HOLOGIC®

Safety Data Sheet Auto Detect 2

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

Product Identifier

Product Name Auto Detect 2

Recommended use of the chemical and restrictions on use

Specific use(s) Progensa PCA3 Assay

Recommended Use In vitro diagnostic

Details of the supplier of the safety data sheet

United States of America Distributo	r Hologic, Inc. 10210 Genetic Center Drive San Diego, CA 92121-4362 USA
Canadian Distributor	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 +1-703-527-3887

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 1
Serious eye damage/eye irritation	Category 1

Emergency Overview

Label Elements



Signal word Danger

Hazard Statements H314 - Causes severe skin burns and eye damage

Precautionary Statements - Prevention

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

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

P310 - Immediately call a POISON CENTER or doctor/physician

P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower P363 - Wash contaminated clothing before reuse

P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P310 - Immediately call a POISON CENTER or doctor/physician

P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting

Precautionary Statements - Storage

P405 - Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant.

Hazards not otherwise classified (HNOC)

Unknown Acute Toxicity

6.04% of the mixture consists of ingredient(s) of unknown toxicity

SECTION 3: Composition/information on ingredients

Substances

Not applicable

<u>Mixtures</u>

Mixtures

OSHA Hazard Classification

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

Component name	CAS No	%
Sodium Hydroxide	1310-73-2	5 - 10

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

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 eq	uipment and emergency procedures	
Personal precautions	Use personal protective equipment as required.	
Environmental precautions	See Section 12 for additional ecological information.	
Methods and material for containme	ent 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

United States of America

Component name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium Hydroxide	Ceiling: 2 mg/m ³	TWA: 2 mg/m ³	IDLH: 10 mg/m ³
1310-73-2		(vacated) Ceiling: 2 mg/m ³	Ceiling: 2 mg/m ³

<u>Canada</u>

Component name	British Columbia OEL	Quebec OEL	Ontario TWA
Sodium Hydroxide 1310-73-2	Ceiling: 2 mg/m ³	Ceiling: 2 mg/m ³	CEV: 2 mg/m ³

<u>Mexico</u>

Component	Carcinogenicity	Exposure Limits
Sodium Hydroxide	-	Mexico: Ceiling 2 mg/m ³
1310-73-2 (5 - 10)		

Appropriate engineering controls

Engineering Controls

Provide adequate ventilation. Showers. Eyewash stations.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields (or goggles).

Skin and body protection Hand Protection Respiratory protection Wear suitable protective clothing. Wear protective gloves. 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 Appearance Color Odor Odor threshold	Liquid Liquid Colorless No information available No information available
<u>Property</u>	Values
рН	~ 14.0
Melting point/freezing point Boiling point / boiling range Flash point	No information available
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	

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	s 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 - (mg/kg)	LD50/dermal/rat - (mg/kg)	Inhalation LC50
Sodium Hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
1310-73-2			

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	No information available.
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 - Pr	roduct Information
Unknown Acute Toxicity	6.04% 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)	5381 mg/kg
ATEmix (dermal)	22351 mg/kg

SECTION 12: Ecological information

<u>Ecotoxicity</u> 20 - 50% of the mixture consists of components(s) of unknown hazards to the aquatic environment.

Persistence and degradability	No information available.
Bioaccumulation	No information available.
Mobility	No information available.
Other adverse effects	No information available.

SECTION 13: Disposal Considerations.

Waste treatment methods

Disposal of wastes	This material, as supplied, is a hazardous waste according to federal regulations (40 CFR 261).
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.

US EPA Waste Number

D002

Component n		California Hazardous Waste Status	
Sodium Hydroxide 1310-73-2		Toxic Corrosive	
SECTION 14: Transport information			
DOT	Regulated		
UN/ID no Proper Shipping Name Hazard Class Packing group Reportable Quantity (RQ) Description Emergency Response Guide Number	UN1824 Sodium hydroxide solutior 8 II Sodium hydroxide: RQ kg UN1824, Sodium hydroxi 154	= 7516.56	
TDG	Regulated		
UN/ID no Proper Shipping Name Hazard Class Packing group Description	UN1824 Sodium hydroxide solutior 8 II UN1824, Sodium hydroxi		
IATA	Regulated		
UN/ID no Proper Shipping Name Hazard Class Packing group ERG Code Description	UN1824 Sodium hydroxide solutior 8 II 8L UN1824, Sodium hydroxi		
IMDG	Regulated		
UN/ID no Proper Shipping Name Hazard Class Packing group EmS No. Description	UN1824 Sodium hydroxide solutior 8 II F-A, S-B UN1824, Sodium hydroxi		

SECTION 15: Regulatory information

International Inventories

Component name	TSCA	EINECS/ELINCS	DSL/NDSL	PICCS
Water 7732-18-5	Present	X	Х	Х
Sodium Hydroxide 1310-73-2	Present	X	Х	Х

Component name	ENCS	IECSC	AICS	KECL
Water 7732-18-5	Present	X	X	Present
Sodium Hydroxide 1310-73-2	Present	X	X	Present

<u>Legend</u> 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

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).

Component name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium Hydroxide 1310-73-2	1000 lb			Х

<u>CERCLA</u>

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).

Component name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Sodium Hydroxide	1000 lb		RQ 1000 lb final RQ
1310-73-2			RQ 454 kg final RQ

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
Water			Х
7732-18-5			
Sodium Hydroxide	X	Х	Х
1310-73-2			

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

Non-controlled

<u>Mexico</u>

No inform	ation available		
	Component name	Carcinogenicity	Exposure Limits

-	Mexico: Ceiling 2 mg/m ³
	-

SECTION 16: Other information

Revision Date

24-Sep-2021

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Version

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