

Safety Data Sheet

Reagent 3 (Selection Reagent)

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

Product Identifier

Product Name Reagent 3 (Selection Reagent)

Recommended use of the chemical and restrictions on use

Specific use(s) AccuProbe, Mycoplasma Tissue Culture (Non-Isotopic) MTC-NI, Amplified Mycobacterium Tuberculosis Direct (MTD) Test, Group A Streptococcus Direct Test (GASD)

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

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

Warning

Hazard Statements

H315 - Causes skin irritation
H319 - Causes serious eye irritation

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Precautionary Statements - Prevention

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

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

ERG Code

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

Precautionary statements

P264 - Wash face, hands and any exposed skin thoroughly after handling P280 - Wear protective gloves P302 + P352 - IF ON SKIN: Wash with plenty of water and soap P321 - Specific treatment (see supplemental first aid instructions on this label) P332 + P313 - If skin irritation occurs: Get medical advice/attention P362 + P364 - Take off contaminated clothing and wash it before reuse P280 - Wear eye protection/ 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

Hazards not otherwise classified (HNOC)

4.57% of the mixture consists of ingredient(s) of unknown toxicity

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

Eye contact

In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If symptoms persist, call a physician.

Skin Contact

Wash skin with soap and water. If symptoms persist, call a physician.

Inhalation

Remove to fresh air. If symptoms persist, call a physician.

Ingestion

Clean mouth with water and drink afterwards plenty of water. If symptoms persist, call a physician.

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.

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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.

Environmental precautions

See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for containment

Cover with absorbent or contain.

Methods for cleaning up

Soak up with inert absorbent material. Dispose of contents/containers in accordance with local regulations.

SECTION 7: Handling and storage

Precautions for safe handling

Avoid prolonged contact with eyes, skin, and clothing. No known effects under normal use conditions.

Advice on safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Wash hands thoroughly after handling. Use personal protection recommended in Section 8.

Conditions for safe storage, including any incompatibilities

Storage

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

SECTION 8: Exposure Controls/Personal Protection.

Exposure Guidelines

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United States of America

None

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

None

Component name	British Columbia OEL	Quebec OEL	Ontario TWA
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

None

Appropriate engineering controls

Engineering Controls

Provide adequate ventilation. Showers. Eyewash stations.

Individual protection measures, such as personal protective equipment

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Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin and body protection	Wear suitable protective clothing.
Hand Protection	Wear protective gloves.
Respiratory protection	Not applicable

Other Information

Environmental exposure controls No information available.

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	~ 8.5
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

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

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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

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

Aspiration hazard No information available.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 4.57% of the mixture consists of ingredient(s) of unknown toxicity

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

ATEmix (oral) 52597 mg/kg
ATEmix (dermal) 56338 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.

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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
Sodium Hydroxide 1310-73-2	Present	X	X	X

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

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

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

DSL/NDSL - 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

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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	No
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
Non-controlled

Mexico

No information available

SECTION 16: Other information

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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