Abbott

Release Date: 6/5/24

REF GTIN	Product Name
04T8120 **04T8130**	***Total Protein2 for use with Alinity c***

Components:

04T81/R1	**Total Protein2 for use with Alinity c R1**

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:** Total Protein2 for use with Alinity c R1

· **ADD List number:** 04T81/R1

· **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.

Corrosive to Metals 1	H290 May be corrosive to metals.
Skin Corrosion 1A	H314 Causes severe skin burns and eye damage.
Aquatic Acute 2	H401 Toxic to aquatic life.
Aquatic Chronic 2	H411 Toxic to aquatic life with long lasting effects.

· **Label elements**

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

· **Hazard pictograms:**



· **Signal word:** Danger

· **Hazard-determining components of labeling:**
Sodium hydroxide
Copper sulfate (pentahydrate)

· **Hazard statements:**
H290 May be corrosive to metals.
H314 Causes severe skin burns and eye damage.
H411 Toxic to aquatic life with long lasting effects.

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Product name: Total Protein2 for use with Alinity c R1

· **Precautionary statements:**

P234	Keep only in original container.
P260	Do not breathe mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection.
P301+P330+P331	If swallowed: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/physician.
P390	Absorb spillage to prevent material damage.
P501	Dispose of contents / container in accordance with local regulations.

· **Routes of Exposure:**
Skin
Eye
· **Health:** Corrosive
· **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: 1310-73-2	Sodium hydroxide	4.49%
CAS: 56-81-5	Glycerol	2.31%
CAS: 7758-99-8	Copper sulfate (pentahydrate)	0.60%

4 First-aid measures

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

· **After inhalation:**
Supply fresh air or oxygen; seek immediate medical attention.
Symptoms (such as breathing difficulty) may be delayed and lead to underestimating the possible damage. Provide medical observation for at least 48 hours after exposure.

· **After skin contact:**
Take off any clothing that the product touched. Rinse skin with running water for 15 to 20 minutes. Seek medical attention.
Symptoms (such as pain) may be delayed and lead to underestimating the possible damage. Provide medical observation for at least 24 hours after exposure.

· **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.
Symptoms (such as pain) may be delayed and lead to underestimating the possible damage. Provide medical observation for at least 48 hours after exposure.

· **After swallowing:** Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

· **Most important symptoms and effects, both acute and delayed:**
Kidney effects
Cramps
Gastric or intestinal disorders
Nausea
Possible chemical burns to the skin and to the eyes
Respiratory irritation

· **Medical conditions aggravated by exposure:**
Pre-existing eye ailments
Pre-existing respiratory ailments
Pre-existing kidney ailments
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**
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 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 following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the remaining constituent has no known exposure limits.

CAS: 56-81-5 Glycerol (2.31 %)	
PEL	TWA: 15* 5** mg/m³ mist; *total dust **respirable fraction
TLV	TLV withdrawn-insufficient data human occup. exp.
CAS: 7758-99-8 Copper sulfate (pentahydrate) (0.60 %)	
ACGIH TLV	STEL/C: 1 mg/m³ for copper dusts & mists as Cu
OSHA PEL	STEL/C: 1 mg/m³ for copper dusts & mists as Cu
CAS: 7681-11-0 Potassium iodide (0.20 %)	
TLV	TWA: 0.01 ppm A4; Skin; *inhalation

· **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.
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.

9 Physical and chemical properties

· **General Information**	
· **Color:**	Blue
· **Odor:**	Not Determined
· **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)**	≥14
· **Dynamic:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible
· **Vapor pressure:**	
· **Density at 20 °C (68 °F)**	1.092 g/cm³ (9.1127 lbs/gal)
· **Form:**	Solution
· **Auto igniting**	Product is not self-igniting.
· **Danger of explosion**	Product does not present an explosion hazard.
· **Water:**	91.2 %
· **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:** Strong exothermic reaction with acids

· **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: 1310-73-2 Sodium hydroxide		
Oral	LD50	2,000 mg/kg (rat)
	LDLo	500 mg/kg (rabbit)
Dermal	LD50	1,350 mg/kg (rabbit)
CAS: 56-81-5 Glycerol		
Oral	LD50	27,200 mg/kg (rat)
	TDLo (Other effects)	1,428 mg/kg (human) Reported headaches, nausea and vomiting.
Dermal	LD50	>10,000 mg/kg (rabbit)
Inhalation	LC50 1 h	0.57 mg/l (Rat)
	Mutagenicity	(Ames Assay)

· **Skin irritation:** Causes severe skin burns and eye damage.
· **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
Kidneys
Gastrointestinal tract
Skin

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 product to reach ground water, water course, or sewage system.
Rinse off of large volumes into drains or the aquatic environment may lead to increased pH values. A high pH value harms aquatic organisms.
Toxic for aquatic organisms

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.

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Product name: Total Protein2 for use with Alinity c R1

14 Transport information

· **DOT, IMDG, IATA** UN1824

· **UN proper shipping name**

· **DOT** Sodium hydroxide solution
· **ADR** SODIUM HYDROXIDE SOLUTION, ENVIRONMENTALLY HAZARDOUS
· **IMDG** SODIUM HYDROXIDE SOLUTION, MARINE POLLUTANT
· **IATA** SODIUM HYDROXIDE SOLUTION

· **Transport hazard class(es)**

· **DOT**



· **Class** 8 Corrosive substances
· **Label** 8
· **Class** 8 Corrosive substances
· **IMDG**



· **Class** 8 Corrosive substances
· **Label** 8
· **IATA**



· **Class** 8 Corrosive substances
· **Label** 8
· **DOT, IMDG, IATA** II

· **Environmental hazards**

· **Marine pollutant:** Symbol (fish and tree)
· **Special marking (IATA):**
· **EMS Number:** F-A,S-B
· **Segregation groups** (SGG18) Alkalis
· **Stowage Category** A
· **Segregation Code** SG35 Stow "separated from" SGG1-acids

· **Additional information** The information in this section reflects the actual chemical name and transport information for the material. Due to legal exceptions that are permitted by transport regulations, the proper shipping name and transport information included on the actual shipping document may differ. When this product is shipped as a component of an in

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·	vitro diagnostic medical device, exceptions that may be used include, but are not limited to, the following: - Chemical Kit - UN3316, class 9 - Excepted Quantity - Consumer Commodity
· **DOT**	
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **IMDG**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml

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:**

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.

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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.

· **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** 06/05/2024 / 9

· **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
Corrosive to Metals 1: Corrosive to metals – Category 1
Skin Corrosion 1A: Skin corrosion/irritation – Category 1A
Aquatic Acute 2: Hazardous to the aquatic environment - acute aquatic hazard – Category 2
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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