

Safety Data Sheet

Procleix Selection Reagent

SECTION 1: Identification of the substance/mixture and of the company/undertaking

Product Identifier

Product Name Procleix Selection Reagent

Recommended use of the chemical and restrictions on use

Specific use(s) Procleix Ultrio Assay, Procleix Ultrio Plus Assay, Procleix WNV Assay, Procleix Ultrio Elite Assay, Procleix Parvo-HAV Assay, Procleix HEV Assay, Procleix Dengue Virus Assay

Recommended Use In vitro diagnostic

Details of the supplier of the safety data sheet

United States of America Supplier Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121-4362

Canadian Supplier Hologic Canada Limited
130 Spadina Avenue
Suite 401
Toronto, ON, M5V-2L4
Canada
1-877-209-7192

Manufacturer Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121-4362

Emergency Telephone - United States of America

24 Hour Emergency Phone Number Chemtrec, U.S. and Canada 1-800-424-9300; Chemtrec International + 1-703-741-5970

For further information, please contact: MolecularSupport@hologic.com

SECTION 2: Hazards identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2

Emergency Overview

Label Elements



Signal word

Procleix Selection Reagent

Warning

Hazard Statements

H315 - Causes skin irritation

H319 - Causes serious eye irritation

Precautionary Statements - Prevention

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear protective gloves/protective clothing/eye protection/face protection

S39 - Wear eye/face protection

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337 + P313 - If eye irritation persists: Get medical advice/attention

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P332 + P313 - If skin irritation occurs: Get medical advice/attention

P362 - Take off contaminated clothing and wash before reuse

Hazards not otherwise classified (HNOC)

Other Information

Not Applicable

SECTION 3: Composition/information on ingredients

Substances

Not Applicable

Mixtures

Mixtures

OSHA Hazard Classification

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Component name	CAS No	%
Boric Acid	10043-35-3	1 - 5

SECTION 4: First aid measures

First aid measures

General advice

If symptoms persist, call a physician.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a physician. Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing.

Skin Contact

Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician. Wash contaminated clothing before reuse. Wash off immediately with plenty of water. Immediate medical attention is not required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation

Remove to fresh air. If symptoms persist, call a physician. Immediate medical attention is not required. Move to fresh air in case of accidental inhalation of vapors.

Ingestion

Immediate medical attention is not required. Rinse mouth. Drink plenty of water. Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

Self-protection of the first aider

Use personal protective equipment as required.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

SECTION 5: Firefighting measures

Flammability Not flammable.

Suitable Extinguishing Media Use extinguishing agent suitable for type of surrounding fire.

Protective equipment and precautions for firefighters As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Use personal protective equipment as required. Avoid contact with eyes and skin. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

Environmental precautions Prevent entry into waterways, sewers, basements or confined areas. Do not flush into surface water or sanitary sewer system. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Soak up with inert absorbent material. Pick up and transfer to properly labeled containers. After cleaning, flush away traces with water. Prevent product from entering drains. Dam up.

SECTION 7: Handling and storage

Precautions for safe handling Avoid contact with skin. Avoid contact with skin and clothing. Wash hands thoroughly after handling.

Advice on safe handling Ensure adequate ventilation, especially in confined areas. Use personal protective equipment as required. Use with local exhaust ventilation. Do not breathe dust/fume/gas/mist/vapors/spray.

Conditions for safe storage, including any incompatibilities

Storage Store in accordance with local regulations. Use appropriate containment to avoid environmental contamination.

Storage Conditions Keep container tightly closed. Keep out of the reach of children. Keep containers tightly closed in a cool, well-ventilated place. Keep in properly labeled containers.

SECTION 8: Exposure Controls/Personal Protection.

Exposure Guidelines

United States of America

Component name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Boric Acid 10043-35-3	STEL: 6 mg/m ³ inhalable fraction TWA: 2 mg/m ³ inhalable fraction	-	-
Sodium Hydroxide 1310-73-2	Ceiling: 2 mg/m ³	TWA: 2 mg/m ³ (vacated) Ceiling: 2 mg/m ³	IDLH: 10 mg/m ³ Ceiling: 2 mg/m ³

Canada

Component name	British Columbia OEL	Quebec OEL	Ontario TWA
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Procleix Selection Reagent

Boric Acid 10043-35-3	TWA: 2 mg/m ³ STEL: 6 mg/m ³	-	TWA: 2 mg/m ³ STEL: 6 mg/m ³
Sodium Hydroxide 1310-73-2	Ceiling: 2 mg/m ³	Ceiling: 2 mg/m ³	CEV: 2 mg/m ³

Mexico

NIOSH IDLH *Immediately Dangerous to Life or Health*

Other Information Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering Controls Provide adequate ventilation. Showers. Eyewash stations.

Individual protection measures, such as personal protective equipment

Eye/face protection	Tight sealing safety goggles. Face protection shield.
Skin and body protection	Wear suitable protective clothing.
Hand Protection	Wear protective gloves.
Respiratory protection	Not Applicable

General Hygiene Considerations When using do not eat, drink or smoke. Wash contaminated clothing before reuse. Regular cleaning of equipment, work area and clothing is recommended.

Other Information

Environmental exposure controls Do not allow into any sewer, on the ground or into any body of water.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical State @20°C	Liquid
Color	Colorless
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>
pH	~ 8.8
Melting point/freezing point	
Boiling point / boiling range	No information available
Flash point	
Method	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limits in Air	
Upper flammability limits	No information available
Lower flammability limit	No information available
Vapor pressure	No information available
Vapor density	No information available
Relative density	
Specific Gravity	1.0
Water solubility	No information available
Solubility(ies)	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Viscosity	No information available
Explosive properties	No information available
Oxidizing properties	No information available

SECTION 10: Stability and reactivity

Procleix Selection Reagent

Reactivity	None under normal use conditions.
Stability	Stable under normal conditions.
Possibility of Hazardous Reactions	None under normal use conditions.
Hazardous polymerization	None under normal use conditions.
Conditions to avoid	None under normal use conditions.
Incompatible materials.	None under normal use conditions.
Hazardous Decomposition Products	None under normal use conditions.
Materials to avoid	None under normal use conditions.

SECTION 11: Toxicological information

Information on likely routes of exposure

Product Information	Product does not present an acute toxicity hazard based on known or supplied information.
Inhalation	None under normal use conditions.
Eye contact	None under normal use conditions.
Skin Contact	None under normal use conditions.
Ingestion	None under normal use conditions.

Component name	LD50/oral/rat - NO UNITS (Wizards mg/kg)	LD50/dermal/rat - NO UNITS (Wizards mg/kg)	Inhalation LC50
Boric Acid 10043-35-3	= 2660 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 0.16 mg/L (Rat) 4 h
Triton X-100 9002-93-1	= 1800 mg/kg (Rat)	-	-
Sodium Hydroxide 1310-73-2	-	= 1350 mg/kg (Rabbit)	-

Information on toxicological effects

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component name	ACGIH	IARC	NTP	OSHA
Boric Acid 10043-35-3		Group 2A		X

IARC (International Agency for Research on Cancer)

Group 2A - Probably Carcinogenic to Humans

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.

Chronic toxicity Avoid repeated exposure.

Aspiration hazard No information available.

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral) 51335 mg/kg

ATEmix (dermal) 55096 mg/kg

SECTION 12: Ecological information

Ecotoxicity

20 - 50% of the mixture consists of components(s) of unknown hazards to the aquatic environment.

Component name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Boric Acid 10043-35-3				115 - 153: 48 h Daphnia magna mg/L EC50

Persistence and degradability No information available.

Bioaccumulation No information available.

Mobility No information available.

Component name	Partition coefficient
Boric Acid 10043-35-3	-0.757

Other adverse effects No information available.

SECTION 13: Disposal Considerations.

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Waste from Residues / Unused Products Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Disposal should be in accordance with applicable regional, national and local laws and regulations.

Component name	California Hazardous Waste Status
Boric Acid 10043-35-3	Toxic

SECTION 14: Transport information

DOT Not regulated

TDG Not regulated

IATA Not regulated

IMDG Not regulated

SECTION 15: Regulatory information

International Inventories

Component name	TSCA	EINECS/ELINCS	DSL/NDSL	PICCS
Water 7732-18-5	Present	X	X	X
Boric Acid 10043-35-3	Present	X	X	X
Triton X-100 9002-93-1	Present	-	X	X

Procleix Selection Reagent

Sodium Hydroxide 1310-73-2	Present	X	X	X
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Component name	ENCS	IECSC	AICS	KECL
Water 7732-18-5	-	X	X	Present
Boric Acid 10043-35-3	Present	X	X	Present
Triton X-100 9002-93-1	Present	X	X	Present
Sodium Hydroxide 1310-73-2	Present	X	X	Present

Legend

X - Present

- Not Listed

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

US Federal Regulations**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product may contain substances regulated by state right-to-know regulations.

Component name	New Jersey	Massachusetts	Pennsylvania
Sodium Hydroxide 1310-73-2	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not Applicable

International Regulations**Canada**

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

WHMIS Hazard Class

D2A - Very toxic materials

Mexico

SECTION 16: Other information

Revision Date

25-Oct-2016

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet