

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: Human Sclerostin HS Enzyme Immunoassay (EIA) Kit (Catalog #: TE1023HS)

Intended Use: Kit for the quantitation of Sclerostin in human plasma and serum. This kit is for Research Use Only.




Components: Sclerostin Standards A → F, Sclerostin Low Control, Sclerostin High Control, Microassay Plate, Stop Solution, 20X Wash Buffer Concentrate, Sample Diluent, Matrix Solution, Sclerostin Antibody Solution, and TMB Substrate.

Section 2 – Hazards Identification

Emergency Overview

Kit Component	OSHA Hazards	Target Organs	GHS Classification
20X Wash Buffer Concentrate (0.035% Proclin 300)	Irritant	Skin	Skin Sensitizer (Category 1)
Stop Solution (<4% Hydrochloric Acid)	Irritant	Eyes and Skin	Skin Irritation (Category 2) Eye Irritation (Category 2)
Sclerostin Antibody Solution (1.5% HEPBS)	Irritant	Eye	Eye Irritation (Category 2)

GHS Classification and Label Elements

Component	Pictogram	Hazard Statements	Precautionary Statements
20X Wash Buffer Concentrate (0.035% Proclin 300)	 Warning	H317 May cause an allergic skin reaction.	P264 Wash hands thoroughly after handling. P303+P361+P353: IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water. P333+P313: If skin irritation or rash occurs: Get medical attention.
Stop Solution (<4% Hydrochloric Acid)	 Warning	H315 Causes skin irritation H319 Causes serious eye irritation.	P264 Wash hands thoroughly after handling. P280 Wear protective gloves and safety glasses. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Sclerostin Antibody Solution (1.5% HEPBS)	 Warning	H319 Causes serious eye irritation.	P264 Wash hands thoroughly after handling. P280 Wear protective gloves and safety glasses. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Section 2 – Hazards Identification (cont'd)

Supplemental Hazard Statements

1. Refer to Universal Precautions information in Section 7, Handling and Storage.
2. BND (5-Bromo-5-nitro-1,3-dioxane) is used as a biocide in the Sclerostin Standards, Sclerostin High Control, Sample Diluent, and the Matrix Solution (<0.14%). CAS#: 30007-47-7
3. Avoid release to the environment.

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
Sclerostin High Control, Sclerostin Low Control, Sclerostin Standards	EDTA, 500 mM	60-00-4	200-449-4	<10	0.5 mL/each
Stop Solution	Hydrochloric Acid	7647-01-0	231-595-7	<4	12 mL
Sclerostin Antibody Solution	HEPBS	161308-36-7	--	1.4	7 mL
20X Wash Buffer Concentrate	Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	--	0.035	50 mL

**The above listed components are mixtures.*

Section 4 – First Aid Measures

General Advice

Move out of exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance, as necessary.

- If inhaled:* Move the person to fresh air and support breathing as required.
- In case of skin contact:* Wash affected area with soap and water. Seek medical advice if irritation develops.
- In case of 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 attention.
- If swallowed:* Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.
- Note to Physicians:* Treat symptomatically.

Section 5 – Fire Fighting Measures

General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

- Extinguishing Media:* For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.
- General Fire Hazards:* The components within this kit will not significantly contribute to the intensity of a fire.
- Hazardous Combustion Products:* No data available
- Fire Fighting Equipment:* Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Large spills of the solutions, controls or reagents contained within this kit are unlikely.

<i>Personal Precautions:</i>	Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.
<i>Materials and Methods for Clean-Up:</i>	Wipe up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.
<i>Recovery and Neutralization:</i>	Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.
<i>Environmental Precautions:</i>	Contain spill to prevent migration to public industrial / sanitary sewers or open water sources. Discharge into the environment must be avoided.

Section 7 – Handling and Storage

Specific Use: For Research Use Only. Not for use by the general public.

Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the components within this kit ON YOU or IN YOU. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Universal Precautions should be followed when handling and working with this kit. Keep out of reach of the general public.

Universal Precautions

No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma used in components of this kit will not transmit infectious agents. All blood products should be treated as potentially infectious; use universal precautions. Users should ensure the use of proper personal protective equipment (PPE), covering of any cuts or abrasions on the skin (hands), and follow standard protocols for the decontamination of work surfaces when testing has been completed. Always wash hands thoroughly after handling the components within this kit.

Universal Precautions must be followed when working with the following components:

- Sclerostin Standards
- Sclerostin Low and High Control
- Matrix Solution

Conditions for Safe Storage: To maintain efficacy, store according to the kit specific Package Insert instructions.

Incompatibilities To maintain efficacy, store according to the kit specific Package Insert instructions.

Section 8 – Exposure Controls and Personal Protection

Exposure Limits: No data available for the specific components within this kit.

Exposure Controls:

Engineering Measures Use with adequate ventilation.

Personal Protective Equipment

Respiratory Protection: None needed under normal conditions of use.

Section 8 – Exposure Controls and Personal Protection (cont'd)

- Hand Protection:* Handle with appropriately rated chemical resistant gloves (e.g., nitrile or equivalent). Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.
- Eye Protection:* Wear safety glasses with side shields or goggles to prevent eye contact.
- Skin and Body Protection:* Use body protection appropriate for the task. A laboratory coat is recommended.
- Hygiene Measures:* Wash hands before and after use and at the end of the workday.

Environmental Exposure Controls

No special environmental controls are required.

Section 9 – Physical and Chemical Properties

Characteristic	20X Wash Buffer Concentrate	Sclerostin Antibody Solution	Stop Solution
Boiling Point (°C)	No data available	No data available	No data available
Melting Point (°C)	No data available	No data available	No data available
Specific Gravity (H ₂ O = 1)	No data available	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available	No data available
pH	6.1 to 6.6	5.8 to 6.20	<1
Solubility in Water	Soluble	Soluble	Soluble
Appearance and Odor	Clear liquid, odorless	Clear liquid, odorless	Clear liquid, mild odor

Section 10 – Stability and Reactivity

Characteristic	20X Wash Buffer Concentrate	Sclerostin Antibody Solution	Stop Solution
Component Stability	Stable	Stable	Stable
Hazard Reaction Potential	No data available	No data available	No data available
Conditions to Avoid	No data available	No data available	No data available
Materials to Avoid	No data available	No data available	Bases, metals, amines, fluorine
Hazardous Decomposition Products	No data available	No data available	No data available

Section 11 – Toxicological Information

Acute Toxicity

Component Analysis – LD50 / LC50 / Irritation (No data available for specific kit components)

Chemical Name	CAS #	RTECS #	Information
Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	Not available	Oral LD ₅₀ Rat 53 mg/kg Inhalation LC ₅₀ No data available Dermal LD ₅₀ No data available
Hydrochloric Acid	7647-01-0	MW4025000	Oral LD ₅₀ Rabbit 900 mg/kg Inhalation LC ₅₀ Mouse 1108 PPM/1H Dermal LD ₅₀ No data available
HEPBS	161308-36-7	Not available	Oral LD ₅₀ No data available Inhalation LC ₅₀ No data available Dermal LD ₅₀ No data available
EDTA	60-00-4	Not available	Oral LD ₅₀ No data available Inhalation LC ₅₀ No data available Dermal LD ₅₀ No data available

Potential Health Effects: Stop Solution, 20X Wash Buffer Concentrate, and Sclerostin Antibody Solution

<i>Skin Corrosion/Irritation:</i>	No data available	<i>Inhalation:</i>	May cause respiratory tract irritation.
<i>Serious Eye Damage / Irritation:</i>	No data available	<i>Skin:</i>	May cause skin irritation upon contact.
<i>Respiratory or Skin Sensitization:</i>	No data available	<i>Eyes:</i>	May cause serious eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available	<i>Ingestion:</i>	May be harmful if swallowed.

Carcinogenicity

No component of this kit present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the ACGIH, NTP or OSHA.

IARC, Group 3: Not classifiable as to its carcinogenicity to humans (Hydrochloric Acid)

Reproductive Toxicity No data available

Teratogenicity No data available

Specified Target Organ General Toxicity (GHS)

Single Exposure (GHS): No data available

Repeated Exposure (GHS): No data available

Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components contained within this kit.

Synergistic Effects No data available

Section 11 – Toxicological Information (cont'd)

Additional Information

Sensitization: Contains a small volume of a very dilute, sensitizing preservative (Proclin 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.

Stomach – Irregularities – Based on Human Evidence (HEPBS)

Section 12 – Ecological Information

Ecotoxicity	No data available	Mobility in Soil	No data available
Persistence / Degradability	No data available	PBT and vPvB Assessment	No data available
Bioaccumulation	No data available		
Other Adverse Effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid release to the environment.		
	<i>Proclin 300 is very toxic to aquatic life with long lasting effects.</i>		

Section 13 – Disposal Considerations

Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge any of the solutions, reagents or controls into drains, water courses or onto the ground.

Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country, federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

Section 14 – Transportation Information

U.S. Department of Transportation (DOT)	This kit is not regulated for transport.
International Air Transportation (IATA)	This kit is not regulated for transport.
International Maritime Dangerous Goods (IMDG)	This kit is not regulated for transport.

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards Stop Solution, 20X Wash Buffer Concentrate, and Sclerostin Antibody Solution: Irritant

SARA 302 The following chemicals are subject to reporting levels established by SARA Title III, Section 302:

No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.

Section 15 – Regulatory Information (cont'd)

SARA 313 The following chemicals are subject to reporting levels established by SARA Title III, Section 313:

Hydrochloric Acid CAS#: 7647-01-0 Revision Date: 1993-04-24

SARA 311/312 Proclin 300 CAS#: 55965-84-9 Acute Health Hazard
 HEPBS CAS#: 161308-36-7 Acute Health Hazard
 Hydrochloric Acid CAS#: 7647-01-0 Acute Health Hazard

State Regulations

The following chemical(s) appear on one or more of the following state hazardous substances lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Proclin 300	55965-84-9	No	No	No	Yes	Yes	No
Hydrochloric Acid	1310-73-2	Yes	Yes	Yes	Yes	Yes	Yes
HEPBS	161308-36-7	No	No	No	Yes	Yes	No
EDTA	60-00-4	No	No	No	Yes	Yes	No

California Prop 65: The components within this kit do not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Additional Regulatory Information

Safety, Health and Environmental regulations/legislation specific for the mixture:

The employer shall assess the working conditions and if there is any risk to the safety or health and effects on the pregnancy or breastfeeding of workers, take necessary measures to adjust the working conditions.

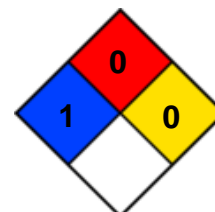
Chemical Safety Assessment:

Not completed for the components contained within this kit.

HMIS Kit Classification:



NFPA Kit Classification:



Section 16 – Other Information

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SUPERCEDES: April 10, 2013

REVISIONS: Revised to Quidel GHS format; updated Section 3; added revised Universal Precautions statement to Section 7; Section 15, removed reference to Canadian IDL; and general formatting updates.

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