-Butanediol, 1,4-dimercapto-, (R*,R*)- (3483-12-3) | |
| ATE US/CA (oral) | 500.00 mg/kg body weight |
| Glycerin (56-81-5) | |
| LD50 Oral Rat | 12600 mg/kg |
| LD50 Dermal Rabbit | > 10 g/kg |
| LC50 Inhalation Rat | > 570 mg/m ³ (Exposure time: 1 h) |

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

| | |
|--|--------|
| Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy- (9002-93-1) | |
| LC50 Fish 1 | 3 mg/l |
| Sodium chloride (7647-14-5) | |

BCR-ABL IS RT Enzyme Mix

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

| | |
|---------------------------|---|
| LC50 Fish 1 | 5560 (5560 - 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through]) |
| EC50 Daphnia 1 | 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna) |
| LC50 Fish 2 | 12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static]) |
| EC50 Daphnia 2 | 340.7 (340.7 - 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static]) |
| NOEC Chronic Fish | 252 mg/l (Species: Pimephales promelas) |
| Glycerin (56-81-5) | |
| LC50 Fish 1 | 54000 (51000 - 57000) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |

12.2. Persistence and Degradability

| | |
|---------------------------------|------------------|
| BCR-ABL IS RT Enzyme Mix | |
| Persistence and Degradability | Not established. |

12.3. Bioaccumulative Potential

| | |
|--|---|
| BCR-ABL IS RT Enzyme Mix | |
| Bioaccumulative Potential | Not established. |
| 1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1) | |
| BCF Fish 1 | 3 (Estimated using a regression-derived equation) |
| Sodium chloride (7647-14-5) | |
| BCF Fish 1 | (no bioaccumulation) |
| Glycerin (56-81-5) | |
| BCF Fish 1 | (no bioaccumulation) |
| Log Pow | -1.76 |

12.4. Mobility in Soil Not available

12.5. 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

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

14.4. In Accordance with TDG Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

| | |
|--|---|
| Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy- (9002-93-1) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |
| EPA TSCA Regulatory Flag | XU - XU - indicates a substance exempt from reporting under the Inventory Update Reporting Rule, i.e, Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(C)). |
| 1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |
| Sodium chloride (7647-14-5) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |
| 2,3-Butanediol, 1,4-dimercapto-, (R*,R*)- (3483-12-3) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |

BCR-ABL IS RT Enzyme Mix

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Glycerin (56-81-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State Regulations

Glycerin (56-81-5)

U.S. - Massachusetts - Right To Know List
 U.S. - New Jersey - Right to Know Hazardous Substance List
 U.S. - Pennsylvania - RTK (Right to Know) List

15.3. Canadian Regulations

Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy- (9002-93-1)

Listed on the Canadian DSL (Domestic Substances List)

1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)

Listed on the Canadian DSL (Domestic Substances List)

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)

Listed on the Canadian DSL (Domestic Substances List)

Sodium chloride (7647-14-5)

Listed on the Canadian DSL (Domestic Substances List)

2,3-Butanediol, 1,4-dimercapto-, (R*,R*)- (3483-12-3)

Listed on the Canadian DSL (Domestic Substances List)

Glycerin (56-81-5)

Listed on the Canadian DSL (Domestic Substances List)

Water (7732-18-5)

Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 05/18/2018

Revision

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

GHS Full Text Phrases:

| | |
|-------------------------------------|--|
| 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 Acute 2 | Hazardous to the aquatic environment - Acute Hazard Category 2 |
| Aquatic Acute 3 | Hazardous to the aquatic environment - Acute Hazard Category 3 |
| Aquatic Chronic 2 | Hazardous to the aquatic environment - Chronic Hazard Category 2 |
| Aquatic Chronic 3 | Hazardous to the aquatic environment - Chronic Hazard Category 3 |
| Comb. Dust | Combustible Dust |
| Eye Dam. 1 | Serious eye damage/eye irritation Category 1 |
| Eye Irrit. 2 | Serious eye damage/eye irritation Category 2 |
| Skin Irrit. 2 | Skin corrosion/irritation Category 2 |
| STOT SE 3 | Specific target organ toxicity (single exposure) Category 3 |
| H302 | Harmful if swallowed |
| H312 | Harmful in contact with skin |
| H315 | Causes skin irritation |
| H318 | Causes serious eye damage |

BCR-ABL IS RT Enzyme Mix

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

| | |
|------|---|
| H319 | Causes serious eye irritation |
| H332 | Harmful if inhaled |
| H335 | May cause respiratory irritation |
| H401 | Toxic to aquatic life |
| H402 | Harmful to aquatic life |
| H411 | Toxic to aquatic life with long lasting effects |
| H412 | Harmful to aquatic life with long lasting effects |

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.

NA GHS SDS 2015 (Can, US, Mex)