

1. Product and Company Identification

Material name IRON-SL Color Reagent (R2)
Version # 01
Issue date 02-04-2013
Revision date -
Supersedes date -
CAS # Mixture
Kit number 157-30
Product use For the quantitative determination of Iron in serum and plasma.
Manufacturer information
Corporate Headquarters Sekisui Diagnostics, LLC
4 Hartwell Place, Lexington, MA 02421, USA
www.sekisuidiagnostics.com
Phone: 800-332-1042
Americas 1-760-476-3962
Emergency Telephone Numbers Europe, Middle East & Africa +1-760-476-3961
Asia Pacific +1-760-476-3960
Access code 333512

2. Hazards Identification

Physical state Liquid.
Appearance Clear, yellow to amber liquid.
Emergency overview CAUTION!
May cause eye, skin and respiratory tract irritation. Possible risk of harm to the unborn child.
Physical and health hazard information on reagent mixtures have not been determined.
OSHA regulatory status This product is hazardous according to OSHA 29 CFR 1910.1200.
Potential health effects
Routes of exposure Inhalation. Ingestion. Skin contact. Eye contact.
Eyes May cause eye irritation. Exposed individuals may experience eye tearing, redness, and discomfort.
Skin May cause skin irritation.
Inhalation Vapors and mist may irritate throat and respiratory system and cause coughing.
Ingestion May cause discomfort if swallowed.
Target organs Eye Skin Respiratory system.
Chronic effects Suspect cancer hazard. May cause toxic effects on the blood system including bone marrow toxicity and reduction in red blood cells, white blood cells, and platelets. Enlargement of the thyroid and spleen has also been reported. May cause lung damage.
Signs and symptoms Ingestion may cause irritation and malaise.
Potential environmental effects The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Ascorbic acid	50-81-7	1 - 5
Thiourea	62-56-6	< 2

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First Aid Measures

First aid procedures

Eye contact

In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact

For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.

Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

Ingestion

If material is ingested, immediately contact a poison control center.

Notes to physician

Provide general supportive measures and treat symptomatically.

5. Fire Fighting Measures

Flammable properties

This product is not flammable.

Extinguishing media

Suitable extinguishing media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media

None known.

Protection of firefighters

Specific hazards arising from the chemical

Fire may produce irritating, corrosive and/or toxic gases.

Protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

Use standard firefighting procedures and consider the hazards of other involved materials.

Hazardous combustion products

Carbon monoxide and carbon dioxide. Nitrogen Oxides Sulfur oxides.

6. Accidental Release Measures

Personal precautions

Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions

Do not allow to enter drains, sewers or watercourses.

Methods for containment

Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up

Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Other information

Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water. Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling

Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

Storage

Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Exposure guidelines

Follow standard monitoring procedures.

Engineering controls

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Personal protective equipment

Eye / face protection

Wear approved safety glasses or goggles.

Skin protection

Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Respiratory protection

In case of inadequate ventilation or risk of inhalation of vapors, use suitable respiratory equipment.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Clear, yellow to amber liquid.
Physical state	Liquid.
Form	Liquid.
Color	Clear. Amber yellow.
Odor	Not available.
Odor threshold	Not available.
pH	2.8
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not available.
Solubility (water)	Not available.
Specific gravity	1.012
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions.
Conditions to avoid	Protect against direct sunlight.
Incompatible materials	Strong oxidizers, strong acids, and strong bases.
Hazardous decomposition products	Carbon oxides. Sulfur oxides. Nitrogen oxides.
Possibility of hazardous reactions	Polymerization will not occur.

11. Toxicological Information

Toxicological data

Components	Species	Test Results
Thiourea (CAS 62-56-6)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 2800 mg/kg
	Rat	> 6810 mg/kg
Sensitization	Not classified.	
Acute effects	May be harmful if swallowed.	
Local effects	May cause eye, skin and respiratory tract irritation.	
Chronic effects	May cause damage to the liver. Prolonged or repeated exposure to thiourea may cause thyroid damage.	
Carcinogenicity	Suspected of causing cancer.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Thiourea (CAS 62-56-6)	3 Not classifiable as to carcinogenicity to humans.	
US NTP Report on Carcinogens: Anticipated carcinogen		
Thiourea (CAS 62-56-6)	Reasonably Anticipated to be a Human Carcinogen.	
Epidemiology	No epidemiological data is available for this product.	
Mutagenicity	Not classified.	
Reproductive effects	Possible risk of harm to the unborn child.	
Symptoms and target organs	Ingestion may cause irritation and malaise.	

Further information No other specific acute or chronic health impact noted.

12. Ecological Information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Environmental effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Aquatic toxicity Not classified.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulation / Accumulation Not available.

Partition coefficient

Thiourea (CAS 62-56-6)	-1.08
------------------------	-------

Mobility in environmental media The product is soluble in water.

13. Disposal Considerations

Disposal instructions Dispose in accordance with all applicable regulations. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.

Waste from residues / unused products Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

DOT
Not regulated as a hazardous material by DOT.

IATA
Not regulated as dangerous goods.

IMDG
Not regulated as dangerous goods.

TDG
Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations This product is hazardous according to OSHA 29 CFR 1910.1200.
All components are on the U.S. EPA TSCA Inventory List.
This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: De minimis concentration

Thiourea (CAS 62-56-6)	0.1 %
------------------------	-------

US EPCRA (SARA Title III) Section 313 - Toxic Chemical: Listed substance

Thiourea (CAS 62-56-6)	Listed.
------------------------	---------

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

Thiourea: 10

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard	- Yes
Delayed Hazard	- Yes
Fire Hazard	- No
Pressure Hazard	- No
Reactivity Hazard	- No

Section 302 extremely hazardous substance (40 CFR 355, Appendix A)

No

Section 311/312 (40 CFR 370)	Yes
Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)	Not controlled
Canadian regulations	This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.
WHMIS status	Controlled
WHMIS classification	D2A - Other Toxic Effects-VERY TOXIC
WHMIS labeling	



Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

State regulations WARNING: This product contains chemical(s) known to the State of California to cause cancer and birth defects or other reproductive harm.

US - California Hazardous Substances (Director's): Listed substance

Thiourea (CAS 62-56-6) Listed.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Thiourea (CAS 62-56-6) Listed.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Thiourea (CAS 62-56-6) Listed: January 1, 1988 Carcinogenic.

US - New Jersey RTK - Substances: Listed substance

Thiourea (CAS 62-56-6) Listed.

US - Pennsylvania RTK - Hazardous Substances: Special hazard

Thiourea (CAS 62-56-6) Special hazard.

US. Massachusetts RTK - Substance List

Thiourea (CAS 62-56-6) Listed.

US. New Jersey Worker and Community Right-to-Know Act

Thiourea (CAS 62-56-6) 500 lbs

US. Pennsylvania RTK - Hazardous Substances

Thiourea (CAS 62-56-6) Listed.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions Use in accordance with supplier's recommendations.

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings

Health: 2*
Flammability: 0
Physical hazard: 0

NFPA ratings

Health: 2
Flammability: 0
Instability: 0

Disclaimer

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Sekisui Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Sekisui Diagnostics has been advised of the possibility of such damages.