

Safety Data Sheet

Procleix Auto Detect 2

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

Product Identifier

Product Name Procleix Auto Detect 2

Recommended use of the chemical and restrictions on use

Specific use(s) Procleix Assays

Recommended Use Test for donated blood

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

Distributor Novartis Pharma KK
Toranomon Hills Mori Tower, 23-1
Toranomon 1-chome, Minato-ku, Tokyo, Japan 105-6333

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 1 |
| Subcategory | Sub-category A |

| | |
|--|------------|
| 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

P310 - Immediately call a POISON CENTER or doctor/physician

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)

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 | % |
|------------------|-----------|--------|
| Sodium Hydroxide | 1310-73-2 | 5 - 10 |

SECTION 4: First aid measures

First aid measures

General advice

Immediate medical attention is required.

| | |
|---|--|
| Eye contact | Immediate medical attention is required. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. |
| Skin Contact | Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. |
| Inhalation | Remove to fresh air. Call a physician or poison control center immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. |
| Ingestion | Immediate medical attention is required. Do NOT induce vomiting. Drink plenty of water. Never give anything by mouth to an unconscious person. Remove from exposure, lie down. Clean mouth with water and drink afterwards plenty of water. Call a physician or poison control center immediately. |
| Self-protection of the first aider | Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. |

Indication of any immediate medical attention and special treatment needed

| | |
|---------------------------|---|
| Note to physicians | Product is a corrosive material. Use of gastric lavage or emesis is contraindicated. Possible perforation of stomach or esophagus should be investigated. Do not give chemical antidotes. Asphyxia from glottal edema may occur. Marked decrease in blood pressure may occur with moist rales, frothy sputum, and high pulse pressure. Treat symptomatically. |
|---------------------------|---|

SECTION 5: Firefighting measures

| | |
|--|--|
| Flammability | Not flammable. |
| Suitable Extinguishing Media | Use extinguishing agent suitable for type of surrounding fire. |
| Specific hazards arising from the chemical | The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating and toxic gases and vapors. In the event of fire and/or explosion do not breathe fumes. |
| 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 | Evacuate personnel to safe areas. Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. Keep people away from and upwind of spill/leak. |
| <u>Environmental precautions</u> | Do not allow into any sewer, on the ground or into any body of water. Should not be released into the environment. 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 | Cover with absorbent or contain. |
| Methods for cleaning up | Dike far ahead of liquid spill for later disposal. Soak up with inert absorbent material. Take up mechanically, placing in appropriate containers for disposal. Clean contaminated surface thoroughly. Prevent product from entering drains. Dam up. After cleaning, flush away traces with water. |

SECTION 7: Handling and storage

| | |
|--------------------------------------|---|
| Precautions for safe handling | Avoid contact with eyes. Avoid contact with skin. Do not breathe dust. Do not breathe dust/fume/gas/mist/vapors/spray. Keep container tightly closed. Ensure adequate ventilation, especially in confined areas. Wash hands thoroughly after handling. Do not taste or swallow. Do not take internally. |
|--------------------------------------|---|

Advice on safe handling Use personal protective equipment as required. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation, especially in confined areas. In case of insufficient ventilation, wear suitable respiratory equipment. Use only with adequate ventilation and in closed systems.

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

Incompatible materials. Incompatible with strong acids and bases. Incompatible with oxidizing agents.

SECTION 8: Exposure Controls/Personal Protection.

Exposure Guidelines

United States of America

| Component name | ACGIH TLV | OSHA PEL | NIOSH IDLH |
|-------------------------------|------------------------------|--|--|
| 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 |
|-------------------------------|------------------------------|------------------------------|--------------------------|
| Sodium Hydroxide 1310-73-2 | Ceiling: 2 mg/m ³ | Ceiling: 2 mg/m ³ | CEV: 2 mg/m ³ |

Mexico

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

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. Keep away from food, drink and animal feeding stuffs. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Avoid contact with skin, eyes or clothing. Take off all contaminated clothing and wash it before reuse. Wear suitable gloves and eye/face protection.

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
 Appearance Liquid
 Color Colorless
 Odor No information available
 Odor threshold No information available

| <u>Property</u> | <u>Values</u> |
|-------------------------------|--------------------------|
| pH | ~ 14.0 |
| 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 Exposure to air or moisture over prolonged periods.

Incompatible materials. Incompatible with strong acids and bases. Incompatible with oxidizing agents.

Hazardous Decomposition Products Thermal decomposition can lead to release of irritating and toxic gases and vapors.

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 |
|-------------------------------|---|---|-----------------|
| 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 No information available.

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

Chronic toxicity Chronic exposure to corrosive fumes/gases may cause erosion of the teeth followed by jaw necrosis. Bronchial irritation with chronic cough and frequent attacks of pneumonia are common. Gastrointestinal disturbances may also be seen. Avoid repeated exposure. Possible risk of irreversible effects.

Target Organ Effects Eyes, Respiratory system, Skin.

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 (dermal) 22351 mg/kg

SECTION 12: Ecological information

Ecotoxicity

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 Do not reuse container.

US EPA Waste Number D002

| Component name | California Hazardous Waste Status |
|-------------------------------|-----------------------------------|
| Sodium Hydroxide 1310-73-2 | Toxic Corrosive |

SECTION 14: Transport information

DOT

UN/ID no UN1824
 Hazard Class 8
 Packing group II
 Reportable Quantity (RQ) Sodium hydroxide: RQ kg= 7516.56
 Emergency Response Guide Number 154

TDG

UN/ID no UN1824
 Hazard Class 8
 Packing group II

IATA

UN/ID no UN1824
 Hazard Class 8
 Packing group II
 ERG Code 8L

IMDG

UN/ID no UN1824
 Hazard Class 8
 Packing group II
 EmS No. F-A, S-B

SECTION 15: Regulatory information

International Inventories

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

| Component name | ENCS | IECSC | AICS | KECL |
|-------------------------------|---------|-------|------|---------|
| Water 7732-18-5 | - | 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/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 Yes
 Chronic Health Hazard Yes
 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 | | | X |

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).

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

Non-controlled

Mexico

SECTION 16: Other information

Revision Date

17-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