

Safety Data Sheet Assay Cartridge

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

Product Identifier

Product Name Assay Cartridge

Recommended use of the chemical and restrictions on use

Specific use(s) Panther Fusion Paraflu, Panther Fusion Flu A/B/RSV, Panther Fusion AdV/hMPV/RV

Recommended Use For Investigational Use/Performance Evaluation Only

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 not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Emergency Overview

Label Elements

The product contains no substances which at their given concentration, are considered to be hazardous to health.

ERG Code

Hazards not otherwise classified (HNOC)

Other Information

99.99% 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

The product contains no substances which at their given concentration, are considered to be hazardous to health.

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

SECTION 5: Firefighting measures

Flammability Not flammable.

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 precautionsUse personal protective equipment as required.

Environmental precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for containmentCover 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 handlingHandle in accordance with good industrial hygiene and safety practice.

Advice on safe handling Use personal protective equipment as required.

Conditions for safe storage, including any incompatibilities

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

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	Ceiling: 2 mg/m ³
1310-73-2		(vacated) 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

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

Provide adequate ventilation. Showers. Eyewash stations. **Engineering Controls**

Individual protection measures, such as personal protective equipment

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

Appearance Lyophilized Cake Color White to off-white

Odor No information available **Odor threshold** No information available

Property Values

Not applicable

Melting point/freezing point

No information available Boiling point / boiling range

Flash point

Method No information available No information available **Evaporation rate** Flammability (solid, gas) No information available Flammability Limits in Air

Upper flammability limits No information available Lower flammability limit Vapor pressure

No information available No information available Vapor density No information available

Relative density Not applicable

Water solubility No information available No information available Solubility(ies) **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 polymerizationNone under normal use conditions.

Conditions to avoidNone 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.

InhalationNone under normal use conditions.Eye contactNone under normal use conditions.Skin ContactNone under normal use conditions.IngestionNone under normal use conditions.

Information on toxicological effects

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

Skin corrosion/irritation
Serious eye damage/eye irritation
Sensitization
Germ cell mutagenicity

No information available.
No information available.
No information available.

Germ cell mutagenicityCarcinogenicity
No information available.
No information available.

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

Chronic toxicity No known effect based on information supplied.

Aspiration hazard No information available.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 99.99% of the mixture consists of ingredient(s) of unknown toxicity

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 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.

SECTION 14: Transport information

DOT Not regulated

<u>TDG</u> Not regulated

IATA Not regulated

IMDG Not regulated

SECTION 15: Regulatory information

International Inventories

Component name	TSCA	EINECS/ELINCS	DSL/NDSL	PICCS
EDTA Disodium Salt 6381-92-6	-	-	X	X
Sodium Hydroxide 1310-73-2	Present	X	X	X
Water 7732-18-5	Present	X	X	X

Component name	ENCS	IECSC	AICS	KECL
EDTA Disodium Salt 6381-92-6	-	Х	X	-
Sodium Hydroxide 1310-73-2	Present	Х	X	Present
Water 7732-18-5	-	Х	X	Present

<u>Legend</u>

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

X - Present - Not Listed

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).

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	Х	X	Х

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

International Regulations

<u>Canada</u>

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 10-Feb-2017

Version 4

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