



Release Date: 11/6/18

REF	Product Name
GTIN	

08P4401	<i>Alinity c UIBC Calibrator Kit</i>
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Components:

08P44/CAL	Alinity c UIBC Calibrator
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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.

1 Identification

· **Product name:** Alinity c UIBC Calibrator

· **ADD List number:** 08P44/CAL

· **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.

- 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**

Skin Sens. 1 H317 May cause an allergic skin reaction.

Carc. 2 H351 Suspected of causing cancer.

Aquatic Acute 3 H402 Harmful to aquatic life.

· **Label elements**

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

· **Hazard pictograms:**



· **Signal word:** Warning

· **Hazard-determining components of labeling:**

Hydroxylamine hydrochloride

· **Hazard statements:**

H317 May cause an allergic skin reaction.

H351 Suspected of causing cancer.

H402 Harmful to aquatic life.

· **Precautionary statements:**

P201 Obtain special instructions before use.

P261 Avoid breathing mist / vapors / spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

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P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection.
P302+P352 If on skin: Wash with plenty of water.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents / container in accordance with local regulations.

· **Routes of Exposure:** Skin

· **Hazard Overview**

· **Health:**

Sensitizer in contact with skin
Contains a suspect carcinogen.

· **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: 5470-11-1	Hydroxylamine hydrochloride
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0.50%

4 First-aid measures

· **General information:** Immediately remove any clothing soiled by the product.

· **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.

· **Information for Medical Personnel**

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

Allergic reactions

Possibly immune response

This product may cause skin sensitization reactions in some people. See Section 11 for additional information.

· **Medical conditions aggravated by exposure:**

Pre-existing skin ailments

Skin allergies

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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.

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 absorbents 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:

Provide local exhaust ventilation if dust or vapor is formed.

Avoid contact with skin.

Avoid inhalation.

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

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Product name: Alinity c UIBC Calibrator**· 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

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.

Immediately remove all soiled and contaminated clothing.

· 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.

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9 Physical and chemical properties

General Information

· **Form:** Solution
· **Color:** Colorless

· **Odor:** Odorless

pH-value at 20 °C (68 °F)

3

· **Melting point/Melting range:** Not determined
· **Boiling point/Boiling range:** Not determined

Flash point

Not applicable

Flammability (solid, gaseous)

Not applicable

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 at 20 °C (68 °F)

1.01 g/cm³ (8.4285 lbs/gal)

· **Evaporation rate:** Not determined

Solubility in / Miscibility with

· **Water:** Fully miscible
· **Dynamic:** Not determined

· **Water:** 99.5 %
· **Solids content:** 0.0 %

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.

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11 Toxicological information

Acute toxicity

LD50/LC50 values for hazardous ingredients per OSHA criteria:

Ingredients (100% pure substance/s):

CAS: 5470-11-1 Hydroxylamine hydrochloride

Oral	LD50	200 mg/kg (mammal) Based on toxicology testing of hydroxylammonium sulfate. Species = cat Repeated vomiting, increased salivation, apathia, cyanosis. 2/6 cats died 2 days after application. BASF study Cited in ECBI/14/03 408 mg/kg (mouse) 141 mg/kg (rat) Angus (1982) values cited in ECBI/14/03: Oral LD50 = 545 mg/kg. At 250 mg/kg: temporary cyanosis At 500 mg/kg: marked cyanosis, convulsions; 2/5 rats died.
Dermal	LD50	100-500 mg/kg (rabbit) Cited in ECBI/14/03. Based on toxicology testing of hydroxylammonium sulfate. Occlusive. At 100 mg/kg: 2/10 rabbits died; 18.7% MetHb At 500 mg/kg: 9/10 rabbits died; 60.8% MetHb >500 mg/kg (rat) Cited in ECBI/14/03. Based on toxicology testing of hydroxylammonium sulfate. No mortality; no cyanosis. Increase in methemoglobin (4%) at 500 mg/kg.
	LD50	1,500-2,000 gm/kg (mammal) Cited in ECBI/14/03. Based on toxicology testing of hydroxylammonium sulfate. Semi-occlusive. < or = 1500: all 10 animals survived. 2000: 7/10 died. >1 gm/kg (rabbit) Cited in ECBI/14/03. Based on toxicology testing of hydroxylammonium sulfate. Semi-occlusive. < or = 1000 mg/kg: 0/10 animals died (no mortality) 1000: 6.2% MetHb; in 3 animals Heinz bodies 4d postexposure.
	Mutagenicity	(Ames Assay) Positive in E. coli and S. cerevisiae mutagenicity assays. (mammalian cells) Positive in cell transformation assay. Negative in cultured human fibroblast unscheduled DNA synthesis assay and the sister chromatid assay.
	Carcinogenicity	3 (rat) Cited in ECBI/14/03. Based on toxicology testing of hydroxylammonium sulfate. Increased evidence of tumors of the spleen in male and female Wistar rats, after administration by oral route.

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- **Primary toxicological effects of the final product:**
 - **Skin irritation:** No irritant effect.
 - **Eye irritation:** No irritant effect.
- **Sensitization:** Sensitization possible through skin contact.
- **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:**

Skin

Immune system

12 Ecological information

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

Product name: Alinity c UIBC Calibrator

· 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.

· ADR

· 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):

The product does not contain listed substances.

· Section 313 (40CFR372.65):

The product does not contain listed substances.

· 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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OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

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.

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** 11/06/2018 / 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
Skin Sens. 1: Skin sensitisation – Category 1
Carc. 2: Carcinogenicity – Category 2
Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard – Category 3

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