



# 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, HPV200  
**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

<b>Acute toxicity - Oral</b>	Category 3 - (H301)
<b>Acute toxicity - Dermal</b>	Category 3 - (H311)
<b>Acute toxicity - Inhalation (Dusts/Mists)</b>	Category 3 - (H331)
<b>Specific target organ toxicity — single exposure</b>	Category 1
<b>Flammable liquids</b>	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, CO<sub>2</sub>, 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 16**This 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**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.
<b>Inhalation</b>	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.
<b>Eye contact</b>	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.
<b>Skin contact</b>	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.
<b>Ingestion</b>	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.
<b>Self-protection of the first aider</b>	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<sub>2</sub>). 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**

<b>Personal precautions</b>	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.
<b>Other information</b>	Ventilate the area. Refer to protective measures listed in Sections 7 and 8.
<b>For emergency responders</b>	Use personal protection recommended in Section 8.

**6.2. Environmental precautions**

<b>Environmental precautions</b>	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.
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**6.3. Methods and material for containment and cleaning up**

<b>Methods for containment</b>	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.
<b>Methods for cleaning up</b>	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.
<b>Prevention of secondary hazards</b>	Clean contaminated objects and areas thoroughly observing environmental regulations.

**6.4. Reference to other sections**

<b>Reference to other sections</b>	See section 8 for more information. See section 13 for more information.
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**SECTION 7: Handling and storage****7.1. Precautions for safe handling**

<b>Advice on safe handling</b>	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.
<b>General hygiene considerations</b>	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**

<b>Storage Conditions</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat,
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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 <sup>3</sup> STEL: 250 ppm STEL: 333 mg/m <sup>3</sup> 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**

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

<b>ATEmix (oral)</b>	181.80 mg/kg
<b>ATEmix (dermal)</b>	545.50 mg/kg
<b>ATEmix (inhalation-dust/mist)</b>	0.911 mg/l
<b>ATEmix (inhalation-vapour)</b>	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**

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitisation</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	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**

<b>Waste from residues/unused products</b>	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.
<b>Contaminated packaging</b>	Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers.

**SECTION 14: Transport information****IATA**

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

**IMDG**

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

**RID**

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

**ADR**

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

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