

BCR-ABL IS AmpliTaq® Gold

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Revision Date: 04/07/2025 | Date of Issue: 31/05/2016 | Version: 2.0

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

# 1.1. Product Identifier

Product Form Mixture

Product Name BCR-ABL IS AmpliTag® Gold

Product Reference # 145393

# 1.2. Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

# 1.2.1. Relevant Identified Uses

Use of the Substance/Mixture CE-IVD for U.S. Export Only

# 1.2.2. Uses Advised Against

No additional information available

# 1.3. Details of the Supplier of the Safety Data Sheet

## Company

Asuragen, Inc.

2150 Woodward Ave Suite 100

Austin, TX 78744

T: +1 512-681-5200

USA, Toll-free T: +1 877-777-1874

E-mail: <a href="mailto:support@asuragen.com">support@asuragen.com</a>

Web address: www.asuragen.com

# 1.4. Emergency Telephone Number

**Emergency Number** Tel: +1 -512-681-5200 US, Toll-free Tel: 1-877-777-1874

# 2 SECTION 2: HAZARDS IDENTIFICATION

## 2.1. Classification of the Substance or Mixture

Classification According to Regulation (EC) No. 1272/2008

Aquatic Chronic 3 H412

Full text of hazard classes, H- and EUH-statements: see section 16

# 2.2. Label Elements

Labelling According to Regulation (EC) No. 1272/2008 [CLP]

Signal Word (CLP)

**Hazard Statements (CLP)** H412 - Harmful to aquatic life with long lasting effects.

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**Precautionary Statements** 

P273 - Avoid release to the environment.

(CLP)

P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

## 2.3. Other Hazards

Other Hazards NotExposure may aggravate those with pre-existing eye, skin, or respiratoryContributing to theconditions. Used product may be biologically contaminated. Follow allClassificationinstitutional protocols concerning the potential release of pathogens.

This substance/mixture does not meet the PBT/vPvB criteria of REACH regulation, annex XIII

The mixture contains substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

Component	
Poly(oxy-1,2-ethanediyl), .alpha	The substance is included in the list established in accordance with Article 59(1) of REACH for having endocrine
(nonylphenyl)omega	disrupting properties, or is identified as having endocrine disrupting properties in accordance with the criteria set
hydroxy-(9016-45-9)	out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

## 3 SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

## 3.1. Substances

Not applicable

# 3.2. Mixtures

Name	Product Identifier	%	Classification According to Regulation (EC) No. 1272/2008
1,2,3-Propanetriol	(CAS-No.) 56-81-5 (EC-No.) 200-289-5	50	Not classified
Water	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	48	Not classified
Potassium chloride	(CAS-No.) 7447-40-7 (EC-No.) 231-211-8	0.75	Not classified
Polyoxyethylene sorbitan monolaurate	(CAS-No.) 9005-64-5 (EC-No.) 500-018-3	0.5	Not classified
Poly(oxy-1,2-ethanediyl), .alpha(nonylphenyl)omegahydroxy-substance listed as REACH Candidate (4-Nonylphenol, branched and linear, ethoxylated) substance listed in REACH Annex XIV (4-Nonylphenol, branched and linear, ethoxylated (substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof))	(CAS-No.) 9016-45-9 (EC-No.) 500-024-6	0.5	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Chronic 1, H410
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-	(CAS-No.) 77-86-1 (EC-No.) 201-064-4	0.24	Not classified

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Name	Product Identifier	%	Classification According to Regulation (EC) No. 1272/2008
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-,	(CAS-No.) 6381-92-6	0.01	·
disodium salt, dihydrate	(EC-No.) 205-358-3;613-386-6		Acute Tox. 4 (Dermal), H312
			Acute Tox. 4 (Inhalation:dust,mist), H332
			Skin Irrit. 2, H315
			Eye Irrit. 2, H319
			STOT SE 3, H335
			Aquatic Chronic 3, H412
2,3-Butanediol, 1,4-dimercapto-, (R*,R*)-	(CAS-No.) 3483-12-3	0.01	Acute Tox. 4 (Oral), H302
	(EC-No.) 222-468-7		Skin Irrit. 2, H315
			Eye Irrit. 2, H319
			STOT SE 3, H335

Full text of H- and EUH-statements: see section 16

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

# 4.1. Description of First-aid Measures

First-Aid Measures	Never give anything by mouth to an unconscious person. If you feel unwell,
General	seek medical advice (show the label where possible). If product is biologically

contaminated, follow all institutional protocols concerning the potential release of

pathogens.

**First-Aid Measures After** When symptoms occur: go into open air and ventilate suspected area. Obtain

**Inhalation** medical attention if breathing difficulty persists.

**First-Aid Measures After** Remove contaminated clothing. Drench affected area with water for at least 5

**Skin Contact** minutes. Obtain medical attention if irritation develops or persists.

First-Aid Measures After Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present **Eye Contact** 

and easy to do. Continue rinsing. Obtain medical attention if irritation develops or

persists.

**First-Aid Measures After** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

Ingestion

# 4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Effects Not expected to present a significant hazard under anticipated conditions

of normal use.

**Symptoms/Effects After Inhalation** Prolonged exposure may cause irritation. Symptoms/Effects After Skin Contact Prolonged exposure may cause skin irritation.

Symptoms/Effects After Eye Contact May cause slight irritation to eyes. **Symptoms/Effects After Ingestion** Ingestion may cause adverse effects.

**Chronic Symptoms** None expected under normal conditions of use.

## 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

#### **SECTION 5: FIREFIGHTING MEASURES** 5

# 5.1. Extinguishing Media

Suitable Extinguishing Media Water spray, fog, carbon dioxide (CO<sub>2</sub>), alcohol-resistant foam, or dry chemical.

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**Unsuitable Extinguishing** 

Do not use a heavy water stream. Use of heavy stream of water may spread fire.

Media

## 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard** Not considered flammable but may burn at high temperatures.

**Explosion Hazard** Product is not explosive.

**Reactivity** Hazardous reactions will not occur under normal conditions.

Hazardous Combustion Acrolein. Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides. Metal oxides. Chlorine

**Products** compounds.

## 5.3. Advice for Firefighters

**Precautionary Measures Fire** Exercise caution when fighting any chemical fire. **Firefighting Instructions** Use water spray or fog for cooling exposed containers.

Protection During Firefighting Do not enter fire area without proper protective equipment, including respiratory

protection.

**Other Information** Do not allow run-off from fire fighting to enter drains or water courses.

## **6 SECTION 6: ACCIDENTAL RELEASE MEASURES**

## 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General** Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapour, mist, spray). If

Measures product is biologically contaminated, follow all institutional protocols concerning the potential

release of pathogens.

# 6.1.1. For Non-Emergency Personnel

**Protective Equipment** Use appropriate personal protective equipment (PPE).

**Emergency Procedures** Evacuate unnecessary personnel.

# **6.1.2. For Emergency Responders**

**Protective** Equip cleanup crew with proper protection.

Equipment

Up

**Emergency** Upon arrival at the scene, a first responder is expected to recognise the presence of

**Procedures** dangerous goods, protect oneself and the public, secure the area, and call for the assistance

of trained personnel as soon as conditions permit. Ventilate area.

## 6.2. Environmental Precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

# 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or

streams.

Methods for Cleaning Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill

with inert material. Transfer spilled material to a suitable container for disposal. Contact

competent authorities after a spill.

# 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.



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## 7 SECTION 7: HANDLING AND STORAGE

## 7.1. Precautions for Safe Handling

**Precautions for** Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapour, mist, spray).

Safe Handling Wash hands and other exposed areas with mild soap and water before eating, drinking

or smoking and when leaving work. If product is biologically contaminated, follow all

institutional protocols concerning the potential release of pathogens.

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

# 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures** Comply with applicable regulations.

**Storage Conditions** Store in accordance with applicable national storage class systems. Keep container

closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight,

extremely high or low temperatures and incompatible materials.

Incompatible Materials

Strong acids, strong bases, strong oxidisers.

# 7.3. Specific End Use(s)

CE-IVD for U.S. Export Only

# 8 SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

## 8.1. Control Parameters

Please see section 16 for the legal basis of limit value information in section 8.1, including the national legislation or provision which gives rise to a given limit.

Potassium chloride (7447-40-7)		
Bulgaria	OEL TWA (Legal Basis:Reg. No. 13/10)	5 mg/m <sup>3</sup>
Latvia	OEL TWA (Legal Basis:Reg. No. 325)	5 mg/m³
Lithuania	OEL TWA (Legal Basis:HN 23:2011)	5 mg/m³

1,2,3-Propanetr	iol (56-81-5)	
Belgium	OEL TWA (Legal Basis:Royal Decree 21/01/2020)	10 mg/m³ (mist)
Croatia	OEL TWA (Legal Basis:OG No. 91/2018)	10 mg/m <sup>3</sup>
Czech Republic	OEL TWA (Legal Basis:Reg. 41/2020)	10 mg/m <sup>3</sup>
Estonia	OEL TWA (Legal Basis:Regulation No. 105)	10 mg/m <sup>3</sup>
Finland	OEL TWA (Legal Basis:HTP-ARVOT 2020)	20 mg/m <sup>3</sup>
France	OEL TWA (Legal Basis:INRS ED 984)	10 mg/m³ (aerosol)
Germany	OEL TWA (Legal Basis:TRGS 900)	200 mg/m³ (the risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed-inhalable fraction)
Greece	OEL TWA (Legal Basis:PWHSE)	10 mg/m <sup>3</sup>



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1,2,3-Propane	riol (56-81-5)	
Poland	OEL TWA (Legal Basis:Dz. U. 2020 Nr. 61)	10 mg/m³ (inhalable fraction)
Portugal	OEL TWA (Legal Basis:Portuguese Norm NP 1796:2014)	10 mg/m³ (mist)
Slovakia	OEL TWA (Legal Basis:Gov. Decree 33/2018)	11 mg/m³
Slovenia	OEL TWA (Legal Basis:No. 79/19)	200 mg/m³ (inhalable fraction)
Slovenia	OEL STEL (Legal Basis:No. 79/19)	400 mg/m³ (inhalable fraction)
Spain	OEL TWA (Legal Basis:OELCAIS)	10 mg/m³ (mist)
Switzerland	OEL STEL (Legal Basis:OLVSNAIF)	100 mg/m³ (inhalable dust)
Switzerland	OEL TWA (Legal Basis:OLVSNAIF)	50 mg/m³ (inhalable dust)

## 8.2. Exposure Controls

**Controls** 

Appropriate Engineering Suitable eye/body wash equipment should be available in the vicinity of any potential

exposure. Ensure adequate ventilation, especially in confined areas. Ensure all

national/local regulations are observed.

**Personal Protective** Equipment

Gloves. Protective clothing. Protective goggles. Personal protective equipment should be chosen in accordance with Regulation (EU) 2016/425, CEN standards, and in

discussion with the supplier of the protective equipment.







Materials for Protective

Clothing

Chemically resistant materials and fabrics.

**Hand Protection** Wear protective gloves. **Eve Protection** Chemical safety goggles.

Skin and Body Wear suitable protective clothing.

**Protection** 

**Respiratory Protection** If exposure limits are exceeded or irritation is experienced, approved respiratory

> protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory

protection.

**Other Information** When using, do not eat, drink or smoke.

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

# 9.1. Information on Basic Physical and Chemical Properties

**Physical State** Liquid

Not specified Colour, Appearance Odour Not specified **Odour Threshold** No data available

No data available рΗ **Evaporation Rate** No data available



Not applicable

**Melting Point** No data available No data available **Freezing Point Boiling Point** No data available **Flash Point** No data available No data available **Auto-Ignition Temperature Decomposition Temperature** No data available **Flammability** Not applicable **Vapour Pressure** No data available Relative Vapour Density At 20°C No data available **Relative Density** No data available Solubility No data available No data available Partition Coefficient n-Octanol/Water Viscosity No data available **Explosive Properties** No data available No data available **Oxidising Properties Explosive Limits** No data available Particle Aspect Ratio Not applicable **Particle Aggregation State** Not applicable **Particle Agglomeration State** Not applicable **Particle Specific Surface Area** Not applicable

## 9.2. Other Information

**Particle Dustiness** 

No additional information available

# 10 SECTION 10: STABILITY AND REACTIVITY

## 10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

# 10.2. Chemical Stability

Stable under recommended handling and storage conditions (see section 7).

# 10.3. Possibility of Hazardous Reactions

Hazardous polymerisation will not occur.

## 10.4. Conditions to Avoid

Direct sunlight, extremely high or low temperatures, and incompatible materials.

# 10.5. Incompatible Materials

Strong acids, strong bases, strong oxidisers.

## 10.6. Hazardous Decomposition Products

Thermal decomposition may produce: Acrolein. Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides. Metal oxides. Chlorine compounds.

## 11 SECTION 11: TOXICOLOGICAL INFORMATION

# 11.1. Information On Hazard Classes As Defined In Regulation (EC) No 1272/2008



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**Likely Routes of Exposure** 

Dermal, Ingestion, Inhalation, Eye contact

**Acute Toxicity (Oral) Acute Toxicity (Dermal) Acute Toxicity (Inhalation)** 

Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met)

Polyoxyethylene sorbitan monolaurate (9005-64-5)	
LD50 Oral Rat	> 18000 mg/kg
LC50 Inhalation Rat	>5,1 mg/l/4h

1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)	
LD50 Oral Rat	5900 mg/kg
LD50 Dermal Rat	> 5000 mg/kg

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)		
LD50 Oral Rat	2000 mg/kg	
ATE CLP (dermal)	1.100,00 mg/kg bodyweight	
ATE CLP (dust,mist)	1,50 mg/l/4h	

Potassium chloride (7447-40-7)	
LD50 Oral Rat	3020 mg/kg (Species: Wistar)

2,3-Butanediol, 1,4-dimercapto-, (R*,R*)- (3483-12-3	
ATE CLP (oral)	500,00 mg/kg bodyweight

1,2,3-Propanetriol (56-81-5)	
LD50 Oral Rat	12600 mg/kg (Source: NLM_CIP)
LD50 Dermal Rabbit	> 10 g/kg (Source: NLM_CIP)
LC50 Inhalation Rat	> 2,75 mg/l/4h (No mortalities)

Poly(oxy-1,2-ethanediyl), .alpha(nonylphenyl)omegahydroxy- (9016-45-9)		
LD50 Oral Rat	1310 mg/kg	
LD50 Dermal Rabbit	2000 mg/kg	

**Skin Corrosion/Irritation Eye Damage/Irritation Respiratory or Skin Sensitisation Germ Cell Mutagenicity** 

Carcinogenicity

Reproductive Toxicity

**Aspiration Hazard** 

Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met) Not classified (Based on available data, the classification criteria are not met)

Not classified (Based on available data, the classification criteria are not met)

**Specific Target Organ Toxicity (Single** Exposure)

Not classified (Based on available data, the classification criteria are

not met)

Specific Target Organ Toxicity (Repeated Not classified (Based on available data, the classification criteria are

not met)

**Exposure**)

Not classified (Based on available data, the classification criteria are

not met)

**Symptoms/Injuries After Inhalation** 

Prolonged exposure may cause irritation. Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Skin Contact Symptoms/Injuries After Eye Contact** 

May cause slight irritation to eyes. Ingestion may cause adverse effects.

Symptoms/Injuries After Ingestion **Chronic Symptoms** 

None expected under normal conditions of use.

# 11.2. Information On Other Hazards

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Based on available data this substance/the substances in this mixture not listed below do(es) not have endocrine disrupting properties with respect to humans as it does not meet the criteria set out in section A of Regulation (EU) No 2017/2100 and/or the criteria set out in Regulation (EU) 2018/605, or the substance(s) are not required to be disclosed.

Component	
Poly(oxy-1,2- ethanediyl), .alpha (nonylphenyl)omega hydroxy- (9016-45-9)	This chemical is considered to have endocrine-disrupting properties with respect to animals in the testis, pituitary gland, producing changes to morphology, reproduction, development, Shows an adverse effect in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences as it meets the criteria set out in section A of Regulation (EU) 2017/2100, and/or the criteria set out in Regulation (EU) 2018/605. This conclusion is based on evidence from studies and data obtained from a literature search conducted on this chemical, and shows a link between the effects above and endocrine activity, which is relevant for humans.

## 12 SECTION 12: ECOLOGICAL INFORMATION

# 12.1. Toxicity

**Ecology - General**Harmful to aquatic life with long lasting effects. **Ecology - Water**Harmful to aquatic life with long lasting effects.

Hazardous To The Aquatic Environment, Not classified (Based on available data, the classification criteria

Short-Term (Acute) are not met)

**Hazardous To The Aquatic Environment,** Harmful to aquatic life with long lasting effects.

Long-Term (Chronic)

Potassium chloride (7447-	40-7)	
LC50 - Fish [1]	1060 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static] Source: EPA)	
EC50 - Crustacea [1]	825 mg/l (Exposure time: 48 h - Species: Daphnia magna)	
LC50 - Fish [2]	750 (750 - 1020) mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])	
EC50 - Crustacea [2]	660 mg/l (Exposure time: 48 h - Species: Daphnia magna)	

1,2,3-Propanetriol (56	6-81-5)
LC50 - Fish [1]	54000 (51000 - 57000) mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

Poly(oxy-1,2-ethanediyl), .alpha(nonylphenyl)omegahydroxy- (9016-45-9)		
LC50 - Fish [1]	1,3 - 7,9 mg/l	
NOEC chronic fish	1 mg/l	

## 12.2. Persistence and Degradability

BCR-ABL IS AmpliTaq® Gold	
Persistence and Degradability	May cause long-term adverse effects in the environment.

# 12.3. Bioaccumulative Potential

BCR-ABL IS AmpliTaq® Gold	
Bioaccumulative Potential	Not established.

1,3-Propanediol, 2-amino-2-	(hydroxymethyl)- (77-86-1)
BCF Fish 1	3 (Estimated using a regression-derived equation)

1,2,3-Propanetriol (56-81-5)		
BCF Fish 1 (no bioaccumulation)		
Partition coefficient n-octanol/water (Log Pow)	-1,75 at 25 °C (at pH 7.4)	



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Poly(oxy-1,2-ethanediyl), .alpha(nonylphenyl)omegahydroxy- (9016-45-9)	
Partition coefficient n-octanol/water (Log Pow)	3,7 (at 25 °C)

## 12.4. Mobility in Soil

No additional information available

#### 12.5. Results of PBT and vPvB Assessment

Component	
Poly(oxy-1,2-ethanediyl), .alpha(nonylphenyl)omega	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
hydroxy- (9016-45-9)	This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

## 12.6. Endocrine Disrupting Properties

Based on available data this substance/the substances in this mixture not listed below do(es) not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100 and/or the criteria set out in Regulation (EU) 2018/605, or the substance(s) are not required to be disclosed.

Component	
Poly(oxy-1,2-	This chemical is considered to have endocrine-disrupting properties with respect to animals, non-target organisms in the
ethanediyl), .alpha	pituitary gland, testis, producing changes to morphology, reproduction, Shows an adverse effect in an intact organism or its
(nonylphenyl)omega	progeny, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism,
hydroxy- (9016-45-9)	system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate
	for additional stress or an increase in susceptibility to other influences as it meets the criteria set out in section B of
	Regulation (EU) 2017/2100, and/or the criteria set out in Regulation (EU) 2018/605. This conclusion is based on evidence
	from studies and data obtained from a literature search conducted on this chemical, and shows a link between the effects
	above and endocrine activity, which is relevant for non-target organisms.

#### 12.7. Other Adverse Effects

**Other Information** Avoid release to the environment.

## 13 SECTION 13: DISPOSAL CONSIDERATIONS

## 13.1. Waste Treatment Methods

Product/Packaging DisposalDispose of contents/container in accordance with local, regional, national,Recommendationsterritorial, provincial, and international regulations.Additional InformationBiologically contaminated materials should be incinerated.Ecology - Waste MaterialsAvoid release to the environment. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

# 14 SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

In accordance with ADR / RID / IMDG / IATA / ADN

## 14.1. UN Number or ID Number

Not regulated for transport

# 14.2. UN Proper Shipping Name

Not regulated for transport

## 14.3. Transport Hazard Class(es)

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Not regulated for transport

# 14.4. Packing Group

Not regulated for transport

## 14.5. Environmental Hazards

Not regulated for transport

## 14.6. Special Precautions For User

No additional information available

# 14.7. Maritime Transport in Bulk According to IMO instruments

Not applicable

## 15 SECTION 15: REGULATORY INFORMATION

# 15.1. Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

# 15.1.1. EU-Regulations

#### 15.1.1.1. REACH Annex XVII Information

Listed on REACH Annex XVII (Restriction Conditions). The following restrictions are applicable:

3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in	Poly(oxy-1,2-ethanediyl), .alpha
Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and	(nonylphenyl)omegahydroxy-
fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	
3(c) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in	BCR-ABL IS AmpliTaq®
Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1	Gold ; Poly(oxy-1,2-ethanediyl), .alpha
	(nonylphenyl)omegahydroxy-
46.a. Nonylphenol ethoxylates (NPE) (C2H4O)nC15H24O	Poly(oxy-1,2-ethanediyl), .alpha
	(nonylphenyl)omegahydroxy-

## 15.1.1.2. REACH Candidate List Information

Contains substance(s) listed on the REACH Candidate List in concentrations ≥ 0.1 % or SCL: 4-Nonylphenol, branched and linear, ethoxylated (EC 500-024-6, CAS 9016-45-9)

# 15.1.1.3. POP (2019/1021) - Persistent Organic Pollutants Information

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

# 15.1.1.4. PIC Regulation EU (649/2012) - Export and Import of Hazardous Chemicals Information

Contains substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals): Nonylphenol ethoxylates (C2H4O)nC15H24O (9016-45-9)

# 15.1.1.5. REACH Annex XIV Information

Contains substance(s) listed on REACH Annex XIV: 4-Nonylphenol, branched and linear, ethoxylated (EC 500-024-6, CAS 9016-45-9)

Substance name	Authorisation number	Sunset date	authorisation
4-Nonylphenol, branched and linear, ethoxylated (substances with a linear and/or branched alkyl		04/01/2021	exemptions
chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual			
isomers and/or combinations thereof) (EC 500-024-6, CAS 9016-45-9)			

# 15.1.1.6. Substances Depleting the Ozone layer (1005/2009) Information

No additional information available



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# 15.1.1.7. EC Inventory Information

#### 1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

## Potassium chloride (7447-40-7)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

#### 2,3-Butanediol, 1,4-dimercapto-, (R\*,R\*)- (3483-12-3)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

#### 1,2,3-Propanetriol (56-81-5)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

#### Water (7732-18-5)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

#### 15.1.1.8. Other Information

No additional information available

## 15.1.2. National Regulations

No additional information available

# 15.1.3. International Inventory Lists

## Polyoxyethylene sorbitan monolaurate (9005-64-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Listed on the Canadian DSL (Domestic Substances List)

Listed on the EU NLP (No Longer Polymers) inventory

Listed introduction on Australian Industrial Chemicals Introduction Scheme (AICIS Inventory)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory

Listed on KECL/KECI (Korean Existing Chemicals Inventory)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on the Japanese ISHL (Industrial Safety and Health Law)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

Listed on the NCI (Vietnam - National Chemical Inventory)

Listed on Thailand Existing Chemicals Inventory (DIW)

# 1,3-Propanediol, 2-amino-2-(hydroxymethyl)- (77-86-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Listed on the Canadian DSL (Domestic Substances List)

Listed introduction on Australian Industrial Chemicals Introduction Scheme (AICIS Inventory)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory

Listed on KECL/KECI (Korean Existing Chemicals Inventory)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on the Japanese ISHL (Industrial Safety and Health Law)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

Listed on the NCI (Vietnam - National Chemical Inventory)

Listed on Thailand Existing Chemicals Inventory (DIW)



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## Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate (6381-92-6)

Listed on the Canadian DSL (Domestic Substances List)

Listed introduction on Australian Industrial Chemicals Introduction Scheme (AICIS Inventory)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Japanese Pollutant Release and Transfer Register Law (PRTR Law)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

Listed on the NCI (Vietnam - National Chemical Inventory)

Listed on Thailand Existing Chemicals Inventory (DIW)

## Potassium chloride (7447-40-7)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Listed on the Canadian DSL (Domestic Substances List)

Listed introduction on Australian Industrial Chemicals Introduction Scheme (AICIS Inventory)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory

Listed on KECL/KECI (Korean Existing Chemicals Inventory)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on the Japanese ISHL (Industrial Safety and Health Law)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

Listed on the NCI (Vietnam - National Chemical Inventory)

Listed on Thailand Existing Chemicals Inventory (DIW)

## 2,3-Butanediol, 1,4-dimercapto-, (R\*,R\*)- (3483-12-3)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Listed on the Canadian DSL (Domestic Substances List)

Listed introduction on Australian Industrial Chemicals Introduction Scheme (AICIS Inventory)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

Listed on the NCI (Vietnam - National Chemical Inventory)

## 1,2,3-Propanetriol (56-81-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Listed on the Canadian DSL (Domestic Substances List)

Listed introduction on Australian Industrial Chemicals Introduction Scheme (AICIS Inventory)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory

Listed on KECL/KECI (Korean Existing Chemicals Inventory)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on the Japanese ISHL (Industrial Safety and Health Law)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

Listed on the NCI (Vietnam - National Chemical Inventory)

Listed on Thailand Existing Chemicals Inventory (DIW)



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# Poly(oxy-1,2-ethanediyl), .alpha.-(nonylphenyl)-.omega.-hydroxy- (9016-45-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Listed on the Canadian DSL (Domestic Substances List)

Subject to reporting requirements of United States SARA Section 313

Listed on the EU NLP (No Longer Polymers) inventory

Listed introduction on Australian Industrial Chemicals Introduction Scheme (AICIS Inventory)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory

Listed on KECL/KECI (Korean Existing Chemicals Inventory)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Japanese Pollutant Release and Transfer Register Law (PRTR Law)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on the Japanese ISHL (Industrial Safety and Health Law)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

Listed on the NCI (Vietnam - National Chemical Inventory)

Listed on Thailand Existing Chemicals Inventory (DIW)

#### Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Listed on the Canadian DSL (Domestic Substances List)

Listed introduction on Australian Industrial Chemicals Introduction Scheme (AICIS Inventory)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory

Listed on KECL/KECI (Korean Existing Chemicals Inventory)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory) Listed on the NCI (Vietnam - National Chemical Inventory)

Listed on Thailand Existing Chemicals Inventory (DIW)

#### 15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out

# 16 SECTION 16: OTHER INFORMATION

Date of Preparation or 04/07/2025

**Latest Revision** 

**Data Sources** Information and data obtained and used in the authoring of this safety data sheet

could come from database subscriptions, official government regulatory body websites, product/ingredient manufacturer or supplier specific information, and/or resources that include substance specific data and classifications according to GHS or their

subsequent adoption of GHS.

Other Information According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation

(EU) 2020/878

## Full Text of H- and FUH-statements:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard, Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard, Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2



Safety	Data	Shoot
Saletv	Data	SHEEL

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity - Single exposure, Category 3, Respiratory tract irritation

# Classification and Procedure Used to Derive the Classification for Mixtures According to Regulation (EC) 1272/2008 [CLP]:

Aquatic Chronic 3	Calculation method

# **Indication of Changes**

Section	Change	Date Changed	Version
2	Classification modified; Language modified	11/12/2023	2.0
1, 4, 5, 6, 7, 9, 10, 13, 14, 15, 16	Language modified	11/12/2023	2.0
3, 8, 11, 12	Data modified ; Language modified	11/12/2023	2.0

## **Abbreviations and Acronyms**

ACGIH - American Conference of Governmental Industrial Hygienists

ADN - European Agreement Concerning the International Carriage of

Dangerous Goods by Inland Waterways

ADR - European Agreement Concerning the International Carriage of

Dangerous Goods by Road

ATE - Acute Toxicity Estimate

BCF - Bioconcentration Factor

BEI - Biological Exposure Indices (BEI)

BOD - Biochemical Oxygen Demand

CAS No. - Chemical Abstracts Service Number

CLP - Classification, Labeling and Packaging Regulation (EC) No 1272/2008

COD - Chemical Oxygen Demand

EC - European Community

EC50 - Median Effective Concentration

EEC - European Economic Community

EINECS - European Inventory of Existing Commercial Chemical Substances

EmS-No. (Fire) - IMDG Emergency Schedule Fire

EmS-No. (Spillage) - IMDG Emergency Schedule Spillage

EU - European Union

ErC50 - EC50 in Terms of Reduction Growth Rate

GHS - Globally Harmonized System of Classification and Labeling of Chemicals

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

IBC Code - International Bulk Chemical Code

IMDG - International Maritime Dangerous Goods

IPRV - Ilgalaikio Poveikio Ribinis Dydis

IOELV - Indicative Occupational Exposure Limit Value

LC50 - Median Lethal Concentration

LD50 - Median Lethal Dose

LOAEL - Lowest Observed Adverse Effect Level

LOEC - Lowest-Observed-Effect Concentration

Log Koc - Soil Organic Carbon-water Partitioning Coefficient

Log Kow - Octanol/water Partition Coefficient

NDS - Najwyzsze Dopuszczalne Stezenie

NDSCh - Najwyzsze Dopuszczalne Stezenie Chwilowe

NDSP - Najwyzsze Dopuszczalne Stezenie Pulapowe

NOAEL - No-Observed Adverse Effect Level

NOEC - No-Observed Effect Concentration

NRD - Nevirsytinas Ribinis Dydis

NTP - National Toxicology Program

OEL - Occupational Exposure Limits

PBT - Persistent, Bioaccumulative and Toxic

PEL - Permissible Exposure Limit

pH - Potential Hydrogen

REACH - Registration, Evaluation, Authorisation, and Restriction of

Chemicals

RID - Regulations Concerning the International Carriage of Dangerous

Goods by Rail

SADT - Self Accelerating Decomposition Temperature

SDS - Safety Data Sheet

STEL - Short Term Exposure Limit

STOT - Specific Target Organ Toxicity

TA-Luft - Technische Anleitung zur Reinhaltung der Luft

TEL TRK - Technical Guidance Concentrations

ThOD - Theoretical Oxygen Demand

TLM - Median Tolerance Limit

TLV - Threshold Limit Value

TPRD - Trumpalaikio Poveikio Ribinis Dydis

TRGS 510 - Technische Regel für Gefahrstoffe 510 - Lagerung von

Gefahrstoffen in ortsbeweglichen Behältern

TRGS 552 - Technische Regeln für Gefahrstoffe - N-Nitrosamine

TRGS 900 - Technische Regel für Gefahrstoffe 900 -

Arbeitsplatzgrenzwerte

TRGS 903 - Technische Regel für Gefahrstoffe 903 - Biologische

Grenzwerte

TSCA - Toxic Substances Control Act

TWA - Time Weighted Average

**VOC - Volatile Organic Compounds** 

Log Pow - Ratio of the equilibrium concentration (C) of a dissolved substance in a two-phase system consisting of two largely immiscible solvents, in this case octanol and water

MAK - Maximum Workplace Concentration/Maximum Permissible Concentration

MARPOL - International Convention for the Prevention of Pollution

VLA-EC - Valor Límite Ambiental Exposición de Corta Duración

VLA-ED - Valor Límite Ambiental Exposición Diaria

VLE - Valeur Limite D'exposition

VME - Valeur Limite De Moyenne Exposition

vPvB - Very Persistent and Very Bioaccumulative

WEL - Workplace Exposure Limit

WGK - Wassergefährdungsklasse

# **Glossary of Data Source Abbreviations**

ATSDR: Agency for Toxic Substances and Disease Registry (U.S.

Department of Health and Human Services)

AU WES: Australia WES

CHEMVIEW: ChemView (U.S. Environmental Protection Agency)

EC\_RAR: European Commission Renewal Assessment Report

 ${\sf EC\_SCOEL:} \ {\sf European} \ {\sf Commission} \ {\sf Scientific} \ {\sf Committee} \ {\sf on} \ {\sf Occupational}$ 

**Exposure Limits** 

ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals

Reports

ECHA\_API: European Chemicals Agency API

ECHA\_RAC: ECHA Committee for Risk Assessment

EFSA: European Food Safety Authority

EPA: U.S. Environmental Protection Agency

EPA\_AEGL: Acute Exposure Guideline Levels (U.S. Environmental

Protection Agency)

EPA\_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act
Reregistration Eligibility Decision (U.S. Environmental Protection Agency)

EPA\_HPV: High Production Volume Chemicals (U.S. Environmental

Protection Agency)

EPA\_TRED: Risk Assessment for Tolerance Reassessment Eligibility

Decision (U.S. Environmental Protection Agency)

EU\_CLH: European Union Harmonised Classification and Labelling

Proposal

EU\_RAR: European Union Risk Assessment Report

FOOD\_JOURN: Food Research Journal (1956)

IARC: The International Agency for Research on Cancer

IDLH: National Institute for Occupational Health and Safety Immediately

Dangerous to Life or Health Value Profiles

IUCLID: International Uniform Chemical Information Database

JAPAN\_GHS: Japan GHS Basis for Classification Data

JP J-CHECK: Japan J-Check

KR\_NIER: South Korea National Institute of Environmental Research Evaluations

NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme

\_\_\_\_\_

NIOSH: National Institute for Occupational Health and Safety (U.S. Department

of Health and Human Services)

NLM\_CIP: National Library of Medicine ChemID plus database

NLM\_HSDB: National Library of Medicine Hazardous Substance Data Bank

NLM\_PUBMED: National Library of Medicine PubMed database

NTP: National Toxicology Program

NZ\_CCID: New Zealand Chemical Classification and Information Database

OECD\_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)

OECD\_SIDS: Screening Information Data Sets (Organisation for Economic Cooperation and Development)

WHO: World Health Organization

# Limit Value Legal Basis\*

\*Includes the below and any related regulations/provisions, and subsequent amendements

EU - 2019/1831 EU in accor. with 98/24/EC - Directive 2019/1831/EU of October 24, 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 2000/39/EC.

EU - 2019/1243/EU, and 98/24/EC) - Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work and amendment Regulation (EU) 2019/1243.

Austria - BGBI. II Nr. 254/2018 - Ordinance on Limit Values for Workplace Substances and on Carcinogens from the Federal Ministry of Economics and Labour, Published in 2003, Appendix 1: Substance List, Published through: Ministry of Economics and Labour of the Republic of Austria amended through the Government Gazette II (BGBL. II) No 119/2004) & BGBI. II No. 242/2006, BGBI. II No. 243/2007, lastly changed through BGBI. I Nr. 51/2011), BGBI. II Nr. 186/2015, BGBI. II Nr. 288/2017 amended by BGBI. II Nr. 254/2018.

Austria - BLV BGBI. II Nr. 254/2018 - Ordinance on health monitoring at the workplace 2008, published through BGBI. II Nr. 224/2007 by Austria Minister for Labor and Social Affairs, Lastly changed through BGBI. II Nr. 254/2018

Belgium - Royal Decree 21/01/2020 - Royal decree amending title 1 relating to chemical agents in Book VI of the code of well-being at work, with regard to the list of limit values of exposure to chemical agents and title 2 relating to carcinogens, mutagens and reprotoxics of Book VI of the code of well-being at work (1)

**Bulgaria - Reg. No. 13/10** - Regulation No. 13 of December 30, 2003 on the Protection of Workers from Hazards Related to Exposure to Chemical

Greece - PWHSE - Occupational Exposure Limits - Protection of workers' health and safety from exposure to certain chemical substances during the workday, (latest amendment 82/2018) and Occupation Exposure Limits - Protection of workers' health and safety from exposure to certain carcinogenic and mutagenic chemical substances (latest amendment 26/2020), and Presidential Decree 212/2006 - Protection of workers that are exposed to asbestos.

**Hungary - Decree 05/2020** - 5/2020. (II. 6.) ITM decree on the protection of the health and safety of workers from the risks related to chemical agents

Ireland - 2020 COP - 2020 Code of Practice for the Chemical Agents
Regulations, Schedule 1

Italy - Decree 81 - Title IX, Annex XLIII and XXXVIII, Professional Exposure Limits and Annex XXXIX Mandatory Biological Limit Values and Health Monitoring, Article 1, Law 123 of August 3, 2007, Legislative Decree 81 of April 9, 2008, Last amended: January 2020

Italy - IMDFN1 - Ministerial Decree of August 20, 1999 Final Note (1)

Latvia - Reg. No. 325 - Cabinet of Ministers Regulation No. 325 - Labour Protection Requirements when Coming in Contact with Chemical Substances at Workplaces, Amended by Cabinet of Ministers Regulation No. 92, 163, 407 and No. 11.

**Lithuania - HN 23:2011** - Lithuanian Hygiene Standard HN 23:2011 Occupational Exposure Limit Values, Amended by Order V-695/A1-272.

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Agents at Work Labor Code, Annex No.1 Limit values of chemical agents in the air of the working environment, and Annex № 2 Biological limit values of chemical agents and their metabolites (bio markers of exposure) or bio markers of effect Amended by: 71/2006, 67/2007, 2/2012, 46/2015, 73/2018, 5/2020), and Regulation No.10 of September 26, 2003 on the Protection of Workers from the Risks Associated with Exposure to Carcinogens and Mutagens at Work Annex No.1 Occupational Exposure Limits, Amended by: 8/2004, 46/2015, 5/2020

**Croatia - OG No. 91/2018 -** Regulation on the Protection of Workers from Exposure to Hazardous Chemicals at Work, the Limit Values of Exposure and the Biological Limit Values. Official Gazette No. 91 of October 12, 2018

Cyprus - KDP 16/2019 - Government of Cyprus Cabinet of Ministers Regulation 268/2001 - Safety and Health in the Working Environment (Chemical Substances) Article 38, As amended by Regulation 16/2019 and Cabinet of Ministers Regulation 153/2001 - Safety and Health in the Working Environment (Chemical Substances-Carcinogens), as amended by Regulation 493/2004 - Safety and Health in the Working Environment (Chemical Substances - Carcinogens) AND Law 47(I) 2000 - Occupational Health and Safety (Asbestos), as amended by Decree 316/2006.

Czech Republic - Reg. 41/2020 - Regulation 41/2020 amending Regulation 361/2007 of Coll. establishing Occupation Exposure Limits as amended

Czech Republic - Decree No. 107/2013 - Decree No. 107/2013 Coll., amending Decree No. 432/2003 Coll., laying down the conditions for the application of the work into categories, limit values for the parameters of biological exposure tests, collection of biological material conditions for the implementation of biological exposure tests and requirements for reporting work with asbestos and biological agents

Denmark - BEK No. 698 of 28/05/2020 - Order on Limit Values for Substances and Materials, The Statutory Order No. 507 of May 17, 2011, Appendix 1 - Limits for air pollution, etc. and Appendix 3 - Biological Exposure Values, Amended by: No. 986 of October 11, 2012, No. 655 of May 31, 2018, No. 1458 December 13, 2019, No. 698 of May 28, 2020

**Estonia - Regulation No. 105** - Health and Safety Requirements for the Use of Dangerous Chemicals and Materials Containing Them and Occupational Exposure Limits to Chemical Agents

Government of the Republic, Regulation No. 105 of 20 March 2001, Amended 17 October 2019, and 17 January, 2020.

**Finland - HTP-ARVOT 2020 -** Concentrations Known to be Hazardous, 654/2020 OEL values 2020 Publications of Ministry of Social Affairs and Health 2020:24 Annexes1. 2 and 3.

France - INRS ED 984 - Occupational Exposure Limit Values to Chemical Agents in France Published 2016 by the INRS National Institute of Research and Safety Health and safety of work, revised, updated by: Decree 2016-344, JORF No 0119, and Decree 2019-1487.

**France - Decree 2009-1570** - Decree 2009-1570 of December 15, 2009, relative to the control of chemical risk on workplaces.

**Germany - TRGS 900 -** Occupational Exposure Limits, Technical Rules for Dangerous Substances, latest amendment March, 2020

**Germany - TRGS 903** - Biological Threshold Limits (BGW-Values), Technical Rules for Dangerous Substances, latest amendment March, 2020

**Gibraltar - LN. 2018/131** - Factories (Control of Chemical Agents at Work) Regulations 2003 LN. 2003/035, amended by LN. 2008/035, LN. 2008/050, LN. 2012/021, LN. 2015/143, LN. 2018/181.

**Luxembourg - A-N 684 -** Grand-Ducal Regulation of 20 July 2018 amending the Grand-Ducal Regulation of 14 November 2016 concerning the protection of the safety and health of employees against the risks associated with chemical agents in the workplace. Official journal of the Grand-Duke of Luxembourg, A-N°684 of 2018

Malta - MOSHAA Ch. 424 - Malta Occupational Health and Safety Authority Act: Chapter 424 as amended by: Legal Notice 353, 53, 198, and 57.

**Netherlands- OWCRLV** - Occupational Working Conditions Regulation, Limit Values for substances harmful to health, Annex XVIII, Updated from August 1, 2020.

Norway - FOR-2020-04-060695 - Regulations concerning action and limit values for physical and chemical agents in the working environment and classified biological agents, FOR-2011-12-06-1358, Updated by: FOR-2020-04-06-695, FOR-2020-03-23-402, FOR-2018-12-20-2186, FOR-2018-08-21-1255, FOR-2017-12-20-2353.

Poland - Dz. U. 2020 Nr. 61 - Regulation of the Minister of Family, Labor and Social Policy of June 12, 2018 on the Highest Allowable Concentrations and Intensities of Factors Harmful to Health in the Work Environment Dz.U. 2018 Nr. 1286 of June 12, 2018, Annex 1 - List of values of the highest permissible chemical concentrations and dust factors harmful to health in the work environment, amended by: Dz. U. 2020 Nr. 61

**Portugal - Portuguese Norm NP 1796:2014** - Occupational exposure limits and biological exposure indices to chemical agents. Table 1 - Occupational exposure limits and biological exposure indices to chemical agents (OELs), Law Decree 35/2020.

Romania - Gov. Dec. No 1.218 - Governmental Decision No. 1.218 from 06/09/2006 on the minimum health and safety requirements for protection of workers from the risks related to exposure to chemical agents, Annex No. 1 Mandatory National Occupational Exposure Limit Values for Chemical Agents. Amended by Decision no. 157, 584, 359, and 1.

Slovakia - Gov. Decree 33/2018 - Government Decree of Slovak Republic 33/2018 on January 17, 2018 amending Government Decree of Slovak Republic 355/2006 about protection of health of employees when working with chemical agents

Slovenia - No. 79/19 - Regulation for protection of workers against risks related to carcinogenic or mutagenic substances exposure. Annex III - Classification and binding levels of carcinogenic or mutagenic substances for occupational exposure. The Official Journal of the Republic of Slovenia, No. 101/2005. Amended by 38/15, 79/19. Regulation for protection of workers against risks related to exposure to chemical substances at the workplace. Republic of Slovenia, No. 100/2001. Annex I - List of Binding Occupational Exposure Limit Values. Amended by 39/05, 53/07, 102/10, 38/15, 78/18, 78/19

Spain - AFS 2018:1 - NATIONAL INSTITUTE FOR HEALTH AND SAFETY AT WORK. Occupational exposure limits for chemical agents in Spain. Tables 1 and 3. Latest edition Feb. 2019

**Sweden - AFS 2018:1** - Statute Book of the Swedish Work Environment Authority, AFS 2018:1

The Swedish Work Environment Authority's Ordinance and General Guidance on Hygienic Limit Values

**Switzerland - OLVSNAIF -** Occupational Limit Values 2020 Swiss National Accident Insurance Fund. List of Biological Limit Values (BAT-Werte) and List of MAK Values.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

EU GHS SDS (2020/878)