Abbott

Release Date: 6/25/23

REF GTIN	Product Name
04T0220 **04T0230**	***Iron2 for Use with ARCHITECT Reagent Kit***

Components:

04T02R	**Iron 2 Reagent 1 for use with ARCHITECT**
04T02T	**Iron2 Reagent 2 for use with ARCHITECT**

Abbott Customers:
For additional information, please contact your Abbott Customer Support Center Representative by calling 1-800-527-1869, 1-800-323-9100, or 1-800-235-5396.

Abbott employees:
For additional information relative to the content of the SDSs, please contact your local Safety Representative.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 06/25/2023 Last alteration on 06/25/2023

1 Identification

· **Product name:** Iron 2 Reagent 1 for use with ARCHITECT

· **ADD List number:** 04T02R

· **Application of the substance / mixture:**
For In Vitro Diagnostic Use
For Performance, Research or Investigational 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

The classification was made according to U.S. OSHA 29 CFR 1910.1200 and 1910.1030 and applicable European regulations, and is expanded upon from supplier company and/or literature data.

Acute Toxicity - Oral 4	H302 Harmful if swallowed.
Acute Toxicity - Inhalation 4	H332 Harmful if inhaled.
Skin Irritation 2	H315 Causes skin irritation.
Eye Irritation 2A	H319 Causes serious eye irritation.
Sensitization - Skin 1	H317 May cause an allergic skin reaction.
Carcinogenicity 2	H351 Suspected of causing cancer.
Toxic to Reproduction 2	H361 Suspected of damaging fertility or the unborn child.
Aquatic Acute 3	H402 Harmful to aquatic life.
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).

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron 2 Reagent 1 for use with ARCHITECT

· **Hazard pictograms:**



· **Signal word:** Warning

· **Hazard-determining components of labeling:**
Guanidine hydrochloride
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)
Thiourea
Acetic acid

· **Hazard statements:**

H302+H332	Harmful if swallowed or if inhaled.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
H351	Suspected of causing cancer.
H361	Suspected of damaging fertility or the unborn child.
H402	Harmful to aquatic life.
H412	Harmful to aquatic life with long lasting effects.

· **Precautionary statements:**

P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing mist / vapors / spray.
P264	Wash hands thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection.
P301+P330+P312	IF SWALLOWED: Rinse mouth. Call a POISON CENTER or doctor / physician if you feel unwell.
P302+P352	If on skin: Wash with plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P333+P313	If skin irritation or rash 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.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron 2 Reagent 1 for use with ARCHITECT

P501 Dispose of contents / container in accordance with local regulations.

· **Routes of Exposure:**
Skin
Eye
Inhalation
· **Health:**
Sensitizer in contact with skin
Causes skin irritation
Causes eye irritation
Possible risk of harm to the unborn child
Harmful if swallowed
· **Fire:** Noncombustible
· **Reactivity:** Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.
· **Special Hazards:** Carcinogen
· **NTP (National Toxicology Program)** Reasonably Anticipated To Be Human Carcinogen
· **Interpretation of the NTP listing**
For the substance or mixture listed above, there is limited evidence of carcinogenicity in humans and/or sufficient evidence for carcinogenicity in experimental animals.
· **IARC (International Agency for Research on Cancer)** Group 3
· **Interpretation of the IARC listing**
Group 3: The substance or mixture listed above is not classifiable as to carcinogenicity in humans. Evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals.

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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):**		
CAS: 50-01-1	Guanidine hydrochloride	34.3016%
CAS: 64-19-7	Acetic acid	6.253%
CAS: 62-56-6	Thiourea	0.3417%
CAS: 55965-84-9	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	0.0032%

4 First-aid measures

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron 2 Reagent 1 for use with ARCHITECT

· **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.

· **Most important symptoms and effects, both acute and delayed:**
Liver effects
Possibly thyroid response
Allergic reactions
Skin irritation
Eye irritation
Possibly immune response
This product may cause skin sensitization reactions in some people. See Section 11 for additional information.

· **Medical conditions aggravated by exposure:**
Pre-existing eye ailments
Pre-existing liver condition
Pregnancy
Pre-existing skin ailments
Skin allergies
Pre-existing thyroid ailments

5 Fire-fighting measures

· **Suitable extinguishing agents**
Dry chemical, carbon dioxide (CO_2), water spray or regular foam.
- Caution: CO_2 will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
- For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.

· **Special hazards arising from the substance or mixture**
There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.
No further relevant information available.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron 2 Reagent 1 for use with ARCHITECT

· **Protective equipment**
For large fires, wear appropriate heat- and flame-resistant personal protective equipment and a NFPA/NIOSH approved positive-pressure, self-contained breathing apparatus.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected persons away.

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

· **Methods and material for containment and cleaning up**
Blot up small volumes of spilled or spattered product with paper towels or similar materials.
- Contain larger spills by placing absorbants around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:
- warm water and detergent or similar cleansing agent

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Precautions for safe handling:**
Provide local exhaust ventilation if dust or vapor is formed.
Avoid contact with skin.
Avoid contact with eyes.
Avoid inhalation.

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

· **Requirements to be met by storerooms and receptacles:** Store only in the original container.

· **Information about storage in one common storage facility:** Store in original packaging.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron 2 Reagent 1 for use with ARCHITECT

· **Further information about storage conditions:**
Refer to the package insert or product label for additional information on storage conditions for product quality.

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8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

CAS: 64-19-7 Acetic acid (6.253 %)	
PEL	TWA: 25 mg/m³, 10 ppm
REL	STEL/C: 37 mg/m³, 15 ppm TWA: 25 mg/m³, 10 ppm
TLV	STEL/C: 15 ppm TWA: 10 ppm
CAS: 7646-85-7 Zinc chloride (0.0612 %)	
PEL	TWA: 1 mg/m³ Fume
REL	STEL/C: 2 mg/m³ TWA: 1 mg/m³
TLV	STEL/C: 2 mg/m³ TWA: 1 mg/m³ fume

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

Avoid contact with the skin.
Avoid contact with the eyes.
Immediately remove all soiled and contaminated clothing.

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

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

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron 2 Reagent 1 for use with ARCHITECT

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

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

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

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

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

9 Physical and chemical properties

· **General Information**

· **Color:**	Colorless
· **Odor:**	Not Determined
· **Melting point/Melting range:**	Not determined
· **Boiling point/Boiling range:**	Not determined
· **Explosion limits**	
· **Lower:**	Not determined
· **Upper:**	Not determined
· **Flash point**	Not applicable
· **pH-value at 20 °C (68 °F)**	4.95-5.05
· **Dynamic:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible
· **Density at 20 °C (68 °F)**	1.114 g/cm³ (9.2963 lbs/gal)
· **Form:**	Solution
· **Auto igniting**	Product is not self-igniting.
· **Danger of explosion**	Product does not present an explosion hazard.
· **Water:**	59.0 %

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron 2 Reagent 1 for use with ARCHITECT

· **Solids content:** 0.0 %
· **Evaporation rate:** Not determined

10 Stability and reactivity

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

· **Possibility of hazardous reactions:** No dangerous reactions known.

· **Conditions to avoid:** No further relevant information available.

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

· **Hazardous decomposition products:** Hydrogen chloride (HCl)

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11 Toxicological information

· **Acute toxicity** Harmful if swallowed or if inhaled.

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

· **Ingredients (100% pure substance/s):**		
CAS: 50-01-1 Guanidine hydrochloride		
Oral	LD50	571 mg/kg (mouse) 475 mg/kg (rat)
Dermal	LD50	>2 gm/kg (rabbit)
Inhalation	LC50 4 h	5.319 mg/l (rat) (OECD Guideline 403)
Irritation of skin	Reported Effect	(rabbit) (Standard Draize Test (Skin)) 500 mg/24 hr
Irritation of eyes	Reported Effect	(other) (Standard Draize Test (Eye)) 81400 mcg
CAS: 64-19-7 Acetic acid		
Oral	LD50	3,310 mg/kg (rat)
Dermal	LD50	1,060 mg/kg (rabbit)
Inhalation	LC50 1 h	5,620 ppm (mouse)
	Mutagenicity	(Ames Assay)
	Target Organ Effects	(human) Workers exposed to 60 ppm 8 hours a day were found to have conjunctivitis, bronchitis, pharyngitis, and erosion of exposed teeth.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron 2 Reagent 1 for use with ARCHITECT

CAS: 62-56-6 Thiourea		
Oral	LD50	125 mg/kg (rat)
	TDLo (Carcinogen)	~25 mg/kg/d (rat) 0.25% thiourea in drinking water produced thyroid tumors and squamous cell carcinomas of the Zymbal gland in rats. 0.1 and 0.25% thiourea in diet produced liver tumors in rats.
Dermal	LD50	2,800 mg/kg (rbt)
	Mutagenicity	(Ames Assay) (mammalian cells) Positive in the cell-transformation assay in rat embryo and SHE cell cultures.
	Target Organ Effects	(rat) Teratogenicity was noted in offspring of female rats receiving 20 mg/kg/day(po) during gestation.

· **Skin irritation:** Causes skin irritation.
· **Eye irritation:** Causes serious eye irritation.

· **Sensitization:**
Sensitization possible through skin contact.
May cause an allergic skin reaction.
· **Carcinogenicity** Suspected of causing cancer.
· **Reproductive toxicity** Suspected of damaging fertility or the unborn child.
· **Aspiration hazard**

· **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)		
CAS: 62-56-6	Thiourea	3

· NTP (National Toxicology Program)		
CAS: 62-56-6	Thiourea	R

· OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients is listed.

· **Target organs/systems:**
Eye
Liver
Thyroid
Skin
Immune system
Reproductive system

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 06/25/2023 Last alteration on 06/25/2023

Product name: Iron 2 Reagent 1 for use with ARCHITECT

12 Ecological information

· **Aquatic toxicity:**

CAS: 62-56-6 Thiourea

LC50 96 h (Static)	mg/l (algae) Species: Scenedesmus abundans (Green algae, 10+4 cells/mL); Conditions: freshwater, static, 22 deg C; Concentration: 4800 ug/L for 96 hr; Effect: inhibition of cell growth /99.5% purity.
LC50 48 h (Static)	mg/l (daphnia) Species: Daphnia magna (Water flea, age <24 hr); Conditions: freshwater, static, 20 deg C, pH 8.2, hardness 250 mg/L CaCO3, dissolved oxygen >6.5 mg/L; Concentration: 9000 ug/L for 48 hr (95% confidence interval: 5600-18000 ug/L) />99% purity.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable

· **vPvB:** Not applicable

· **Additional ecological information**

· **General notes:**

Do not allow product to reach ground water, water course, or sewage system.

Harmful to aquatic organisms.

13 Disposal considerations

· **Recommendation for disposal of unused product:**

Dispose in accordance with federal, state and local regulations.

· **Waste disposal key:**

· **Recommendation for disposal of packaging:**

Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

· **Recommended cleansing agent:** Water with cleansing agents, if necessary.

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14 Transport information

· **DOT, ADN, IMDG, IATA** none

· **UN proper shipping name**

· **DOT, ADR, ADN, IMDG, IATA** none

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron 2 Reagent 1 for use with ARCHITECT

· Transport hazard class(es)

· **DOT, ADR, ADN, IMDG, IATA**
· **Class** none
· **DOT, IMDG, IATA** none

· Environmental hazards

· **Marine pollutant:** No

· Additional information

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

15 Regulatory information

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

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**	
CAS: 7647-01-0	hydrochloric acid

· **Section 313 (40CFR372.65):**	
CAS: 62-56-6	Thiourea
CAS: 7646-85-7	Zinc chloride
CAS: 7647-01-0	hydrochloric acid

· **Hazardous Air Pollutants**	
CAS: 7647-01-0	hydrochloric acid

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

· **Chemicals known to cause cancer:**	
CAS: 62-56-6	Thiourea

· **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.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron 2 Reagent 1 for use with ARCHITECT

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

None of the ingredients is listed.

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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.

This information is not a substitute for the advice of a health care professional, nor is it a recommendation for any particular course of treatment. It is not intended to supplement, modify or supersede any information (e.g. labeling and package inserts) provided with respect to the medical use of the product. Abbott Laboratories assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

The information in this Safety Data Sheet (SDS) reflects the most current hazard information for this product.

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

· **Contact**
- General information about this product:
Abbott Diagnostics
Technical Support
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision** 06/25/2023

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

Safety Data Sheet

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Product name: Iron 2 Reagent 1 for use with ARCHITECT

OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Acute Toxicity - Oral 4: Acute toxicity – Category 4
Skin Irritation 2: Skin corrosion/irritation – Category 2
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
Sensitization - Skin 1: Skin sensitisation – Category 1
Carcinogenicity 2: Carcinogenicity – Category 2
Toxic to Reproduction 2: Reproductive toxicity – Category 2
Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard – Category 3
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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1 Identification

· **Product name:** Iron2 Reagent 2 for use with ARCHITECT

· **ADD List number:** 04T02T

· **Application of the substance / mixture:**
For In Vitro Diagnostic Use
For Performance, Research or Investigational 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

The classification was made according to U.S. OSHA 29 CFR 1910.1200 and 1910.1030 and applicable European regulations, and is expanded upon from supplier company and/or literature data.

Sensitization - Skin 1	H317 May cause an allergic skin reaction.
Aquatic Acute 3	H402 Harmful to aquatic life.
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:**



· **Signal word:** Warning

Safety Data Sheet

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Product name: Iron2 Reagent 2 for use with ARCHITECT

· **Hazard-determining components of labeling:**
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)

· **Hazard statements:**
H317 May cause an allergic skin reaction.
H402 Harmful to aquatic life.
H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements:**
P261 Avoid breathing mist / vapors / spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection.
P302+P352 If on skin: Wash with plenty of water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents / container in accordance with local regulations.

· **Routes of Exposure:** Skin
· **Health:** Sensitizer in contact with skin
· **Fire:** Noncombustible
· **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):**

CAS: 55965-84-9	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	0.0035%

4 First-aid measures

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

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron2 Reagent 2 for use with ARCHITECT

· **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.

· **Most important symptoms and effects, both acute and delayed:**
Cramps
Gastric or intestinal disorders
Nausea
Allergic reactions
Possibly immune response
This product may cause skin sensitization reactions in some people. See Section 11 for additional information.

· **Medical conditions aggravated by exposure:**
Pre-existing gastrointestinal tract ailments
Pre-existing skin ailments
Skin allergies

5 Fire-fighting measures

· **Suitable extinguishing agents**
Dry chemical, carbon dioxide (CO2), water spray or regular foam.
- Caution: CO2 will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
- For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.

· **Special hazards arising from the substance or mixture**
There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.
No further relevant information available.

· **Protective equipment**
For large fires, wear appropriate heat- and flame-resistant personal protective equipment and a NFPA/NIOSH approved positive-pressure, self-contained breathing apparatus.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron2 Reagent 2 for use with ARCHITECT

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected persons away.

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

· **Methods and material for containment and cleaning up**
Blot up small volumes of spilled or spattered product with paper towels or similar materials.
- Contain larger spills by placing absorbants around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:
- warm water and detergent or similar cleansing agent

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Precautions for safe handling:** Avoid contact with skin.

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

· **Requirements to be met by storerooms and receptacles:** Store only in the original container.

· **Information about storage in one common storage facility:** Store in original packaging.

· **Further information about storage conditions:**
Refer to the package insert or product label for additional information on storage conditions for product quality.

8 Exposure controls/personal protection

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

Safety Data Sheet

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© Abbott Laboratories Release date 06/25/2023 Last alteration on 06/25/2023

Product name: Iron2 Reagent 2 for use with ARCHITECT

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

Avoid contact with the skin.
Immediately remove all soiled and contaminated clothing.

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

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

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

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

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

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

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

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

9 Physical and chemical properties

· **General Information**

· **Color:**	Yellow tint
· **Odor:**	Not Determined

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 06/25/2023 Last alteration on 06/25/2023

Product name: Iron2 Reagent 2 for use with ARCHITECT

· **Melting point/Melting range:**	Not determined
· **Boiling point/Boiling range:**	Not determined
· **Explosion limits**	
· **Lower:**	Not determined
· **Upper:**	Not determined
· **Flash point**	Not applicable
· **pH-value at 20 °C (68 °F)**	2.75-2.85
· **Dynamic:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible
· **Density at 20 °C (68 °F)**	1.041 g/cm³ (8.6871 lbs/gal)
· **Form:**	Solution
· **Auto igniting**	Product is not self-igniting.
· **Danger of explosion**	Product does not present an explosion hazard.
· **Water:**	90.1 %
· **Solids content:**	0.0 %
· **Evaporation rate:**	Not determined

10 Stability and reactivity

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

· **Possibility of hazardous reactions:** No dangerous reactions known.

· **Conditions to avoid:** No further relevant information available.

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

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

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11 Toxicological information

· **Acute toxicity** Based on available data, the classification criteria are not met.
· **LD50/LC50 values for hazardous ingredients per OSHA criteria:**
· **Ingredients (100% pure substance/s):** Not applicable.

· **Sensitization:**
Sensitization possible through skin contact.
May cause an allergic skin reaction.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 06/25/2023 Last alteration on 06/25/2023

Product name: Iron2 Reagent 2 for use with ARCHITECT

· **Aspiration hazard**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Target organs/systems:**
Gastrointestinal tract
Skin
Immune system

12 Ecological information

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

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

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

13 Disposal considerations

· **Recommendation for disposal of unused product:**
Dispose in accordance with federal, state and local regulations.
· **Waste disposal key:**
· **Recommendation for disposal of packaging:**
Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.
For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 06/25/2023 Last alteration on 06/25/2023

Product name: Iron2 Reagent 2 for use with ARCHITECT

· **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.

· **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):**

CAS: 7647-01-0	hydrochloric acid

· **Section 313 (40CFR372.65):**

CAS: 7647-01-0	hydrochloric acid

· **Hazardous Air Pollutants**

CAS: 7647-01-0	hydrochloric acid

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron2 Reagent 2 for use with ARCHITECT

· **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.

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16 Other information

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The information in this Safety Data Sheet (SDS) reflects the most current hazard information for this product.

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

· **Contact**
- General information about this product:
Abbott Diagnostics
Technical Support
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision** 06/25/2023

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Product name: Iron2 Reagent 2 for use with ARCHITECT

· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Sensitization - Skin 1: Skin sensitisation – Category 1
Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard – Category 3
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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