Abbott

Release Date: 5/14/24

REF GTIN	Product Name
8L91-44	***Activated Aspartate Aminotransferase FOR USE WITH ARCHITECT***

Components:

8L91/R1 NEW	**Activated Aspartate Aminotransferase Reagent 1 FOR USE WITH ARCHITECT**
8L91/R2 NEW	**Activated Aspartate Aminotransferase Reagent 2 FOR USE WITH ARCHITECT**

Abbott Customers:
For additional information, please contact your Abbott Customer Support Center Representative by calling 1-800-527-1869, 1-800-323-9100, or 1-800-235-5396.

Abbott employees:
For additional information relative to the content of the SDSs, please contact your local Safety Representative.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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1 Identification

· **Product name:** **Activated Aspartate Aminotransferase Reagent 1 FOR USE WITH ARCHITECT**

· **ADD List number:** 8L91/R1 NEW

· **Application of the substance / mixture:** For In Vitro Diagnostic Use

· **Manufacturer / Supplier:**
Abbott Diagnostics
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· **Department issuing SDS:** Abbott Diagnostics Environmental Health and Safety

· **Emergency telephone number**
Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.
Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

2 Hazard(s) identification

· **Classification of the substance or mixture**
The classification was made according to U.S. OSHA 29 CFR 1910.1200 and 1910.1030 and applicable European regulations, and is expanded upon from supplier company and/or literature data.

Skin Irritation 2 H315 Causes skin irritation.

Eye Irritation 2A H319 Causes serious eye irritation.

· **Label elements**

· **GHS label elements:** The product is labelled according to the Globally Harmonized System (GHS).

· **Hazard pictograms:**



· **Signal word:** Warning

· **Hazard statements:**
H315 Causes skin irritation.
H319 Causes serious eye irritation.

· **Precautionary statements:**

P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection.
P302+P352	If on skin: Wash with plenty of water.
P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P337+P313	If eye irritation persists: Get medical advice/attention.

· **Routes of Exposure:**
Skin
Eye
· **Health:**
Causes skin irritation
Causes eye irritation
· **Fire:** Noncombustible
· **Reactivity:** Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.

3 Composition/information on ingredients

· **Chemical characterization:** Mixture of chemical and/or biological substances for in vitro diagnostic use.

· **Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):**

CAS: 56-84-8	Aspartic acid	3.617%
CAS: 1310-73-2	Sodium hydroxide	1.1573%

4 First-aid measures

· **After inhalation:** Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.

· **After skin contact:**
Take off any clothing that the product touched.
Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.

· **After eye contact:**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists, get medical advice/attention. Wash hands after handling.

· **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.

· **Most important symptoms and effects, both acute and delayed:**
Cramps
Gastric or intestinal disorders
Nausea
Skin irritation
Eye irritation
Respiratory irritation
· **Medical conditions aggravated by exposure:**
Pre-existing eye ailments
Pre-existing respiratory ailments
Pre-existing gastrointestinal tract ailments

Pre-existing skin ailments

5 Fire-fighting measures

· **Suitable extinguishing agents**
Dry chemical, carbon dioxide (CO2), water spray or regular foam.
- Caution: CO2 will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
- For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.

· **Special hazards arising from the substance or mixture**
There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.
No further relevant information available.

· **Protective equipment**
For large fires, wear appropriate heat- and flame-resistant personal protective equipment and a NFPA/NIOSH approved positive-pressure, self-contained breathing apparatus.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected persons away.

· **Environmental precautions**
Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

· **Methods and material for containment and cleaning up**
Blot up small volumes of spilled or spattered product with paper towels or similar materials.
- Contain larger spills by placing absorbants around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:
- warm water and detergent or similar cleansing agent

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

· **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.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Activated Aspartate Aminotransferase Reagent 1 FOR USE WITH ARCHITECT

7 Handling and storage

· **Precautions for safe handling:**
Avoid contact with skin.
Avoid contact with eyes.

· **Information about protection against explosions and fires:** The product is not flammable.

· **Requirements to be met by storerooms and receptacles:** Store only in the original container.

· **Information about storage in one common storage facility:** Store in original packaging.

· **Further information about storage conditions:**
Refer to the package insert or product label for additional information on storage conditions for product quality.

8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**
The product does not contain any hazardous ingredients with occupational exposure limits established by OSHA, ACGIH, or NIOSH.

· **General protective and hygienic measures:**
Always maintain good housekeeping and follow general precautionary measures. Do not eat, drink or store food and beverages in areas where chemicals or specimens are used. Wash hands before breaks, after handling reagents and specimens, and at the end of the workshift.

Avoid contact with the skin.
Avoid contact with the eyes.

· **Breathing equipment:**
Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

Other unusual conditions (e.g. volume spilled too big to clean up with materials in arm's reach) - Use appropriate NIOSH-approved air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use NIOSH/NFPA-approved respiratory protection.

· **Hand protection:**
Wear impervious gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

· **Material of gloves and breakthrough time of the glove material:**
The glove material must be suitable for use in a microbiological laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Activated Aspartate Aminotransferase Reagent 1 FOR USE WITH ARCHITECT

· **Eye protection:**
Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

· **Body protection:**
Normal use: protect personal clothing from spatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution).
Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

9 Physical and chemical properties

· **General Information**	
· **Color:**	Yellow
· **Odor:**	Odorless
· **Melting point/Melting range:**	Not determined
· **Boiling point/Boiling range:**	Not determined
· **Flammability (solid, gaseous)**	Not applicable
· **Explosion limits**	
· **Lower:**	Not determined
· **Upper:**	Not determined
· **Flash point**	Not applicable
· **pH-value at 20 °C (68 °F)**	8.65-8.75
· **Dynamic:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible
· **Vapor pressure:**	
· **Density at 20 °C (68 °F)**	1.023 g/cm³ (8.5369 lbs/gal)
· **Form:**	Liquid
· **Auto igniting**	Product is not self-igniting.
· **Danger of explosion**	Product does not present an explosion hazard.
· **Water:**	94.7 %
· **Solids content:**	4.2 %
· **Evaporation rate:**	Not determined

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided**
No decomposition if used and stored 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.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Activated Aspartate Aminotransferase Reagent 1 FOR USE WITH ARCHITECT

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

11 Toxicological information

· **Acute toxicity** Based on available data, the classification criteria are not met.
· **LD50/LC50 values for hazardous ingredients per OSHA criteria:**

· **Ingredients (100% pure substance/s):**		
CAS: 56-84-8 Aspartic acid		
	Mutagenicity	(Ames Assay) (Multiple methods) (mammalian cells) Positive in the human sperm morphology assay (experimental, oral, 5 men in study vs. 5 controls, unknown if dose-response relationship demonstrated). (mouse) (In vivo single gavage 2000 mg/kg bw) Bone marrow erythrocytes; endpoint = in vivo micronucleus (other) (E. coli with and without activation standard plate)
	Target Organ Effects	(human) Poisoning may cause liver changes.
CAS: 1310-73-2 Sodium hydroxide		
Oral	LD50	2,000 mg/kg (rat)
	LDLo	500 mg/kg (rabbit)
Dermal	LD50	1,350 mg/kg (rabbit)

· **Skin irritation:** Causes skin irritation.
· **Eye irritation:** Causes serious eye irritation.
· **Aspiration hazard**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Target organs/systems:**
Eye
Respiratory tract
Gastrointestinal tract
Skin

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Activated Aspartate Aminotransferase Reagent 1 FOR USE WITH ARCHITECT

12 Ecological information

· **Aquatic toxicity:** No further relevant information available.

· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable
· **vPvB:** Not applicable

· **Additional ecological information**
· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course, or sewage system.

13 Disposal considerations

· **Recommendation for disposal of unused product:** Dispose in accordance with federal, state and local regulations.
· **Waste disposal key:**
· **Recommendation for disposal of packaging:**
Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.
For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

· **Recommended cleansing agent:** Water with cleansing agents, if necessary.

14 Transport information

· **DOT, ADN, IMDG, IATA**	none

· **UN proper shipping name**
· **DOT, ADR, ADN, IMDG, IATA** none

· **Transport hazard class(es)**

· **DOT, ADR, ADN, IMDG, IATA**

· **Class**	none
· **DOT, IMDG, IATA**	none

· **Environmental hazards**
· **Marine pollutant:** No

· **Additional information**

· **DOT**
· **Remarks:** Not restricted for transportation.
· **IMDG**
· **Remarks:** Not restricted for transportation.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Activated Aspartate Aminotransferase Reagent 1 FOR USE WITH ARCHITECT

· **IATA**
· **Remarks:** Not restricted for transportation.

15 Regulatory information

· **SARA (Superfund Amendments and Reauthorization Act of 1986 - USA):**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
The product does not contain listed substances.

· **Section 313 (40CFR372.65):**
The product does not contain listed substances.

· **Hazardous Air Pollutants**
None of the ingredients is listed.

· **California Proposition 65 (USA):**

· **Chemicals known to cause cancer:**
The product does not contain listed substances.

· **Chemicals known to cause female reproductive toxicity:**
None of the ingredients is listed.

· **Chemicals known to cause male reproductive toxicity:**
None of the ingredients is listed.

· **Chemicals known to cause developmental reproductive toxicity:**

CAS: 1405-41-0	Gentamicin sulfate

16 Other information

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This information is not a substitute for the advice of a health care professional, nor is it a recommendation for any particular course of treatment. It is not intended to supplement, modify or supersede any information (e.g. labeling and package inserts) provided with respect to the medical use of the product. Abbott Laboratories assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

The information in this Safety Data Sheet (SDS) reflects the most current hazard information for this product.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Activated Aspartate Aminotransferase Reagent 1 FOR USE WITH ARCHITECT

· **Department issuing SDS**
- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

· **Contact**
- General information about this product:
Abbott Diagnostics
Technical Support
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision** 05/14/2024

· **Abbreviations and acronyms:**
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
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
DOT: US Department of Transportation
IATA: International Air Transport Association
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Skin Irritation 2: Skin corrosion/irritation – Category 2
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A

· *** Sections marked with an asterisk (*) have been altered since the previous version.**

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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1 Identification

· **Product name:** **Activated Aspartate Aminotransferase Reagent 2 FOR USE WITH ARCHITECT**

· **ADD List number:** 8L91/R2 NEW

· **Application of the substance / mixture:** For In Vitro Diagnostic Use

· **Manufacturer / Supplier:**
Abbott Diagnostics
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· **Department issuing SDS:** Abbott Diagnostics Environmental Health and Safety

· **Emergency telephone number**
Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.
Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

2 Hazard(s) identification

· **Classification of the substance or mixture**
The classification was made according to U.S. OSHA 29 CFR 1910.1200 and 1910.1030 and applicable European regulations, and is expanded upon from supplier company and/or literature data.

This product has been evaluated per the classification criteria in the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This product does not meet the criteria for classification in accordance with the GHS.

· **Label elements**

· **GHS label elements:** The product is labelled according to the Globally Harmonized System (GHS).

· **Hazard pictograms:** none

· **Signal word:** none

· **Hazard statements:** none

· **Routes of Exposure:**
- Skin: No adverse effects expected when used as directed.
- Eye: No adverse effects expected when used as directed.
- Inhalation: No adverse effects expected when used as directed.
- Ingestion: No adverse effects expected when used as directed.

· **Health:** No adverse effects expected if used as directed.
· **Fire:** Noncombustible
· **Reactivity:** Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.
· **IARC (International Agency for Research on Cancer)** Group 3

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Activated Aspartate Aminotransferase Reagent 2 FOR USE WITH ARCHITECT

· **Interpretation of the IARC listing**
Group 3: The substance or mixture listed above is not classifiable as to carcinogenicity in humans. Evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals.

3 Composition/information on ingredients

· **Chemical characterization:** Mixture of chemical and/or biological substances for in vitro diagnostic use.

· **Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):**

CAS: 77-86-1	Tris hydroxymethyl aminomethane	3.4561%
CAS: 56-84-8	Aspartic acid	1.5659%

4 First-aid measures

· **After inhalation:** Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.

· **After skin contact:**
Take off any clothing that the product touched.
Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.

· **After eye contact:**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists, get medical advice/attention. Wash hands after handling.

· **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.

· **Most important symptoms and effects, both acute and delayed:**
Kidney effects
Liver effects

· **Medical conditions aggravated by exposure:**
Pre-existing liver condition
Pre-existing kidney ailments

5 Fire-fighting measures

· **Suitable extinguishing agents**
Dry chemical, carbon dioxide (CO2), water spray or regular foam.
- Caution: CO2 will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
- For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.

· **Special hazards arising from the substance or mixture**
There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.
No further relevant information available.

· **Protective equipment**
For large fires, wear appropriate heat- and flame-resistant personal protective equipment and a NFPA/NIOSH approved positive-pressure, self-contained breathing apparatus.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected persons away.

· **Environmental precautions**
Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

· **Methods and material for containment and cleaning up**
Blot up small volumes of spilled or spattered product with paper towels or similar materials.
- Contain larger spills by placing absorbants around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:
- warm water and detergent or similar cleansing agent

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

· **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.

7 Handling and storage

· **Precautions for safe handling:**
Avoid direct contact with material. If handled, wash thoroughly. Practice general safety precautions.

· **Information about protection against explosions and fires:** The product is not flammable.

· **Requirements to be met by storerooms and receptacles:** Store only in the original container.

· **Information about storage in one common storage facility:** Store in original packaging.

· **Further information about storage conditions:**
Refer to the package insert or product label for additional information on storage conditions for product quality.

8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

CAS: 7647-01-0 hydrochloric acid (0.2145 %)	
PEL	Ceiling limit value: 7 mg/m³, 5 ppm
REL	Ceiling limit value: 7 mg/m³, 5 ppm
TLV	Ceiling limit value: 2 ppm A4

· **General protective and hygienic measures:**
Always maintain good housekeeping and follow general precautionary measures. Do not eat, drink or store food and beverages in areas where chemicals or specimens are used. Wash hands before breaks, after handling reagents and specimens, and at the end of the workshift.

· **Breathing equipment:**
Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

Other unusual conditions (e.g. volume spilled too big to clean up with materials in arm's reach) - Use appropriate NIOSH-approved air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use NIOSH/NFPA-approved respiratory protection.

· **Hand protection:**
Wear impervious gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

· **Material of gloves and breakthrough time of the glove material:**
The glove material must be suitable for use in a microbiological laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.

· **Eye protection:**
Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

· **Body protection:**
Normal use: protect personal clothing from spatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution).
Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

9 Physical and chemical properties

· **General Information**
· **Color:** Colorless
· **Odor:** Odorless

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 05/14/2024 Last alteration on 04/16/2024

Product name: Activated Aspartate Aminotransferase Reagent 2 FOR USE WITH ARCHITECT

· **Melting point/Melting range:**	Not determined
· **Boiling point/Boiling range:**	Not determined
· **Flammability (solid, gaseous)**	Not applicable
· **Explosion limits**	
· **Lower:**	Not determined
· **Upper:**	Not determined
· **Flash point**	Not applicable
· **pH-value at 20 °C (68 °F)**	4.95-5.05
· **Dynamic:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible
· **Vapor pressure:**	
· **Density at 20 °C (68 °F)**	1.02 g/cm³ (8.5119 lbs/gal)
· **Form:**	Solution
· **Auto igniting**	Product is not self-igniting.
· **Danger of explosion**	Product does not present an explosion hazard.
· **Water:**	93.9 %
· **Solids content:**	5.0 %
· **Evaporation rate:**	Not determined

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided**
No decomposition if used and stored 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.

11 Toxicological information

· **Acute toxicity** Based on available data, the classification criteria are not met.
· **LD50/LC50 values for hazardous ingredients per OSHA criteria:**

· **Ingredients (100% pure substance/s):**		
CAS: 77-86-1 Tris hydroxymethyl aminomethane		
Oral	LD50	5,900 mg/kg (rat)
	LDLo	1,000 mg/kg (rabbit)

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 05/14/2024 Last alteration on 04/16/2024

Product name: Activated Aspartate Aminotransferase Reagent 2 FOR USE WITH ARCHITECT

CAS: 56-84-8 Aspartic acid		
	Mutagenicity	(Ames Assay) (Multiple methods) (mammalian cells) Positive in the human sperm morphology assay (experimental, oral, 5 men in study vs. 5 controls, unknown if dose-response relationship demonstrated). (mouse) (In vivo single gavage 2000 mg/kg bw) Bone marrow erythrocytes; endpoint = in vivo micronucleus (other) (E. coli with and without activation standard plate)
	Target Organ Effects	(human) Poisoning may cause liver changes.

· **Skin irritation:** Based on available data, the classification criteria are not met.
· **Eye irritation:** Based on available data, the classification criteria are not met.

· **Sensitization:** Based on available data, the classification criteria are not met.
· **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.
· **Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.
· **Specific target organ toxicity - repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**		
CAS: 7647-01-0	hydrochloric acid	3

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Target organs/systems:** Kidneys

12 Ecological information

· **Aquatic toxicity:** No further relevant information available.

· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable
· **vPvB:** Not applicable

· **Additional ecological information**
· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course, or sewage system.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Activated Aspartate Aminotransferase Reagent 2 FOR USE WITH ARCHITECT

13 Disposal considerations

· **Recommendation for disposal of unused product:** Dispose in accordance with federal, state and local regulations.
· **Waste disposal key:**
· **Recommendation for disposal of packaging:**
Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.
For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

· **Recommended cleansing agent:** Water with cleansing agents, if necessary.

14 Transport information

· **DOT, ADN, IMDG, IATA** none

· **UN proper shipping name**
· **DOT, ADR, ADN, IMDG, IATA** none

· **Transport hazard class(es)**

· **DOT, ADR, ADN, IMDG, IATA**
· **Class** none
· **DOT, IMDG, IATA** none

· **Environmental hazards**
· **Marine pollutant:** No

· **Additional information**

· **DOT**
· **Remarks:** Not restricted for transportation.
· **IMDG**
· **Remarks:** Not restricted for transportation.
· **IATA**
· **Remarks:** Not restricted for transportation.

15 Regulatory information

· **SARA (Superfund Amendments and Reauthorization Act of 1986 - USA):**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**	
CAS: 7647-01-0	hydrochloric acid

· **Section 313 (40CFR372.65):**	
CAS: 7647-01-0	hydrochloric acid

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Activated Aspartate Aminotransferase Reagent 2 FOR USE WITH ARCHITECT

· **Hazardous Air Pollutants**

CAS: 7647-01-0	hydrochloric acid

· **California Proposition 65 (USA):**

· **Chemicals known to cause cancer:**

The product does not contain listed substances.

· **Chemicals known to cause female reproductive toxicity:**

None of the ingredients is listed.

· **Chemicals known to cause male reproductive toxicity:**

None of the ingredients is listed.

· **Chemicals known to cause developmental reproductive toxicity:**

None of the ingredients is listed.

16 Other information

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The information in this Safety Data Sheet (SDS) reflects the most current hazard information for this product.

· **Department issuing SDS**
- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

· **Contact**
- General information about this product:
Abbott Diagnostics
Technical Support
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision** 05/14/2024

· **Abbreviations and acronyms:**
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

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Product name: Activated Aspartate Aminotransferase Reagent 2 FOR USE WITH ARCHITECT

ICAO: International Civil Aviation Organisation
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
DOT: US Department of Transportation
IATA: International Air Transport Association
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)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

· *** Sections marked with an asterisk (*) have been altered since the previous version.**