

# 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** In vitro diagnostic

**Details of the supplier of the safety data sheet**

**United States of America Distributor** 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 not 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

**Precautionary Statements - Prevention**

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

**ERG Code**

IF ON SKIN: Wash with plenty of water and soap  
 Call a POISON CENTER or doctor if you feel unwell  
 Take off contaminated clothing and wash it before reuse

**Precautionary Statements - Disposal**

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

**Hazards not otherwise classified (HNOC)**

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

**SECTION 3: Composition/information on ingredients**

**Substances**

Not applicable

**Mixtures**

Mixtures

**OSHA Hazard Classification**

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

Component name	CAS No	%
Human Serum / Human Plasma	90989-72-3	95 - 100
Sodium azide	26628-22-8	< 1

**SECTION 4: First aid measures**

**First aid measures**

<b>Eye contact</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If symptoms persist, call a physician.
<b>Skin Contact</b>	Wash skin with soap and water. If symptoms persist, call a physician.
<b>Inhalation</b>	Remove to fresh air. If symptoms persist, call a physician.
<b>Ingestion</b>	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**

<b>Flammability</b>	Not flammable.
<b>Suitable Extinguishing Media</b>	Use extinguishing agent suitable for type of surrounding fire.
<b>Protective equipment and precautions for firefighters</b>	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**

**United States of America**

Component name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium azide 26628-22-8	Ceiling: 0.29 mg/m <sup>3</sup> Sodium azide Ceiling: 0.11 ppm Hydrazoic acid vapor	(vacated) S* (vacated) Ceiling: 0.1 ppm HN3 (vacated) Ceiling: 0.3 mg/m <sup>3</sup> NaN3	Ceiling: 0.1 ppm HN3 Ceiling: 0.3 mg/m <sup>3</sup> NaN3

**Canada**

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

**Mexico**

Component	Carcinogenicity	Exposure Limits
Sodium azide 26628-22-8 (< 1)	-	Mexico: Ceiling 0.29 mg/m <sup>3</sup> Mexico: Ceiling 0.11 ppm

**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** 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

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

<u>Property</u>	<u>Values</u>
<b>pH</b>	
<b>Melting point/freezing point</b>	
<b>Boiling point / boiling range</b>	No information available
<b>Flash point</b>	
<b>Method</b>	No information available
<b>Evaporation rate</b>	No information available
<b>Flammability (solid, gas)</b>	No information available
<b>Flammability Limits in Air</b>	
<b>Upper flammability limits</b>	No information available
<b>Lower flammability limit</b>	No information available
<b>Vapor pressure</b>	No information available
<b>Vapor density</b>	No information available
<b>Relative density</b>	No information available
<b>Water solubility</b>	No information available
<b>Solubility(ies)</b>	No information available
<b>Partition coefficient</b>	No information available
<b>Autoignition temperature</b>	No information available
<b>Decomposition temperature</b>	No information available
<b>Viscosity</b>	No information available
<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available

## SECTION 10: Stability and reactivity

<b>Reactivity</b>	None under normal use conditions.
<b>Stability</b>	Stable under normal conditions.
<b>Possibility of Hazardous Reactions</b>	None under normal use conditions.
<b>Hazardous polymerization</b>	None under normal use conditions.
<b>Conditions to avoid</b>	None under normal use conditions.
<b>Incompatible materials</b>	None under normal use conditions.
<b>Hazardous Decomposition Products</b>	None under normal use conditions.
<b>Materials to avoid</b>	None under normal use conditions.

## SECTION 11: Toxicological information

### Information on likely routes of exposure

<b>Product Information</b>	Product does not present an acute toxicity hazard based on known or supplied information.
<b>Inhalation</b>	None under normal use conditions.
<b>Eye contact</b>	None under normal use conditions.
<b>Skin Contact</b>	None under normal use conditions.
<b>Ingestion</b>	None under normal use conditions.

Component name	LD50/oral/rat - (mg/kg)	LD50/dermal/rat - (mg/kg)	Inhalation LC50
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## HCV VL Kit Controls

Sodium azide 26628-22-8	= 27 mg/kg ( Rat )	= 20 mg/kg ( Rabbit )	-
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### Information on toxicological effects

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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.

<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.

<b>Aspiration hazard</b>	No information available.
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#### Numerical measures of toxicity - Product Information

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

<b>ATEmix (oral)</b>	9000 mg/kg
<b>ATEmix (dermal)</b>	1667

## SECTION 12: Ecological information

### Ecotoxicity

20 - 50% of the mixture consists of components(s) of unknown hazards to the aquatic environment.

<b>Persistence and degradability</b>	No information available.
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<b>Bioaccumulation</b>	No information available.
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<b>Mobility</b>	No information available.
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<b>Other adverse effects</b>	No information available.
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## SECTION 13: Disposal Considerations.

### Waste treatment methods

<b>Disposal of wastes</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.
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<b>Waste from residues/unused products</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.
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<b>Contaminated packaging</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.
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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

HCV VL Kit Controls

<b>DOT</b>	Not regulated
<b>TDG</b>	Not regulated
<b>IATA</b>	Not regulated
<b>IMDG</b>	Not regulated

**SECTION 15: Regulatory information**

**International Inventories**

Component name	TSCA	EINECS/ELINCS	DSL/NDSL	PICCS
Human Serum / 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

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 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).

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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

Non-controlled

#### Mexico

No information available

Component name	Carcinogenicity	Exposure Limits
Sodium azide	-	Mexico: Ceiling 0.29 mg/m <sup>3</sup> Mexico: Ceiling 0.11 ppm

## SECTION 16: Other information

**Revision Date** 04-Nov-2021

**Version** 7

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**