



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
UK REACH Regulations (SI 2019/758 as amended)

Revision date 15-Sep-2023

Revision Number 1

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

1.1. Product identifier

Product Name Exact Diagnostics HPV

Catalogue Number(s) HPVP100, HPV16C, HPV18C, HPV68C, HPVNEG, HPVP200, HPVVB200

Pure substance/mixture Mixture

Contains Methanol

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Corporate Headquarters

Bio-Rad Laboratories Inc.
1000 Alfred Nobel Drive
Hercules, CA 94547
USA

Manufacturer

Exact Diagnostics
100 South Jones Street, Suite 100,
Fort Worth, Texas 76104
USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd
The Junction
Station Road
Watford, WD17 1ET
UK

For further information, please contact

Technical Service 00800 00246 723
Techsupport.UK@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Acute toxicity - Oral	Category 3 - (H301)
Acute toxicity - Dermal	Category 3 - (H311)
Acute toxicity - Inhalation (Dusts/Mists)	Category 3 - (H331)
Specific target organ toxicity — single exposure	Category 1
Flammable liquids	Category 3 - (H226)

2.2. Label elements

Contains Methanol

**Signal word**

Danger

Hazard statements

H301 - Toxic if swallowed

H311 - Toxic in contact with skin

H331 - Toxic if inhaled

H370 - Causes damage to organs

H226 - Flammable liquid and vapour

Precautionary statements

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

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

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

P370 + P378 - In case of fire: Use dry chemical, CO₂, water spray or alcohol-resistant foam to extinguish

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

2.3. Other hazards

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Methanol 67-56-1	50 - 100	(603-001-00-X) 200-659-6	-	Flam. Liq. 2 (H225) Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) STOT SE 1 (H370)	-	-	-

Full text of H- and EUH-phrases: see section 16This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (UK REACH Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.
Inhalation	Remove to fresh air. IF exposed or concerned: Get medical advice/attention. If breathing has stopped, give artificial respiration. Get medical attention immediately. Immediate medical attention is required. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen.
Eye contact	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. Get immediate medical attention. Contains human source material and / or potentially infectious components. Call a doctor.
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get immediate medical attention. Wash with soap and water.
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get immediate medical attention. Contains human source material and / or potentially infectious components. Call a doctor.
Self-protection of the first aider	Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Do not breathe vapour or mist.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms	Coughing and/ or wheezing. Difficulty in breathing.
-----------------	---

4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors	Contains human source material and / or potentially infectious components.
------------------------	--

SECTION 5: Firefighting measures**5.1. Extinguishing media**

Suitable Extinguishing Media	Dry chemical. Carbon dioxide (CO ₂). Water spray. Alcohol resistant foam.
-------------------------------------	---

Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
-------------------	--

Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
---------------------------------------	---

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
---	---

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
---	--

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material. Do not breathe vapour or mist.
Other information	Ventilate the area. Refer to protective measures listed in Sections 7 and 8.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	Refer to protective measures listed in Sections 7 and 8. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.
----------------------------------	--

6.3. Methods and material for containment and cleaning up

Methods for containment	Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapour suppressing foam may be used to reduce vapours. Dyke far ahead of spill to collect run-off water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. Do not allow into any sewer, on the ground or into any body of water.
Methods for cleaning up	Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labelled containers. Use: Disinfectant. Clean contaminated surface thoroughly.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections	See section 8 for more information. See section 13 for more information.
------------------------------------	--

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Advice on safe handling	Use personal protection equipment. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Take off contaminated clothing and wash it before reuse. Do not breathe vapour or mist. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product.
General hygiene considerations	Do not eat, drink or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Do not breathe vapour or mist. Follow universal and standard precautions for handling potentially infectious materials.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat,
---------------------------	---

sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labelled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Keep out of the reach of children. Store locked up. Store according to product and label instructions.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical name	United Kingdom
Methanol 67-56-1	TWA: 200 ppm TWA: 266 mg/m ³ STEL: 250 ppm STEL: 333 mg/m ³ Sk*

Biological occupational exposure limits This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering controls No information available.

Personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves. Impervious gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Do not eat, drink or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Do not breathe vapour or mist. Follow universal and standard precautions for handling potentially infectious materials.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Appearance	clear liquid
Colour	clear
Odour	Alcohol.
Odour threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	71 °C	
Boiling point / boiling range	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	26 °C	
Autoignition temperature	464 °C	
Decomposition temperature		None known
pH		
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information**SECTION 10: Stability and reactivity****10.1. Reactivity**

Reactivity	No information available.
------------	---------------------------

10.2. Chemical stability

Stability	Stable under normal conditions.
-----------	---------------------------------

Explosion data

Sensitivity to mechanical impact	None.
Sensitivity to static discharge	Yes.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	None under normal processing.
------------------------------------	-------------------------------

10.4. Conditions to avoid

Conditions to avoid	Heat, flames and sparks. Excessive heat.
---------------------	--

10.5. Incompatible materials

Incompatible materials	None known based on information supplied.
------------------------	---

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information**11.1. Toxicological information****Information on likely routes of exposure****Product Information**

Inhalation	Specific test data for the substance or mixture is not available. Toxic by inhalation. (based on components).
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available. Toxic in contact with skin. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Coughing and/ or wheezing. Difficulty in breathing.

Acute toxicity**Numerical measures of toxicity**

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

ATEmix (oral)	181.80 mg/kg
ATEmix (dermal)	545.50 mg/kg
ATEmix (inhalation-dust/mist)	0.911 mg/l
ATEmix (inhalation-vapour)	75.80 mg/l

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Methanol	= 6200 mg/kg (Rat)	= 15840 mg/kg (Rabbit)	= 22500 ppm (Rat) 8 h

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.
Respiratory or skin sensitisation	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.

Reproductive toxicity No information available.

STOT - single exposure Based on the classification criteria of the Globally Harmonized System as adopted in the country or region with which this safety data sheet complies, this product has been determined to cause systemic target organ toxicity from acute exposure. (STOT SE). Causes damage to organs if swallowed. Causes damage to organs in contact with skin.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

Unknown aquatic toxicity Contains 0 % of components with unknown hazards to the aquatic environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Methanol	-	LC50: =28200mg/L (96h, Pimephales promelas) LC50: >100mg/L (96h, Pimephales promelas) LC50: 19500 - 20700mg/L (96h, Oncorhynchus mykiss) LC50: 18 - 20mL/L (96h, Oncorhynchus mykiss) LC50: 13500 - 17600mg/L (96h, Lepomis macrochirus)	-	-

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Component Information

Chemical name	Partition coefficient
Methanol	-0.77

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Methanol	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

No information available.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Waste from residues/unused products**

Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging

Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers.

SECTION 14: Transport information**IATA**

14.1 UN number or ID number	UN1992
14.2 UN proper shipping name	Flammable liquid, toxic, n.o.s. (Methanol Solution)
14.3 Transport hazard class(es)	3
Subsidiary hazard class	6.1
14.4 Packing group	III
Description	UN1992, Flammable liquid, toxic, n.o.s. (Methanol Solution), 3 (6.1), III
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	A3

IMDG

14.1 UN number or ID number	UN1992
14.2 UN proper shipping name	FLAMMABLE LIQUID, TOXIC, N.O.S. (Methanol Solution)
14.3 Transport hazard class(es)	3
Subsidiary hazard class	6.1
14.4 Packing group	III
Description	UN1992, FLAMMABLE LIQUID, TOXIC, N.O.S. (Methanol Solution), 3 (6.1), III, (26°C C.C.)
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	223, 274
EmS-No	F-E, S-D
14.7 Maritime transport in bulk according to IMO instruments	No information available

RID

14.1 UN number	UN1992
14.2 UN proper shipping name	FLAMMABLE LIQUID, TOXIC, N.O.S. (Methanol Solution)
14.3 Transport hazard class(es)	3
Subsidiary hazard class	6.1
14.4 Packing group	III
Description	UN1992, FLAMMABLE LIQUID, TOXIC, N.O.S. (Methanol Solution), 3 (6.1), III
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	274
Classification code	FT1

ADR

14.1 UN number or ID number	1992
14.2 UN proper shipping name	FLAMMABLE LIQUID, TOXIC, N.O.S. (Methanol Solution)

14.3 Transport hazard class(es)	3
Subsidiary class	6.1
14.4 Packing group	III
Description	1992, FLAMMABLE LIQUID, TOXIC, N.O.S. (Methanol Solution), 3 (6.1), III
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	274
Classification code	FT1
Tunnel restriction code	(D/E)

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

Authorisations and/or restrictions on use:

This product contains one or more substances subject to restriction (UK REACH - Annex XVII).

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorisation per REACH Annex XIV
Methanol - 67-56-1	Use restricted. See item 69.	-

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Dangerous substance category per COMAH Regulations 2015 (as amended)

H2 - ACUTE TOXIC

H3 - STOT SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

P5a - FLAMMABLE LIQUIDS

P5b - FLAMMABLE LIQUIDS

P5c - FLAMMABLE LIQUIDS

Named dangerous substances per COMAH Regulations 2015 (as amended)

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
Methanol - 67-56-1	500	5000

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Not applicable

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended)

Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

International Inventories

Contact supplier for inventory compliance status

15.2. Chemical safety assessment

Chemical Safety Report

No information available

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet**Full text of H-Statements referred to under section 3**

H225 - Highly flammable liquid and vapour

H301 - Toxic if swallowed

H311 - Toxic in contact with skin

H331 - Toxic if inhaled

H370 - Causes damage to organs

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation
+	Sensitisers		

Classification procedure

Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
 U.S. Environmental Protection Agency ChemView Database
 European Food Safety Authority (EFSA)
 European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
 European Chemicals Agency (ECHA) (ECHA_API)
 EPA (Environmental Protection Agency)
 Acute Exposure Guideline Level(s) (AEGL(s))
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
 U.S. Environmental Protection Agency High Production Volume Chemicals
 Food Research Journal
 Hazardous Substance Database
 International Uniform Chemical Information Database (IUCLID)
 National Institute of Technology and Evaluation (NITE)
 Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
 NIOSH (National Institute for Occupational Safety and Health)
 National Library of Medicine's ChemID Plus (NLM CIP)
 National Library of Medicine's PubMed database (NLM PUBMED)
 National Toxicology Program (NTP)
 New Zealand's Chemical Classification and Information Database (CCID)
 Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
 Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
 Organisation for Economic Co-operation and Development Screening Information Data Set
 World Health Organization

Revision date 15-Sep-2023

Revision Note Reviewed existing information and made minor updates
This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended)
Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Disclaimer

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