Release Date: 10/2/14

REF GTIN	Product Name
7K62-35 **00380740105969**	***ARCHITECT TSH Reagent Kit***

Components:

7K62G	**ARCHITECT TSH Microparticles**
7K62H	**ARCHITECT TSH Conjugate**
7K62J	**ARCHITECT TSH Assay Diluent**

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:** ARCHITECT TSH Microparticles

· **ADD List number:** 7K62G

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

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

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

· **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.

· **Classification system:**
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 company and/or literature data.

· **Label elements**

· **GHS label elements:** none

· **Hazard pictograms:** none

· **Signal word:** none

· **Hazard statements:** none

· **Routes of Exposure:**
- Skin: No adverse effects expected when used as directed.
- Eye: No adverse effects expected when used as directed.
- Inhalation: No adverse effects expected when used as directed.
- Ingestion: No adverse effects expected when used as directed.

· **National Fire Protection Association (NFPA) ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0

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

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Product name: ARCHITECT TSH Microparticles

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

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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):**		
9002-93-1	Polyethylene glycol octylphenyl ether	0.936%

· **SVHC**	
9002-93-1	Polyethylene glycol octylphenyl ether

*

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

*

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: ARCHITECT TSH Microparticles

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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.

· **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.

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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.

*

8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**

25322-68-3 Polyethylene glycol (0.0016 %)	
WEEL ()	TWA: 10 mg/m³ (H); MW>200
26628-22-8 Sodium azide (0.0005 %)	
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.

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9 Physical and chemical properties

· **General Information**
· **Form:** Liquid
· **Color:** Brown

· **Odor:** Odorless

· **pH-value at 20 °C (68 °F)** 8
· **Melting point/Melting range:** Not determined
· **Boiling point/Boiling range:** Not determined

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

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Product name: ARCHITECT TSH Microparticles

· **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)**	1.062 g/cm³ (8.862 lbs/gal)
· **Evaporation rate:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible
· **Dynamic:**	Not determined
· **Water:**	82.5 %

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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):**		
9002-93-1 Polyethylene glycol octylphenyl ether		
Oral	LD50	1800 mg/kg (rat)

· **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.

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Product name: ARCHITECT TSH Microparticles

· **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.
· **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.

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Product name: ARCHITECT TSH Microparticles

· **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):**

7783-20-2	Ammonium sulfate
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.

*
16 Other information

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· **Department issuing MSDS**
- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

· **Contact**
- General information about this product:
Abbott Diagnostics

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Product name: ARCHITECT TSH Microparticles

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

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision** 10/02/2014 / 14

· **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 Organization
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)
NFPA: National Fire Protection Association (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
SVHC: Substance of Very High Concern (REACH)

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

Safety Data Sheet

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*
1 Identification

· **Product name:** ARCHITECT TSH Conjugate

· **ADD List number:** 7K62H

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

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

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

· **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.

· **Classification system:**
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 company and/or literature data.

· **Label elements**

· **GHS label elements:** none

· **Hazard pictograms:** none

· **Signal word:** none

· **Hazard statements:** none

· **Routes of Exposure:**
- Skin: No adverse effects expected when used as directed.
- Eye: No adverse effects expected when used as directed.
- Inhalation: No adverse effects expected when used as directed.
- Ingestion: No adverse effects expected when used as directed.

· **National Fire Protection Association (NFPA) ratings (scale 0-4)**
Health = 0
Fire = 0
Reactivity = 0

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

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Product name: ARCHITECT TSH Conjugate

· **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):**		
9002-93-1	Polyethylene glycol octylphenyl ether	0.4706%

· **SVHC**	
9002-93-1	Polyethylene glycol octylphenyl ether

*

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

*

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: ARCHITECT TSH Conjugate

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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.

· **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 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.

*

8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**

Propylene glycol (0.1694 %)	
WEEL ()	TWA: 10 mg/m³
25322-68-3 Polyethylene glycol (0.0016 %)	
WEEL ()	TWA: 10 mg/m³ (H); MW>200

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Product name: ARCHITECT TSH Conjugate

68-12-2 N,N-dimethylformamide (0.0001 %)	
PEL ()	TWA: 30 mg/m³, 10 ppm Skin
REL ()	TWA: 30 mg/m³, 10 ppm Skin
TLV ()	TWA: 30 mg/m³, 10 ppm Skin; BEI
26628-22-8 Sodium azide (<0.00001 %)	
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

· **Ingredients with biological limit values:**

68-12-2 N,N-dimethylformamide (0.0001 %)	
BEI ()	15 mg/L Medium: urine Time: end of shift Parameter: N-Methylformamide 40 mg/L Medium: urine Time: prior to last shift of workweek Parameter: N-Acetyl-S-(N-methylcarbamoyl) cysteine (semi-quantitative)

· **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.

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Product name: ARCHITECT TSH Conjugate

· **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:** Liquid
· **Color:** Colorless

· **Odor:** Odorless

· **pH-value at 20 °C (68 °F)** 6.3
· **Melting point/Melting range:** Not determined
· **Boiling point/Boiling range:** Not determined

· **Flash point** Not applicable
· **Flammability (solid, gaseous)** Not applicable
· **Auto igniting** Product is not self-igniting.

· **Danger of explosion** Product does not present an explosion hazard.
· **Explosion limits**
· **Lower:** Not determined
· **Upper:** Not determined

· **Density at 20 °C (68 °F)** 1.052 g/cm³ (8.779 lbs/gal)
· **Evaporation rate:** Not determined

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

· **Water:** 85.8 %

*

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.

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Product name: ARCHITECT TSH Conjugate

· **Hazardous decomposition products:** No dangerous decomposition products known.

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11 Toxicological information

· **Acute toxicity**

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

· **Ingredients (100% pure substance/s):**		
9002-93-1 Polyethylene glycol octylphenyl ether		
Oral	LD50	1800 mg/kg (rat)

· **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.
· **Recommendation for disposal of packaging:**
Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.

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Product name: ARCHITECT TSH Conjugate

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):**

68-12-2	N,N-dimethylformamide
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.

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Product name: ARCHITECT TSH Conjugate

· **Chemicals known to cause developmental reproductive toxicity:**

None of the ingredients is listed.

*
16 Other information

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· **Department issuing MSDS**

- 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** 10/02/2014 / 13

· **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 Organization
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)
NFPA: National Fire Protection Association (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
SVHC: Substance of Very High Concern (REACH)

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

Safety Data Sheet

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*
1 Identification

· **Product name:** **ARCHITECT TSH Assay Diluent**

· **ADD List number:** 7K62J

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

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

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

· **Emergency telephone number:**

Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.
- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.
- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea.

*
2 Hazard(s) identification

· **Classification of the substance or mixture**

Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
STOT SE 3 H335 May cause respiratory irritation.

· **Classification system:**
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 company and/or literature data.

· **Label elements**

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

· **Hazard pictograms:**



· **Signal word:** Warning

· **Hazard statements:**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

· **Precautionary statements:**

P261	Avoid breathing mist / vapors / spray.
P280	Wear protective gloves/protective clothing/eye protection.
P264	Wash hands thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.

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Product name: ARCHITECT TSH Assay Diluent

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312	Call a POISON CENTER/doctor/…/if you feel unwell.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P302+P352	IF ON SKIN: Wash with plenty of water/…
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	This material and its container must be disposed of in a safe way.

· **Routes of Exposure:**
Skin
Eye
Inhalation

· **National Fire Protection Association (NFPA) ratings (scale 0-4)**
Health = 2
Fire = 0
Reactivity = 0

· **Hazard Overview**
· **Health:**
Causes skin irritation
Irritant by inhalation
Causes eye irritation
· **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):**

77-86-1	Tris hydroxymethyl aminomethane	16.2712%
1185-53-1	Tromethamine hydrochloride	6.9447%

*
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 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. If irritation or signs of toxicity occur, seek medical attention.

· **Information for Medical Personnel**

· **Most important symptoms and effects, both acute and delayed:**
Kidney effects
Breathing difficulty
Coughing
Skin irritation
Eye irritation
Respiratory irritation

· **Medical conditions aggravated by exposure:**
Pre-existing eye ailments
Pre-existing kidney ailments
Pre-existing respiratory ailments
Pre-existing skin 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.

· **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.

· **Methods and material for containment and cleaning up**
Ensure adequate ventilation.
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.

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Product name: ARCHITECT TSH Assay Diluent

· **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.

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7 Handling and storage

· **Precautions for safe handling:**
Ensure good ventilation in the workplace.
Avoid contact with skin.
Avoid contact with eyes.
Avoid inhalation.

· **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:**
Keep containers tightly sealed.
Protect from heat and direct sunlight.

*
8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**
The product does not contain any hazardous ingredients with occupational exposure limits established by OSHA, ACGIH, or NIOSH.

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

Avoid contact with the skin.
Avoid contact with the eyes.

· **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:**	Liquid
· **Color:**	Brown
· **Odor:**	Odorless
· **pH-value at 20 °C (68 °F)**	8.8
· **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)**	1.121 g/cm³ (9.355 lbs/gal)
· **Evaporation rate:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible
· **Dynamic:**	Not determined
· **Water:**	69.5 %

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Product name: ARCHITECT TSH Assay Diluent

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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):**		
77-86-1 Tris hydroxymethyl aminomethane		
Oral	LD50	5900 mg/kg (rat)
	LDLo	1000 mg/kg (rabbit)
1185-53-1 Tromethamine hydrochloride		
Oral	LD50	<1000 mg/kg (rabbit)
		1780 - 5900 mg/kg (rat)

· **Primary toxicological effects of the final product:**
· **Skin irritation:** Irritating to skin and mucous membranes.
· **Eye irritation:** Irritating.

· **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:**
Eye
Kidneys
Skin
Respiratory tract

Safety Data Sheet

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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.
· **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.

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· **IATA**
· **Remarks:** Not restricted for transportation.

*
15 Regulatory information

· **SARA (Superfund Amendments and Reauthorization Act of 1986 - USA):**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**
The product does not contain listed substances.

· **Section 313 (40CFR372.65):**
The product does not contain listed substances.

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

· **Chemicals known to cause cancer:**
The product does not contain listed substances.

· **Chemicals known to cause female reproductive toxicity:**
None of the ingredients is listed.

· **Chemicals known to cause male reproductive toxicity:**
None of the ingredients is listed.

· **Chemicals known to cause developmental reproductive toxicity:**
None of the ingredients is listed.

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

· **Hazard designation of product:**



Irritant

· **Hazard determining substance/s of labeling:**
Tris hydroxymethyl aminomethane
· **Risk phrases:**
36/37/38 Irritating to eyes, respiratory system and skin.
· **Safety phrases:**
26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
35 This material and its container must be disposed of in a safe way.
36 Wear suitable protective clothing.
46 If swallowed, seek medical advice immediately and show this container or label.

*
16 Other information

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· **Department issuing MSDS**

- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

· **Contact**

- General information about this product:

Abbott Diagnostics
Technical Support
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Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

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LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

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