



Safety Data Sheet

HCV VL Kit Controls

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

Product Identifier

Product Name HCV VL Kit Controls

Recommended use of the chemical and restrictions on use

Specific use(s) Aptima HCV Quant DX Assay

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

Acute toxicity - Dermal

Category 4

Emergency Overview

Label Elements



Signal word

Warning

Hazard Statements

H312 - Harmful in contact with skin

HCV VL Kit Controls

EUH032 - Contact with acids liberates very toxic gas

H302 - Harmful if swallowed

Precautionary Statements - Prevention

P280 - Wear protective gloves and eye/face protection

ERG Code

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

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

P363 - Wash contaminated clothing before reuse

Precautionary Statements - Disposal

P501 - Dispose of contents/container in accordance with local/regional/national/international regulation.

Hazards not otherwise classified (HNOC)

H412 - Harmful to aquatic life with long lasting effects. H402 - Harmful to aquatic life.

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	%
Human Plasma	90989-72-3	95 - 100
Sodium azide	26628-22-8	< 1

SECTION 4: First aid measures

First aid measures

General advice

If symptoms persist, call a physician. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing.

Eye contact

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. If symptoms persist, call a physician.

Skin Contact

Consult a physician if necessary. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation

Remove to fresh air. Call a physician. If breathing is irregular or stopped, administer artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.

Ingestion

Rinse mouth. Drink plenty of water. If symptoms persist, call a physician. Do NOT induce vomiting.

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.
<u>Environmental precautions</u>	Prevent entry into waterways, sewers, basements or confined areas. Do not flush into surface water or sanitary sewer system. 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	Cover liquid spill with sand, earth or other non-combustible absorbent material. Cover powder spill with plastic sheet or tarp to minimize spreading. Pick up and transfer to properly labeled containers.

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	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

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.

SECTION 8: Exposure Controls/Personal Protection.

Exposure Guidelines

United States of America

Component name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium azide 26628-22-8	Ceiling: 0.29 mg/m ³ NaN ₃ Ceiling: 0.11 ppm Hydrazoic acid vapor	(vacated) S* (vacated) Ceiling: 0.1 ppm HN ₃ (vacated) Ceiling: 0.3 mg/m ³ NaN ₃	Ceiling: 0.1 ppm HN ₃ Ceiling: 0.3 mg/m ³ NaN ₃

Canada

Component name	British Columbia OEL	Quebec OEL	Ontario TWA
Sodium azide 26628-22-8	Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm	Ceiling: 0.11 ppm Ceiling: 0.3 mg/m ³	CEV: 0.29 mg/m ³ CEV: 0.11 ppm

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.
Skin and body protection	Wear suitable protective clothing.
Hand Protection	Wear protective gloves.
Respiratory protection	Not applicable

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
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Information on basic physical and chemical properties

Physical State @20°C	Liquid
Appearance	Frozen
Color	amber
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>
pH	
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	No information available
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

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 azide 26628-22-8	= 27 mg/kg (Rat)	-	-

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 - Product Information

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

ATEmix (oral)	9000 mg/kg
ATEmix (dermal)	1667 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

HCV VL Kit Controls

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.
US EPA Waste Number	P105

Component name	RCRA - Halogenated Organic Compounds	RCRA - P Series Wastes	RCRA - F Series Wastes	RCRA - K Series Wastes
Sodium azide 26628-22-8		P105		
Component name		California Hazardous Waste Status		
Sodium azide 26628-22-8		Ignitable Reactive		

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/NDL	PICCS
Human Plasma 90989-72-3	-	X	-	-
Trehalose 6138-23-4	-	-	-	X
Sodium azide 26628-22-8	Present	X	X	X
Gentamicin Sulfate 1403-66-3	-	X	-	X

Component name	ENCS	IECSC	AICS	KECL
Trehalose 6138-23-4	-	X	X	-
Sodium azide 26628-22-8	Present	X	X	Present
Gentamicin Sulfate 1403-66-3	-	X	X	-

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 does not contain any substances regulated as 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).

Component name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Sodium azide 26628-22-8	1000 lb	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 azide 26628-22-8	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

Biohazard

**Mexico****SECTION 16: Other information****Revision Date**

22-Feb-2017

Version

3

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