Release Date: 8/4/15

REF GTIN	Product Name
7D80-31 **00380740013042**	***CLINICAL CHEMISTRY Lipase Reagent Kit***

Components:

7D80-R1 (New)	**CLINICAL CHEMISTRY Lipase Reagent 1**
7D80-R1A (New)	**CLINICAL CHEMISTRY Lipase Reagent 1A**
7D80/R2	**CLINICAL CHEMISTRY Lipase Reagent 2**
7D80 R1A Recons	**CLINICAL CHEMISTRY Lipase Reagent 1A (Reconstituted / As-Used)**

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 MSDSs, please contact your local Safety Representative.

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1 Identification

· **Product name:** CLINICAL CHEMISTRY Lipase Reagent 1

· **ADD List number:** 7D80-R1 (New)

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

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

Phone: 1-877-4 ABBOTT

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

· **Emergency telephone number:**

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

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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:** Inhalation

· **Hazard Overview**
· **Health:** No adverse effects expected if used as directed.
· **Fire:** Noncombustible
· **Reactivity:** Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.

3 Composition/information on ingredients

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

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1

· **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.

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4 First-aid measures

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

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

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

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

· **Information for Medical Personnel**

· **Most important symptoms and effects, both acute and delayed:** None expected
· **Medical conditions aggravated by exposure:** None known

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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.

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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.

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1

· **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

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 manufacturer's 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:**
Avoid direct contact with material. If handled, wash thoroughly. Practice general safety precautions.

· **Information about protection against explosions and fires:** No special measures required.

· **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.

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1

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8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**

12125-02-9 ammonium chloride (0.07 %)	
REL	STEL/C: 20 mg/m³ TWA: 10 mg/m³
TLV	STEL/C: 20 mg/m³ TWA: 10 mg/m³
26628-22-8 Sodium azide (0.05 %)	
REL	Ceiling limit value: 0.3** mg/m³, 0.1* ppm *as HN3; **as NaN3; Skin
TLV	Ceiling limit value: 0.29** mg/m³, 0.11* ppm *as HN3 vapor **as NaN3

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

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

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

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

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

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

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

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

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

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1

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9 Physical and chemical properties

· **General Information**
· **Form:** Solution
· **Color:** Whitish

· **Odor:** Odorless

· **pH-value at 20 °C (68 °F)** 6.6
· **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 g/cm³ (8.345 lbs/gal)
· **Evaporation rate:** Not determined

· **Solubility in / Miscibility with**
· **Water:** Fully miscible
· **Dynamic:** Not determined

· **Water:** 98.9 %

*
10 Stability and reactivity

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

· **Possibility of hazardous reactions:**
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.

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1

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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:** 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 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:
- 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.

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1

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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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.

· **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):**

26628-22-8	Sodium azide

· **Section 313 (40CFR372.65):**

26628-22-8	Sodium azide

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

· **Chemicals known to cause cancer:**

Igepal CO-720

· **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.

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1

· **Chemicals known to cause developmental reproductive toxicity:**
Igepal CO-720

· **Labelling according to Directives 67/548/EEC or 1999/45/EC**

· **Hazard determining substance/s of labeling:**
Sodium azide

· **Risk phrases:**
32 Contact with acids liberates very toxic gas.

· **Safety phrases:**
35 This material and its container must be disposed of in a safe way.

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

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision** 08/04/2015 / 11

· **Abbreviations and acronyms:**
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic

vPvB: very persistent and very bioaccumulative

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

Safety Data Sheet

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1 Identification

· **Product name:** CLINICAL CHEMISTRY Lipase Reagent 1A

· **ADD List number:** 7D80-R1A (New)

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

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

Phone: 1-877-4 ABBOTT

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

· **Emergency telephone number:**

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

Aquatic Chronic 3 H412 Harmful 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:** none

· **Signal word:** none

· **Hazard statements:**
H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements:**
P273 Avoid release to the environment.
P501 This material and its container must be disposed of in a safe way.

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

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1A

· **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):**

	Igepal CO-720	3.566%
4432-31-9	2-Morpholinoethanesulphonic acid	1.46%
7791-18-6	Magnesium chloride hexahydrate	1.286%

*
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 anti-HCV (antibodies to hepatitis C virus)
- Nonreactive for HIV-1 Ag or HIV-1 RNA (human immunodeficiency virus type 1 antigen or human immunodeficiency virus type 1 ribonucleic acid)
- Nonreactive for anti-HIV-1 (antibodies to human immunodeficiency virus type 1)
- Nonreactive for anti-HIV-2 (antibodies to human immunodeficiency virus type 2)
- Nonreactive for syphilis bacteria (Treponema pallidum pallidum)

· **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.

*
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.
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.
Do not discharge to storm drains or sewage system.

· **Information about protection against explosions and fires:** Combustible - finely divided dust may be explosive.

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1A

· **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**

57-50-1 Sucrose, pure (71.318 %)

PEL	TWA: 15* 5** mg/m³ *total dust **respirable fraction
REL	TWA: 10* 5** mg/m³ *total dust **respirable fraction
TLV	TWA: 10 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.

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1A

· **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**
· **Form:** Spray dried powder
· **Color:** Whitish

· **Odor:** Odorless

· **pH-value at 20 °C (68 °F)** 6.6
Not applicable.
· **Melting point/Melting range:** Not determined
· **Boiling point/Boiling range:** Not determined

· **Flash point** Not applicable
· **Flammability (solid, gaseous)** Not determined.
· **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 applicable.

· **Solubility in / Miscibility with**
· **Water:** Soluble
· **Dynamic:** Not applicable.
· **Solids content:** 100.0 %

*

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.

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1A

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11 Toxicological information

· **Acute toxicity**

· **LD50/LC50 values for hazardous ingredients per OSHA criteria:**

· **Ingredients (100% pure substance/s):**		
Igepal CO-720		
Oral	LD50	4000 mg/kg (rat)
4432-31-9 2-Morpholinoethanesulphonic acid		
Oral	LD50	316 mg/kg (bird) Quail 1880 mg/kg (rat) By analogy to morpholinopropylchloride hydrochloride.
7791-18-6 Magnesium chloride hexahydrate		
Oral	LD50	8100 mg/kg (rat) LD50 (ip) = 775mg/kg in mice LDlo (iv) = 250 mg/kg in guinea pigs

· **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:**	
Igepal CO-720	
LC50 96 h	> 10 mg/l (other) Fish toxicity reported in Lepomis macrochirus (bluegill).

· **Additional ecological information**

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

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1A

· **vPvB:** Not applicable

*
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.

· **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.
· **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.

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1A

· **Section 313 (40CFR372.65):**

The product does not contain listed substances.

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

· **Chemicals known to cause cancer:**

Igepal CO-720

· **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:**

Igepal CO-720

· **Labelling according to Directives 67/548/EEC or 1999/45/EC**

· **Risk phrases:**

52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

· **Safety phrases:**

60 This material and its container must be disposed of as hazardous waste.

*

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

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision** 08/04/2015 / 19

· **Abbreviations and acronyms:**

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

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1A

ICAO: International Civil Aviation Organisation
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

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

Safety Data Sheet

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*
1 Identification

· **Product name:** CLINICAL CHEMISTRY Lipase Reagent 2

· **ADD List number:** 7D80/R2

· **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**
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:** Inhalation

· **Hazard Overview**
· **Health:** No adverse effects expected if used as directed.
· **Fire:** Noncombustible
· **Reactivity:** Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.

*
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):**		
29915-38-6	Tromethamine	4.77%

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 2

83-44-3	Deoxycholic acid	1.39%

*
4 First-aid measures

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

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

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

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

· **Information for Medical Personnel**

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

*
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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Product name: CLINICAL CHEMISTRY Lipase Reagent 2

*

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

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 manufacturer's 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:**
Avoid direct contact with material. If handled, wash thoroughly. Practice general safety precautions.

· **Information about protection against explosions and fires:** No special measures required.

· **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.

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Product name: CLINICAL CHEMISTRY Lipase Reagent 2

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

*

8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**

26628-22-8 Sodium azide (0.05 %)

REL	Ceiling limit value: 0.3** mg/m³, 0.1* ppm *as HN3; **as NaN3; Skin
TLV	Ceiling limit value: 0.29** mg/m³, 0.11* ppm *as HN3 vapor **as NaN3

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

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

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

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

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

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

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

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

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

*

9 Physical and chemical properties

· **General Information**

· **Form:** Solution

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 2

· **Color:**	White
· **Odor:**	Odorless
· **pH-value at 20 °C (68 °F)**	8.9
· **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)**	1.02 g/cm³ (8.512 lbs/gal)
· **Evaporation rate:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible
· **Dynamic:**	Not determined
· **Water:**	93.7 %

*

10 Stability and reactivity

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

· **Possibility of hazardous reactions:**
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.

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 2

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11 Toxicological information

· **Acute toxicity**

· **LD50/LC50 values for hazardous ingredients per OSHA criteria:**

· **Ingredients (100% pure substance/s):**		
29915-38-6 Tromethamine		
Oral	LD50	1780-5900 mg/kg (rat) By analogy to tromethane.
83-44-3 Deoxycholic acid		
Oral	LD50	1000 mg/kg (mouse)
	Mutagenicity	Negative (Ames Assay) Negative in the standard Ames test. Positive in the Ames fluctuation assay.
	Target Organ Effects	See Comment (mammal) Sodium deoxycholate has produced pancreatic hyperplasia in dogs and has produced fetal toxicity and abnormalities in the offspring of rats. Bile acids have been reported to produce liver and kidney injury in animals studies and are considered to promote colon cancer in rats.

· **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:**
Liver
Gastrointestinal tract
Reproductive system
DNA
Pancreas

*

12 Ecological information

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

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 2

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

· **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:
- 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, 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.

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 2

· **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):**

26628-22-8	Sodium azide

· **Section 313 (40CFR372.65):**

26628-22-8	Sodium azide

· **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.

· **Labelling according to Directives 67/548/EEC or 1999/45/EC**
· **Hazard determining substance/s of labeling:**
Sodium azide
· **Risk phrases:**
32 Contact with acids liberates very toxic gas.
· **Safety phrases:**
35 This material and its container must be disposed of in a safe way.

*
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

Safety Data Sheet

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Product name: CLINICAL CHEMISTRY Lipase Reagent 2

· **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** 08/04/2015 / 22

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative

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

Safety Data Sheet

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*
1 Identification

· **Product name:** CLINICAL CHEMISTRY Lipase Reagent 1A (Reconstituted / As-Used)

· **ADD List number:** 7D80 R1A Recons

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

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1A (Reconstituted / As-Used)

· **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):**	
Igepal CO-720	0.7132%

*
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 anti-HCV (antibodies to hepatitis C virus)
- Nonreactive for HIV-1 Ag or HIV-1 RNA (human immunodeficiency virus type 1 antigen or human immunodeficiency virus type 1 ribonucleic acid)
- Nonreactive for anti-HIV-1 (antibodies to human immunodeficiency virus type 1)
- Nonreactive for anti-HIV-2 (antibodies to human immunodeficiency virus type 2)
- Nonreactive for syphilis bacteria (Treponema pallidum pallidum)

· **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**

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1A (Reconstituted / As-Used)

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**
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:** No special measures required.

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1A (Reconstituted / As-Used)

· **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.

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

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1A (Reconstituted / As-Used)

*
9 Physical and chemical properties

· **General Information**
· **Form:** Solution
· **Color:** Whitish

· **Odor:** Odorless

· **pH-value at 20 °C (68 °F)** 6.6
· **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** Not determined
· **Evaporation rate:** Not determined

· **Solubility in / Miscibility with**
· **Water:** Not miscible or difficult to mix
· **Dynamic:** Not determined

· **Water:** 80.0 %
· **Solids content:** 100.0 %

*
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.

*
11 Toxicological information

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

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Product name: CLINICAL CHEMISTRY Lipase Reagent 1A (Reconstituted / As-Used)

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

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

· **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. 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.
· **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.

Safety Data Sheet

© Abbott Laboratories Release date 08/04/2015 Last alteration on 08/04/2015

Product name: CLINICAL CHEMISTRY Lipase Reagent 1A (Reconstituted / As-Used)

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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.
· **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:**
Igepal CO-720

· **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:**
Igepal CO-720

*
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

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· 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** 08/04/2015 / 16

· **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)
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organisation
ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)
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

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