



# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:  
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 15-Sep-2023

Revision Number 1.2

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

### 1.1. Product identifier

Product Name	Exact Diagnostics CT/NG Run Control
Catalogue Number(s)	CTNGRC
Nanoforms	Not applicable
Pure substance/mixture	Mixture

### 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

Bio-Rad Laboratories Pvt. Ltd.  
Bio-Rad House  
86-87, Udyog Vihar Phase IV Gurgaon  
122005  
Haryana India

Bio-Rad Laboratories (Pty) Ltd.  
34 Bolton Road  
Parkwood, Johannesburg 2193  
South Africa

For further information, please contact

Technical Service	00800 00246 723 Ireland: Techsupport.UK@bio-rad.com India: support.india@bio-rad.com South Africa: cdg_techsupport_eemea@bio-rad.com
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### 1.4. Emergency telephone number

24 Hour Emergency Phone Number	CHEMTREC Ireland: 353-19014670 CHEMTREC India: 000-800-100-7141 CHEMTREC South Africa: 0-800-983-611
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## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

**2.2. Label elements**

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

**Hazard statements**

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

EUH208 - Contains 5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone May produce an allergic reaction.

**2.3. Other hazards**

Contains human source material and / or potentially infectious components

## SECTION 3: Composition/information on ingredients

**3.1 Substances**

Not applicable

**3.2 Mixtures**

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Trade secret	20 - 35	No data available	.?	No data available	-	-	-
Trade secret	1 - 2.5	No data available	.?	No data available	-	-	-
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	0.001 - 0.01	No data available	(613-167-00-5)	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) Skin Corr. 1B (H314) Eye Dam. 1 (H318) Skin Sens. 1A (H317) (EUH071) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Eye Irrit. 2 :: 0.06%≤C<0.6% Skin Corr. 1C :: C≥0.6% Skin Irrit. 2 :: 0.06%≤C<0.6% Skin Sens. 1A :: C≥0.0015% Eye Dam. 1 :: C≥0.6%	100	100

**Full text of H- and EUH-phrases: see section 16**

**Acute Toxicity Estimate**

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Trade secret	29700	No data available	No data available	No data available	No data available
Trade secret	3000	10000	Inhalation LC50 Rat >42 mg/L 1 h (no deaths occurred, aerosol, Source: ECHA_API)	>42	Inhalation LC50 Rat >42 mg/L 1 h (no deaths occurred, aerosol, Source: ECHA_API)
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with	53	87.12	No data available	No data available	No data available

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
2-methyl-3(2H)-isothiazolone 55965-84-9					

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

Inhalation	Remove to fresh air.
Eye contact	Contains human source material and / or potentially infectious components. Call a doctor. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Skin contact	Wash with soap and water.
Ingestion	Contains human source material and / or potentially infectious components. Call a doctor.

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

Symptoms	No information available.
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### 4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors	Contains human source material and / or potentially infectious components.
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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
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Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
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### 5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	No information available.
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### 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.
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## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.
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**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** See Section 12 for additional Ecological Information.

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Do not allow into any sewer, on the ground or into any body of water.

**Methods for cleaning up** 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** Ensure adequate ventilation.

**General hygiene considerations** Follow universal and standard precautions for handling potentially infectious materials.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** 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	European Union	Austria	Belgium	Bulgaria	Croatia
Trade secret	-	-	TWA: 10 mg/m <sup>3</sup>	TWA: 10.0 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> STEL: 20 mg/m <sup>3</sup>
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	-	TWA: 0.05 mg/m <sup>3</sup> Sh+	-	-	-
Chemical name	Cyprus	Czech Republic	Denmark	Estonia	Finland
Trade secret	-	-	-	TWA: 10 mg/m <sup>3</sup>	-
Chemical name	France	Germany TRGS	Germany DFG	Greece	Hungary
Trade secret	TWA: 10 mg/m <sup>3</sup>	-	-	-	-
Chemical name	Ireland	Italy MDLPS	Italy AIDII	Latvia	Lithuania
Trade secret	TWA: 10 mg/m <sup>3</sup> STEL: 20 mg/m <sup>3</sup>	-	TWA: 10 mg/m <sup>3</sup>	TWA: 5 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
Trade secret	-	-	-	TWA: 5 mg/m <sup>3</sup>	TWA: 5 mg/m <sup>3</sup>

Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
Trade secret	TWA: 10 mg/m <sup>3</sup>	-	-	-	TWA: 10 mg/m <sup>3</sup>
Chemical name	Sweden	Switzerland	United Kingdom		
Trade secret	-	-	TWA: 10 mg/m <sup>3</sup> STEL: 20 mg/m <sup>3</sup>		
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone 55965-84-9	-	S+ TWA: 0.2 mg/m <sup>3</sup> STEL: 0.4 mg/m <sup>3</sup>	-		

**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)**

**8.2. Exposure controls****Personal protective equipment**

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

**Hand protection** Wear suitable 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** Follow universal and standard precautions for handling potentially infectious materials.

**Environmental exposure controls** No information available.

## SECTION 9: Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

**Physical state** Liquid  
**Colour** clear  
**Odour** No information available.  
**Odour threshold** No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>Melting point / freezing point</b>	No data available	None known
<b>Boiling point / boiling range</b>	No data available	None known
<b>Flammability (solid, gas)</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Flash point</b>	No data available	None known
<b>Autoignition temperature</b>	200 °C	
<b>Decomposition temperature</b>		None known
<b>pH</b>	No data available	None known

pH (as aqueous solution)	No data available	No information available
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****9.2.1. Information with regards to physical hazard classes**

Not applicable

**9.2.2. Other safety characteristics**

No information available

**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 None.

**10.3. Possibility of hazardous reactions**

Possibility of hazardous reactions None under normal processing.

**10.4. Conditions to avoid**

Conditions to avoid None known based on information supplied.

**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. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Information on likely routes of exposure****Product Information**

Inhalation Specific test data for the substance or mixture is not available.

<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.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available.

**Symptoms related to the physical, chemical and toxicological characteristics**

**Symptoms** No information available.

**Acute toxicity****Numerical measures of toxicity**

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

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Trade secret	= 29700 mg/kg ( Rat )	-	-
Trade secret	= 3 g/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 42 mg/L ( Rat ) 1 h
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	= 53 mg/kg ( Rat )	= 87.12 mg/kg ( Rabbit )	-

**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** No information available.

**STOT - repeated exposure** No information available.

**Aspiration hazard** No information available.

**11.2. Information on other hazards****11.2.1. Endocrine disrupting properties**

**Endocrine disrupting properties** This product does not contain any known or suspected endocrine disruptors.

**11.2.2. Other information**

**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
Trade secret	-	LC50: 5560 - 6080mg/L (96h, <i>Lepomis macrochirus</i> ) LC50: =12946mg/L (96h, <i>Lepomis macrochirus</i> ) LC50: 6020 - 7070mg/L (96h, <i>Pimephales promelas</i> ) LC50: =7050mg/L (96h, <i>Pimephales promelas</i> ) LC50: 6420 - 6700mg/L (96h, <i>Pimephales promelas</i> ) LC50: 4747 - 7824mg/L (96h, <i>Oncorhynchus mykiss</i> )	-	EC50: =1000mg/L (48h, <i>Daphnia magna</i> ) EC50: 340.7 - 469.2mg/L (48h, <i>Daphnia magna</i> )

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

#### Bioaccumulation

#### Component Information

Chemical name	Partition coefficient
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	0.7

### 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
Trade secret	The substance is not PBT / vPvB
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone	The substance is not PBT / vPvB

### 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 12.7. Other adverse effects



No information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

## SECTION 14: Transport information

### IATA

<b>14.1 UN number or ID number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special Precautions for Users</b>	
<b>Special Provisions</b>	None

### IMDG

<b>14.1 UN number or ID number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special Precautions for Users</b>	
<b>Special Provisions</b>	None
<b>14.7 Maritime transport in bulk according to IMO instruments</b>	No information available

### RID

<b>14.1 UN number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special Precautions for Users</b>	
<b>Special Provisions</b>	None

### ADR

<b>14.1 UN number or ID number</b>	Not regulated
<b>14.2 UN proper shipping name</b>	Not regulated
<b>14.3 Transport hazard class(es)</b>	Not regulated
<b>14.4 Packing group</b>	Not regulated
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6 Special Precautions for Users</b>	
<b>Special Provisions</b>	None

## SECTION 15: Regulatory information

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

#### National regulations

##### France

##### Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
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Trade secret	RG 78	-
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**Germany**

**Water hazard class (WGK)** slightly hazardous to water (WGK 1)

**European Union**

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.

**Authorisations and/or restrictions on use:**

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorisation per REACH Annex XIV
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone - 55965-84-9	75.	-

**Persistent Organic Pollutants**

Not applicable

**Ozone-depleting substances (ODS) regulation (EC) 1005/2009**

Not applicable

**EU - Plant Protection Products (1107/2009/EC)**

Chemical name	EU - Plant Protection Products (1107/2009/EC)
Trade secret -	Plant protection agent
Trade secret -	Plant protection agent

**Biocidal Products Regulation (EU) No 528/2012 (BPR)**

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Trade secret -	Product-type 1: Human hygiene
5-Chloro-2-methyl-3(2H)-isothiazolone, mixture with 2-methyl-3(2H)-isothiazolone - 55965-84-9	Product-type 2: Disinfectants and algicides not intended for direct application to humans or animals Product-type 4: Food and feed area Product-type 6: Preservatives for products during storage Product-type 11: Preservatives for liquid-cooling and processing systems Product-type 12: Slimicides Product-type 13: Working or cutting fluid preservatives

**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**

EUH071 - Corrosive to the respiratory tract

H301 - Toxic if swallowed

H311 - Toxic in contact with skin

H314 - Causes severe skin burns and eye damage

H317 - May cause an allergic skin reaction  
H318 - Causes serious eye damage  
H331 - Toxic if inhaled  
H400 - Very toxic to aquatic life  
H410 - Very toxic to aquatic life with long lasting effects

**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

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 Note** Significant changes throughout SDS. Review all sections

**Revision date** 15-Sep-2023

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

**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**