Abbott

Release Date: 3/18/24

REF GTIN	Product Name
08P4301	***Alinity c Hemoglobin A1c Calibrators***

Components:

08P43 CAL 1 **08P43 CAL 2**	**Alinity c Hemoglobin A1c Calibrators 1-2 (as sold)**
08P43 CAL1 RECO **08P43 CAL2 RECO**	**Alinity c Hemoglobin A1c Calibrators 1 and 2 as used (reconstituted)**

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

 Release date 03/18/2024 Last alteration on 03/18/2024

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1 Identification

· **Product name:** Alinity c Hemoglobin A1c Calibrators 1-2 (as sold)

· **ADD List number:**
08P43 CAL 1
08P43 CAL 2

· **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.
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:** none

· **Signal word:** none

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

· **Hazard statements:**
H402 Harmful to aquatic life.

· **Precautionary statements:**
P273 Avoid release to the environment.
P501 Dispose of contents / container in accordance with local regulations.

· **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)

· **Health:** No adverse effects expected if used as directed.

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Product name: Alinity c Hemoglobin A1c Calibrators 1-2 (as sold)

· **Fire:** Noncombustible
· **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

· **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: 145224-94-8	Morpholinoethanesulfonic acid, monohydrate	4.9999%
CAS: 26027-38-3	Ethoxylated p-nonylphenol	1.9999%
CAS: 7632-00-0	Sodium nitrite	0.9999%

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 material. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced material should be considered potentially infectious.

The human-sourced material used in this product has been tested and found to be:
- Nonreactive for HBsAg (hepatitis B surface antigen)
- Nonreactive for HCV (hepatitis C virus)
- Nonreactive for HIV-1 Ag (human immunodeficiency virus type 1 antigen)
- Nonreactive for anti-HIV-1 (antibodies to human immunodeficiency virus type 1)
- Nonreactive for anti-HIV-2 (antibodies to human immunodeficiency virus type 2)

· **Most important symptoms and effects, both acute and delayed:**
Liver effects
Cramps
Gastric or intestinal disorders
Nausea
· **Medical conditions aggravated by exposure:**
Pre-existing liver condition

Pre-existing gastrointestinal tract 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**
Handle as a potentially infectious material.
Avoid formation of dust.
If material is released or spilled, minimize exposure by using appropriate personal protective equipment as listed in Section 8. Keep unprotected persons away.

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

· **Methods and material for containment and cleaning up**
Damp down dust with water spray.
Sweep up material and place into a suitable disposal container.
Vacuum (HEPA filter or equivalent recommended) or wet sweep products that are powders to avoid dust dispersal.

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 manufacturer's safety information before using the disinfectant.

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.

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Product name: Alinity c Hemoglobin A1c Calibrators 1-2 (as sold)

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.

· **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: 1310-73-2 Sodium hydroxide (0.199 %)	
PEL	TWA: 2 mg/m³
REL	Ceiling limit value: 2 mg/m³
TLV	Ceiling limit value: 2 mg/m³

· **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.

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:**	Brown
· **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**	Not applicable.
· **Dynamic:**	Not applicable.
· **Solubility in / Miscibility with**	
· **Water:**	Soluble
· **Vapor pressure:**	
· **Density**	Not determined
· **Form:**	Powder
· **Auto igniting**	Product is not self-igniting.
· **Danger of explosion**	Product is a carbon-rich organic solid, and is presumed to be capable of producing a combustible dust.
· **Evaporation rate:**	Not applicable.

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.

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Product name: Alinity c Hemoglobin A1c Calibrators 1-2 (as sold)

· **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: 145224-94-8 Morpholinoethanesulfonic acid, monohydrate		
Oral	LD50	1,880 mg/kg (rat) By analogy to morpholinopropylchloride.
CAS: 26027-38-3 Ethoxylated p-nonylphenol		
Oral	LD50	1,310 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)
Inhalation	LC50 1 h	>200 mg/l species unknown
	Target Organ Effects	In reproductive studies in rats and rabbits it showed effects on fertility including pre-implantaion mortality, reduced pup weight as well as some maternal effects. A 22 day subchronic mouse study indicated changes in liver and spleen weights, and weight loss in animals.
CAS: 7632-00-0 Sodium nitrite		
Oral	LD50	330 mg/kg (dog) 175 mg/kg (mouse) 186 mg/kg (rabbit) 180 mg/kg (rat)
Dermal	LD50	150 mg/kg (mouse) Subcutaneous route. 60 mg/kg (rabbit) Subcutaneous route. 97 mg/kg (rat) Subcutaneous route.
Inhalation	LC50 4 h	5.5 mg/l (rat)
	Mutagenicity	(Ames Assay) Positive in the Ames test, D. melanogaster mutation assay and the S. cerevisae gene reversion assay. (mammalian cells) Positive in the in vivo cytogenetic assay. Negative in the in vivo rodent dominant lethal assay.
	Target Organ Effects	(Unknown / Not specified) Has been used as a vasodilator, as a circulatory (blood pressure) depressant and to relieve smooth muscle spasm.

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		(human) In clinical use, sodium nitrite produces methemoglobinaemia. Adverse reactions include nausea, vomiting, abdominal pain, cyanosis, vasodilation and hypotension. (mammal) In reproductive studies, sodium nitrite was fetotoxic in mice and rats at maternally toxic dosages. Reported to cause gastrointestinal tumors in mice and rats after oral administration. It is believed that sodium nitrite is converted to carcinogenic/ mutagenic nitrosamines in the gastrointestinal tract.

· **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.

· **Additional toxicological information:**
Endocrine disrupting effects caused by this substance have been observed in the environment. No adverse human health effects are known. See Section 12 for more information.

· **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:**
Liver
Gastrointestinal tract
Spleen
Reproductive system

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**
4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO) degrade to 4-Nonylphenol, branched and linear, either already in wastewater treatment plants, or via further degradation processes in sediments (e.g. of aquatic bodies receiving the wastewater effluents) and soils (e.g. receiving sewage sludge). Available information for 4-NPnEO

indicate that 4-NPnEO contribute to the 4-NP concentration in the environment. A significant amount is either degraded to 4-NP itself in waste water treatment plants or is released to rivers in a form which may undergo further degradation to 4-NP.

· **General notes:**
Do not allow product to reach ground water, water course, or sewage system.
Harmful to aquatic organisms.

13 Disposal considerations

· **Recommendation for disposal of unused product:**
Dispose in accordance with federal, state and local regulations and institutional requirements. 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.

· **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.

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Product name: Alinity c Hemoglobin A1c Calibrators 1-2 (as sold)

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):**

CAS: 26027-38-3	Ethoxylated p-nonylphenol
CAS: 7632-00-0	Sodium nitrite

· **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:**

None of the ingredients is listed.

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.

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.

· **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

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Product name: Alinity c Hemoglobin A1c Calibrators 1-2 (as sold)

Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision** 03/18/2024

· **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
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.**

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1 Identification

· **Product name:** **Alinity c Hemoglobin A1c Calibrators 1 and 2 as used (reconstituted)**

· **ADD List number:**
08P43 CAL1 RECO
08P43 CAL2 RECO

· **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:** 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)

· **Health:** No adverse effects expected if used as directed.
· **Fire:** Noncombustible

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Product name: Alinity c Hemoglobin A1c Calibrators 1 and 2 as used (reconstituted)

· **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

· **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):**
While this product is not considered hazardous by the criteria in 29 CFR 1910.1200, important information regarding the safe handling, transport and disposal of this product is contained in this SDS.

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 material. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced material should be considered potentially infectious.

The human-sourced material used in this product has been tested and found to be:
- Nonreactive for HBsAg (hepatitis B surface antigen)
- Nonreactive for HCV (hepatitis C virus)
- Nonreactive for HIV-1 Ag (human immunodeficiency virus type 1 antigen)
- Nonreactive for anti-HIV-1 (antibodies to human immunodeficiency virus type 1)
- Nonreactive for anti-HIV-2 (antibodies to human immunodeficiency virus type 2)

· **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 (CO_2), water spray or regular foam.
- Caution: CO_2 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.

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Product name: Alinity c Hemoglobin A1c Calibrators 1 and 2 as used (reconstituted)

· **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**
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 manufacturer's safety information before using the disinfectant.

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.

· **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.

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.

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.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

 Release date 03/18/2024 Last alteration on 03/18/2024

Product name: Alinity c Hemoglobin A1c Calibrators 1 and 2 as used (reconstituted)

9 Physical and chemical properties

· **General Information**	
· **Color:**	Light brown
· **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)**	6
· **Dynamic:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible
· **Vapor pressure:**	
· **Density at 20 °C (68 °F)**	1.01 g/cm³ (8.4285 lbs/gal)
· **Form:**	Solution
· **Auto igniting**	Product is not self-igniting.
· **Danger of explosion**	Product does not present an explosion hazard.
· **Water:**	94.2 %
· **Solids content:**	0.0 %
· **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):** Not applicable.
· **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.

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· **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.

· **Additional toxicological information:**
Endocrine disrupting effects caused by this substance have been observed in the environment. No adverse human health effects are known. See Section 12 for more information.

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

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

· **Additional ecological information**
4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO) degrade to 4-Nonylphenol, branched and linear, either already in wastewater treatment plants, or via further degradation processes in sediments (e.g. of aquatic bodies receiving the wastewater effluents) and soils (e.g. receiving sewage sludge). Available information for 4-NPnEO indicate that 4-NPnEO contribute to the 4-NP concentration in the environment. A significant amount is either degraded to 4-NP itself in waste water treatment plants or is released to rivers in a form which may undergo further degradation to 4-NP.
· **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 and institutional requirements. 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.

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· **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):**
The product does not contain listed substances.

· **Section 313 (40CFR372.65):**

CAS: 26027-38-3	Ethoxylated p-nonylphenol
CAS: 7632-00-0	Sodium nitrite

· **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.

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· **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:
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Technical Support
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision** 03/18/2024

· **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)
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

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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.**