

Revision Date 08-Dec-2023 Revision Number 19

# SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Description: ImmunoCAP ECP Curve Control Strip

Cat No.: 10-9352-02

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

Recommended Use In vitro diagnostic Uses advised against All other uses

1.3. Details of the supplier of the safety data sheet

**Company** Phadia AB

Rapsgatan 7P P.O. Box 6460 751 37 UPPSALA

Sweden

+46 18 16 50 00

E-mail address safetydatasheet.idd@thermofisher.com

1.4. Emergency telephone number

CHEMTREC Ireland (Dublin) +(353)-19014670 CHEMTREC Belgium (Brussels) +(32)-28083237

Malta 112 Emergency phone number

## **SECTION 2: HAZARDS IDENTIFICATION**

## 2.1. Classification of the substance or mixture

#### CLP Classification - Regulation (EC) No 1272/2008

#### Physical hazards

Based on available data, the classification criteria are not met

## **Health hazards**

Based on available data, the classification criteria are not met

#### **Environmental hazards**

Based on available data, the classification criteria are not met

For the full text of the H-statements mentioned in this Section, see Section 16.

## 2.2. Label elements

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#### 2.3. Other hazards

This product contains human sourced material. The donors have been tested and found to be non-reactive for HBsAg, HIV-1 Ag, anti-HCV and anti HIV-1/HIV-2. This product does not contain any known or suspected endocrine disruptors. This preparation contains no substance considered to be persistent, bioaccumulating nor toxic (PBT). This preparation contains no substance considered to be very persistent nor very bioaccumulating (vPvB). This product contains human sourced material. The donors have been tested and found to be non-reactive for HBsAg, HIV-1 Ag, anti-HCV and anti HIV-1/HIV-2.

## **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

#### 3.1. Substances

#### 3.2. Mixtures

Component	CAS No	EC No	Weight %	CLP Classification - Regulation (EC) No 1272/2008
Human proteins in buffer	-		>99	-
Sodium azide	26628-22-8	EEC No. 247-852-1	<0.05	Acute Tox. 2 (H300) (EUH032) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

Component	Specific concentration limits (SCL's)	M-Factor	Component notes
Sodium azide	-	1	-

For the full text of the H-statements mentioned in this Section, see Section 16.

## **SECTION 4: FIRST AID MEASURES**

#### 4.1. Description of first aid measures

Eye Contact Rinse thoroughly with plenty of water, also under the eyelids.

**Skin Contact** Wash off immediately with soap and plenty of water.

**Ingestion** Rinse mouth. If possible drink milk afterwards.

**Inhalation** Not applicable.

Self-Protection of the First Aider Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination.

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

No information available.

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

**Notes to Physician** 

Treat symptomatically.

## **SECTION 5: FIREFIGHTING MEASURES**

#### 5.1. Extinguishing media

#### **Suitable Extinguishing Media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

## Extinguishing media which must not be used for safety reasons

None known.

#### 5.2. Special hazards arising from the substance or mixture

None known.

#### **Hazardous Combustion Products**

None known.

### 5.3. Advice 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**

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

Wear protective gloves/clothing and eye/face protection.

#### 6.2. Environmental precautions

Dispose of in accordance with local regulations.

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

Wipe up with adsorbent material (e.g. cloth, fleece). Dispose of waste product or used containers according to local regulations.

#### 6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

## **SECTION 7: HANDLING AND STORAGE**

#### 7.1. Precautions for safe handling

Wash thoroughly after handling. Do not eat, drink or smoke when using this product.

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

Keep at temperatures between 2° and 8 °C.

## 7.3. Specific end use(s)

Observe instructions for use.

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## **SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

## 8.1. Control parameters

#### **Exposure limits**

List source(s): **EU** - Commission Directive (EU) 2019/1831 of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC **CH** - The Government of Switzerland has set a directive on limit values for working materials (Grenzwerte am Arbeitsplatz) which is based on the Swiss Federal Regulation "Verordnung über die Verhütung von Unfällen und Berufskrankheiten". This directive is administered, periodically revised and enforced by SUVA (Swiss National Accident Insurance Fund).

European Union	The United Kingdom	France	Belgium	Spain
TWA: 0.1 mg/m³ (8h) STEL: 0.3 mg/m³ (15min) Skin	STEL: 0.3 mg/m³ 15 min TWA: 0.1 mg/m³ 8 hr Skin	TWA / VME: 0.1 mg/m³ (8 heures). restrictive limit STEL / VLCT: 0.3 mg/m³. restrictive limit Peau	TWA: 0.1 mg/m³ 8 uren Huid	STEL / VLA-EC: 0.3 mg/m³ (15 minutos). TWA / VLA-ED: 0.1 mg/m³ (8 horas) Piel
Italy	Germany	Portugal	The Netherlands	Finland
	TWA: 0.2 mg/m <sup>3</sup> (8	STEL: 0.3 mg/m <sup>3</sup> 15	huid	TWA: 0.1 mg/m <sup>3</sup> 8
	Stunden). AGW -	minutos	STEL: 0.3 mg/m <sup>3</sup> 15	tunteina
	TWA: 0.1 mg/m³ (8h) STEL: 0.3 mg/m³ (15min) Skin  Italy TWA: 0.1 mg/m³ 8 ore.	TWA: 0.1 mg/m³ (8h) STEL: 0.3 mg/m³ 15 min TWA: 0.1 mg/m³ 8 hr (15min) Skin  Skin  Skin  Germany TWA: 0.1 mg/m³ 8 ore.  TWA: 0.2 mg/m³ (8	TWA: 0.1 mg/m³ (8h)   STEL: 0.3 mg/m³ 15 min   TWA / VME: 0.1 mg/m³ (8h   STEL: 0.3 mg/m³ 8 hr   (15min)   Skin   Skin   Stendard   Stendard	TWA: 0.1 mg/m³ (8h)   STEL: 0.3 mg/m³ 15 min   TWA / VME: 0.1 mg/m³   TWA: 0.1 mg/m³ 8 uren   STEL: 0.3 mg/m³   Skin   Skin   Skin   Stel: 0.3 mg/m³ 8 hr   (8 heures). restrictive   Huid   Huid   STEL / VLCT: 0.3 mg/m³. restrictive limit   Peau   Portugal   The Netherlands   TWA: 0.1 mg/m³ 8 ore.   TWA: 0.2 mg/m³ (8   STEL: 0.3 mg/m³ 15   huid   Number   STEL: 0.3 mg/m³ 15   Huid   STEL: 0.3 mg/m³ 15   STEL: 0.3 mg/m³ 15   STEL: 0.3 mg/m³ 15   Number   STEL: 0.3 mg/m³ 15   STEL: 0.3 mg/m³ 15   Number   STEL:

		STEL: 0.3 mg/m³ 15 minuti. Short-term Pelle	exposuré factor 2 TWA: 0.2 mg/m³ (8 Stunden). MAK Höhepunkt: 0.4 mg/m³	Ceiling: 0.29 mg/m³ Ceiling: 0.11 ppm TWA: 0.1 mg/m³ 8 horas Pele	minuten TWA: 0.1 mg/m³ 8 uren	STEL: 0.3 mg/m³ 15 minuutteina Iho
[	Component	Austria	Denmark	Switzerland	Poland	Norway
- 1	Codium ozido	Llout	TMA. 0. 1 ma/m3 0 times	CTCL : 0.4 m a/m3.4F	CTCL : 0.2 m a/m3.4E	TIMA. O 1 ma/m3 0 times

L	Component	Austria	Denmark	Switzerland	Poland	Norway
Ī	Sodium azide	Haut	TWA: 0.1 mg/m <sup>3</sup> 8 timer	STEL: 0.4 mg/m <sup>3</sup> 15	STEL: 0.3 mg/m <sup>3</sup> 15	TWA: 0.1 mg/m <sup>3</sup> 8 timer
		MAK-KZGW: 0.3 mg/m <sup>3</sup>	STEL: 0.3 mg/m <sup>3</sup> 15	Minuten	minutach	STEL: 0.3 mg/m <sup>3</sup> 15
		15 Minuten	minutter	TWA: 0.2 mg/m <sup>3</sup> 8	TWA: 0.1 mg/m <sup>3</sup> 8	minutter. value from the
		MAK-TMW: 0.1 mg/m <sup>3</sup> 8	Hud	Stunden	godzinach	regulation
		Stunden			_	_

Component	Bulgaria	Croatia	Ireland	Cyprus	Czech Republic
Sodium azide	TWA: 0.1 mg/m <sup>3</sup>	kože	TWA: 0.1 mg/m <sup>3</sup> 8 hr.	Skin-potential for	TWA: 0.1 mg/m <sup>3</sup> 8
	STEL: 0.3 mg/m <sup>3</sup>	TWA-GVI: 0.1 mg/m <sup>3</sup> 8	STEL: 0.3 mg/m <sup>3</sup> 15 min	cutaneous absorption	hodinách.
	Skin notation	satima.	Skin	STEL: 0.3 mg/m <sup>3</sup>	Potential for cutaneous
		STEL-KGVI: 0.3 mg/m <sup>3</sup>		TWA: 0.1 mg/m <sup>3</sup>	absorption
		15 minutama.			Ceiling: 0.3 mg/m <sup>3</sup>

Component	Estonia	Gibraltar	Greece	Hungary	Iceland
Sodium azide	Nahk	Skin notation	STEL: 0.1 ppm	STEL: 0.3 mg/m <sup>3</sup> 15	STEL: 0.3 mg/m <sup>3</sup>
	TWA: 0.1 mg/m <sup>3</sup> 8	TWA: 0.1 mg/m <sup>3</sup> 8 hr	STEL: 0.3 mg/m <sup>3</sup>	percekben. CK	TWA: 0.1 mg/m <sup>3</sup> 8
	tundides.	STEL: 0.3 mg/m <sup>3</sup> 15 min	TWA: 0.1 ppm	TWA: 0.1 mg/m <sup>3</sup> 8	klukkustundum.
	STEL: 0.3 mg/m <sup>3</sup> 15		TWA: 0.3 mg/m <sup>3</sup>	órában. AK	Skin notation
	minutites.		_		

Component	Latvia	Lithuania	Luxembourg	Malta	Romania
Sodium azide	skin - potential for cutaneous exposure STEL: 0.3 mg/m <sup>3</sup> TWA: 0.1 mg/m <sup>3</sup>			possibility of significant uptake through the skin TWA: 0.1 mg/m³ STEL: 0.3 mg/m³ 15 minuti	

Component	Russia	Slovak Republic	Slovenia	Sweden	Turkey
Sodium azide		Ceiling: 0.3 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup> 8 urah	Binding STEL: 0.3	Deri
		Potential for cutaneous	Koža	mg/m <sup>3</sup> 15 minuter	TWA: 0.1 mg/m <sup>3</sup> 8 saat
		absorption	STEL: 0.3 mg/m <sup>3</sup> 15	TLV: 0.1 mg/m <sup>3</sup> 8	STEL: 0.3 mg/m <sup>3</sup> 15
		TWA: 0.1 mg/m <sup>3</sup>	minutah	timmar. NGV	dakika

## **Biological limit values**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific

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regulatory bodies

## **Monitoring methods**

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

## Derived Minimum Effect Level (DMEL) / Derived No Effect Level (DNEL)

See table for values

Component	Acute effects local (Dermal)	Acute effects systemic (Dermal)	Chronic effects local (Dermal)	Chronic effects systemic (Dermal)
Sodium azide 26628-22-8 ( <0.05 )				DNEL = 46.7µg/kg bw/day

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
Sodium azide 26628-22-8 ( <0.05 )				DNEL = 0.164mg/m <sup>3</sup>

## **Predicted No Effect Concentration (PNEC)**

See values below.

Component	Fresh water	Fresh water	Water Intermittent	Microorganisms in	Soil (Agriculture)
		sediment		sewage treatment	I
Sodium azide	PNEC = $0.35\mu g/L$	$PNEC = 16.7 \mu g/kg$	PNEC = 3.5µg/L	PNEC = 30µg/L	
26628-22-8 ( < 0.05 )		sediment dw			

Component	Marine water	Marine water sediment	Marine water Intermittent	Food chain	Air
Sodium azide 26628-22-8 ( <0.05 )	PNEC = 15ng/L	PNEC = 0.72µg/kg sediment dw	PNEC = 150ng/L		

## 8.2. Exposure controls

## **Engineering Measures**

None under normal use conditions.

## Personal protective equipment

**Eye Protection** No special protective equipment required.

Hand Protection Protective gloves.

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Nitrile rubber	See manufacturers	-	EN 374	(minimum requirement)
	recommendations			

**Skin and body protection**No special protective equipment required.

**Respiratory Protection** No protective equipment is needed under normal use conditions.

Large scale/emergency use No protective equipment is needed under normal use conditions

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Small scale/Laboratory use No personal respiratory protective equipment normally required.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

**Environmental exposure controls** Dispose of contents/containers in accordance with local regulations.

## **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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

Physical State Liquid

Appearance Colorless to yellow

Odor None Odor Threshold None

Melting Point/RangeNo data availableSoftening PointNo data available

Boiling Point/Range 100 °C

Flammability (liquid)
Plammability (solid,gas)
No data available
Not flammable
Not applicable

Flash Point Not applicable Method - No information available

Autoignition Temperature Not applicable Decomposition Temperature Not applicable

**pH** 7.0

Viscosity

Water Solubility

Soluble in water

No information available

No information available

Partition Coefficient (n-octanol/water)

Componentlog PowSodium azide0.3

Vapor Pressure No data available

Density / Specific Gravity 1 g/cm3

Bulk Density
No data available
Vapor Density
No data available

Particle characteristics Not applicable (liquid)

9.2. Other information

Explosive Properties Not applicable Oxidizing Properties Not applicable

## **SECTION 10: STABILITY AND REACTIVITY**

(Air = 1.0)

10.1. Reactivity

None known.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerization Hazardous polymerization does not occur.

**Hazardous Reactions** None under normal processing.

10.4. Conditions to avoid

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None known.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

## **SECTION 11: TOXICOLOGICAL INFORMATION**

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

**Product Information** Product does not present an acute toxicity hazard based on known or supplied information.

(a) acute toxicity;

OralNo data available.DermalNo data available.InhalationNo data available.

Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation	
Sodium azide			37 mg/l ( Rat )	

(b) skin corrosion/irritation; No data available.

(c) serious eye damage/irritation;

(d) respiratory or skin sensitization;

(e) germ cell mutagenicity;

Respiratory
Skin
No data available.
No data available.

(f) carcinogenicity:

There are no known carcinogenic chemicals in this product

No data available.

(i) carcinogenicity,	enerty, There are no known carolingenic chemicals in this product.						
Component	Test method	Test species / Duration	Study result				
Sodium azide			No ingredient of this product				
			present at levels greater than or				
			equal to 0.1% is identified as				
			probable, possible or confirmed				
			human carcinogen by IARC.				

(g) reproductive toxicity; No data available.

(h) STOT-single exposure; No data available.

(i) STOT-repeated exposure; No data available.

(j) aspiration hazard; No data available.

Component	Other Adverse Effects
Sodium azide	Symptoms of overexposure are dizziness, headache, tiredness,
	nausea, unconsciousness, cessation of breathing. Harmful to
	central nervous system and heart. Fatal if swallowed.

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Symptoms / effects,both acute and delayed No information available.

#### 11.2. Information on other hazards

**Endocrine Disrupting Properties** This product does not contain any known or suspected endocrine disruptors.

#### **SECTION 12: ECOLOGICAL INFORMATION**

12.1. Toxicity

**Ecotoxicity effects** No information available.

Component	Freshwater Fish	Water Flea	Freshwater Algae	Microtox
Sodium azide	LC50 96 h 0.7 mg/L	EC50 4.2 mg/l 48 h (		EC50 38.5 mg/l (
	LC50 96 h	Daphnia pulex)	IC50 272 mg/l ( green	Photobacterium
	LC50 0.7 mg/l 96 H (		algae )	phosphoreum)
	Lepomis macrochirus)			

#### **12.2. Persistence and degradability** No information available.

## **12.3. Bioaccumulative potential** No information available.

Component	log Pow	Bioconcentration factor (BCF)
Sodium azide	0.3	

12.4. Mobility in soil No information available.

12.5. Results of PBT and vPvB

assessment

This preparation contains no substance considered to be persistent, bioaccumulating nor toxic (PBT). This preparation contains no substance considered to be very persistent nor very bioaccumulating (vPvB). This product contains human sourced material. The donors have been tested and found to be non-reactive for HBsAg, HIV-1 Ag, anti-HCV and anti HIV-1/HIV-2.

12.6. Endocrine disrupting

properties

Endocrine Disruptor Information This produ

This product does not contain any known or suspected endocrine disruptors

12.7. Other adverse effects

Persistent Organic Pollutant Ozone Depletion Potential No known effect. No known effect.

## **SECTION 13: DISPOSAL CONSIDERATIONS**

#### 13.1. Waste treatment methods

Waste from Residues/Unused

**Products** 

Dispose of in accordance with local regulations.

**Contaminated Packaging** Dispose of in accordance with local regulations.

**European Waste Catalogue (EWC)** 

Other Information

18 01 07 Chemicals other than those mentioned in 18 01 06.

No information available.

## **SECTION 14: TRANSPORT INFORMATION**

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IMDG/IMO Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

ADR Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

<u>IATA</u> Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

**14.5. Environmental hazards** No hazards identified.

14.6. Special precautions for user No special precautions required.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable, packaged goods.

## **SECTION 15: REGULATORY INFORMATION**

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

International Inventories X = listed

Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	IECSC	AICS	KECL
Sodium azide	247-852-1	-		X	Х	-	Х	Х	Χ	Х	KE-3135
											7

Component	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements
Sodium azide	H2 50-200 ton, E1 100-200 ton	H2 50-200 ton, E1 100-200 ton

# Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

## **National Regulations**

Component	Germany - Water Classification (AwSV)	Germany - TA-Luft Class
Sodium azide	WGK2	

**UK** - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment. Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values .

#### 15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) is not required.

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## **SECTION 16: OTHER INFORMATION**

#### Full text of H-Statements referred to under sections 2 and 3

H300 - Fatal if swallowed H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects EUH032 - Contact with acids liberates very toxic gas

#### Legend

**CAS** - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances **IECSC** - Chinese Inventory of Existing Chemical Substances **KECL** - Korean Existing and Evaluated Chemical Substances

Substances List **ENCS** - Japanese Existing and New Chemical Substances

AICS - Australian Inventory of Chemical Substances NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

**ACGIH** - American Conference of Governmental Industrial Hygienists

**DNEL** - Derived No Effect Level

**RPE** - Respiratory Protective Equipment LC50 - Lethal Concentration 50% NOEC - No Observed Effect Concentration PBT - Persistent, Bioaccumulative, Toxic

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

Predicted No Effect Concentration (PNEC)

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50% POW - Partition coefficient Octanol:Water vPvB - very Persistent, very Bioaccumulative

ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

OECD - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

ICAO/IATA - International Civil Aviation Organization/International Air **Transport Association** 

MARPOL - International Convention for the Prevention of Pollution from

Ships

ATE - Acute Toxicity Estimate VOC (volatile organic compound)

#### Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

Physical hazards On basis of test data **Health Hazards** Calculation method **Environmental hazards** Calculation method

#### **Training Advice**

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

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**Revision Summary** SDS sections updated, 7.

## This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 COMMISSION REGULATION (EU) 2020/878 amending Annex II to 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**