

Last alteration on 05/29/2017

1 Identification

Product name: ISTAT BNP Control Level 1 / ISTAT BNP Control Level 2 / ISTAT BNP Control Level 3 / ISTAT BNP CalVer Control Level 1, 2 & 3

• ADD List number: 06P17-05

06P17-06 06P17-07 06P17-08

· Application of the substance / mixture:

Release date 05/29/2017

For In Vitro Diagnostic Use To verify the integrity of newly received i-STAT BNP cartridges

· 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 675922.

- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the

Virgin Islands.

- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from

outside the United States or from a ship at sea.

2 Hazard(s) identification

Classification of the substance or mixture

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: none

- · Hazard pictograms: none
- · Signal word: none
- · Hazard statements: none

· Routes of Exposure:

For bloodborne pathogens and potentially infectious materials:

- non-intact skin
- mucous membranes (which includes, but is not limited to, the lining of the nose, mouth and throat)
- parenteral contact (e.g. by injection, puncture)
- Hazard Overview
 - · Health: No adverse effects expected if used as directed.
 - · Fire: Noncombustible



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0.09%

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• Reactivity: Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.

[•] Other hazards

This product contains potentially infectious material. Refer to the US OSHA Bloodborne pathogens standard (29 CFR 1910.1030) for additional relevant information.

3 Composition/information on ingredients

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· 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: 26628-22-8 Sodium azide

4 First-aid measures

• After inhalation: Remove from source of exposure. Seek medical attention and appropriate follow-up.

After skin contact:

Take off any clothing that the product touched. Wash affected area with soap and water. Seek medical attention and appropriate follow-up.

After eye contact:

Rinse open eye(s) cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention and appropriate follow-up. Wash hands after handling.

• After swallowing: Rinse mouth with water. Seek medical attention and appropriate follow-up.

Information for Medical Personnel

This product contains human sourced and/or potentially infectious components. See package insert / instructions for use for details. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection.

· Most important symptoms and effects, both acute and delayed: None expected

Medical conditions aggravated by exposure: None known

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.

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.



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6 Accidental release measures

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Personal precautions, protective equipment and emergency procedures

Handle as a potentially infectious material.

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

Apply a suitable disinfectant. Select a disinfectant that is effective against bloodborne infectious agents, as well as other microbial agents that you might expect to be prevalent in your population. A disinfectant that is effective against Mycobacterium tuberculosis is generally effective against all known viruses and non-sporeforming bacteria, and is suitable for most clinical laboratory situations.

NOTE: Commercial disinfectants must be used according to manufacturer directions. Disinfectants are typically hazardous chemicals that react with many chemicals, materials and living tissues. Obtain and review the manufacturers safety information before using the disinfectant.

This product contains sodium azide, which is toxic and reactive. See Sections 10 and 13 for additional information that could affect handling and disposal of contaminated spill materials.

NOTE FOR LARGE-VOLUME SPILL: This product contains sodium azide, which reacts with acid to liberate hydrazoic acid, a very toxic gas. Select a disinfectant with the following properties if disinfection of materials used to absorb a large volume of spilled product is required:

- Do not use any chemical or product with a pH below 6 to disinfect waste that contains sodium azide. Hydrazoic acid, a toxic gas, will be released when the pH is lower than 6.

- Do not use any chemical or product that contains mercury or any other metal to disinfect waste that contains sodium azide. This will create metal azide compounds, which can be highly explosive under pressure or shock (percussion).

- Select a disinfectant that does not bubble, effervesce or otherwise generate aerosols.

- Do not use excess disinfectant.
- Failure to follow manufacturers directions may lead to unexpected reactions with the waste.

- Do not use a disinfectant if you do not have the proper facility, equipment and other appropriate protective measures available to work with it safely.

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: Handle as a potentially infectious material.



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· 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. Refer to the package insert or product label for additional information on storage conditions for product quality.
- · Information about storage in one common storage facility: Store in original packaging.

· Further information about storage conditions: Protect from heat and direct sunlight.

8 Exposure controls/personal protection Components with Occupational Exposure Limits CAS: 67-56-1 Methanol (1.00 %) PEL TWA: 260 mg/m³, 200 ppm REL STEL/C: 325 mg/m³, 250 ppm TWA: 260 mg/m³, 200 ppm Skin TLV STEL/C: 328 mg/m³, 250 ppm TWA: 262 mg/m³, 200 ppm Skin; BEI CAS: 56-75-7 Chloramphenicol (0.10 %) WEEL TWA: 0.5 mg/m³ CAS: 26628-22-8 Sodium azide (0.09 %) REL Ceiling limit value: 0.3** mg/m3, 0.1* ppm *as HN3; **as NaN3; Skin Ceiling limit value: 0.29** mg/m3, 0.11* ppm TLV *as HN3 vapor **as NaN3 CAS: 7647-01-0 hydrochloric acid (0.02 %) PEL Ceiling limit value: 7 mg/m³, 5 ppm REL Ceiling limit value: 7 mg/m³, 5 ppm TLV Ceiling limit value: 2.98 mg/m³, 2 ppm · Ingredients with biological limit values: CAS: 67-56-1 Methanol (1.00 %) BEI 15 mg/L Medium: urine Time: end of shift Parameter: Methanol (background, nonspecific) · 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. Observe universal precautions and other appropriate biosafety practices for handling potentially infectious material. · 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.



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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:

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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.

\cdot 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.

General Information		
· Form:	Liquid	
· Color:	Light yellow	
· Odor:	Mild	
pH-value	Not determined	
• Melting point/Melting range:	Not determined	
· Boiling point/Boiling range:	Not determined	
Flash point	Not applicable	
Flammability (solid, gaseous		
Auto igniting	Product is not self-igniting.	
Danger of explosion	Product does not present an explosion hazard.	
Explosion limits	' '	
· Lower:	Not determined	
· Upper:	Not determined	
Density	Not determined	
· Evaporation rate:	Not determined	
Solubility in / Miscibility with	า	
· Water:	Not miscible or difficult to mix	
· Dynamic:	Not determined	



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· Water:

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0.1 %

10 Stability and reactivity

 Thermal decomposition / conditions to be avoided No decomposition if used and stored according to specifications.

Possibility of hazardous reactions:

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This product contains sodium azide. Sodium azide solutions are reported to:

- react with acids to release hydrazoic acid, a very toxic gas. Higher quantities of hydrazoic acid are released as the solution becomes more acidic (i.e., as the pH of the solution gets lower). Low quantities of hydrazoic acid can be released from sodium azide in water.

- react with certain metals (copper, lead, silver, brass) to form explosive metal azide compounds. Violent explosions have been reported during plumbing work on drain systems containing accumulations of azide on copper, lead, brass, or solder.

• 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

• LD50/LC50 values for hazardous ingredients per OSHA criteria: • Ingredients (100% pure substance/s): Not applicable.

- · Primary toxicological effects of the final product:
 - Skin irritation: No irritant effect.
 - · Eye irritation: No irritant effect.
- · Sensitization: No sensitizing effects known.

· Additional toxicological information: None

· 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: Unknown

12 Ecological information

· Aquatic toxicity:

Harmful to aquatic organisms. May cause long-term adverse effects in the aquatic environment.



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Additional ecological information

· General notes: Not known to be a water pollutant.

Results of PBT and vPvB assessment

· PBT: Not applicable

· vPvB: Not applicable

13 Disposal considerations

· Recommendation for disposal of unused product:

Dispose in accordance with federal, state and local regulations and institutional requirements. Waste containing this product may be considered hazardous per U.S. EPA, state or local regulations. The following may be particularly important when identifying appropriate disposal:

- Potentially infectious. See Section 4, Information for Medical Personnel, for more information.

- See Section 6 for information when institutional or regulatory requirements include any sort of treatment of potentially infectious waste.

- Contains sodium azide. See Section 10 when considering how to appropriately dispose of unused product. For drain systems with pipes or solder containing copper, lead, brass and/or silver, flush drains thoroughly with copious amounts of water to prevent the formation of potentially explosive metal azides in plumbing. Detailed information about azides in drains is available from the U.S. NIOSH Current Intelligence Bulletin No. 13 (August 16, 1976).

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, IAT	
Transport hazard class(e	s)
· DOT, ADR, ADN, IMDG, IAT · Class · DOT, IMDG, IATA	A none none
• Environmental hazards • Marine pollutant:	No
Additional information	
· DOT · Remarks: · ADR · Remarks:	Not restricted for transportation.
· IMDG · Remarks:	Not restricted for transportation.



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· IATA · Remarks:

Not restricted for transportation.

15 Regulatory information

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 SARA (Superfund Amendments and Reauthorization) 	on Act of 1986 - USA):
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	China (Superiana Amerianente ana ricadinenzation Act of 1000 - 00A)			
	· Section 302/304 (40CFR355.30 / 40CFR355.40):			
	CAS: 143-33-9	sodium cyanide		
	CAS: 26628-22-8	Sodium azide		
	CAS: 7647-01-0	hydrochloric acid		
Ē	Section 313 (40CFR372.65):			
	CAS: 67-56-1	Methanol		
	CAS: 143-33-9	sodium cyanide		
	CAS: 26628-22-8	Sodium azide		
	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:				
	CAS: 143-33-9 sodium cyanide			
Chemicals known to cause developmental reproductive toxicity:				
	CAS: 67-56-1	Methanol		
	CAS: 3810-74-0	Streptomycin sulphate		

16 Other information

The information and recommendations contained herein are based upon information or tests believed to be reliable. Abbott Laboratories does not guarantee the accuracy or completeness of this information or recommendations contained herein, NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

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Department issuing SDS

 Abbott Diagnostics Safety, Health and Environmental Assurance Department 0571

· Contact

- General information about this product: Abbott Diagnostics



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USA

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Technical Support 100 Abbott Park Road Abbott Park, IL 60064-3500

Release date 05/29/2017

Phone: 1-877-4 ABBOTT • Date of preparation / last revision 05/29/2017 / 2

· 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 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** BEI: Biological Exposure Limit

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