

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

#### 1.1. Product Identifier

Product Form	: Mixture
Product Name	: KOVA-Trol® III: (Normal)
Synonyms	: 87331 KOVA-Trol® III: normal w/ hCG 87327 KOVA-Trol® III: normal w/ hCG 87528 KOVA-Trol® III: normal w/ hCG 87331E KOVA-Trol® III: normal w/ hCG 87327E KOVA-Trol® III: normal w/ hCG

#### 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 : In vitro diagnostic use

##### 1.2.2. Uses Advised Against

Uses Advised Against : For in vitro diagnostic use only

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

##### Company

Kova International, Inc.  
7272 Chapman Avenue, Suite B  
Garden Grove, CA 92841  
Tel: 1-714-902-1700  
Fax: 1-714-908-7945  
Business hours: (8:00 a.m. - 5:00 p.m., PST, Monday - Friday)  
Email: Kova.CustomerService@LGCGroup.com  
Website: [www.kovaintl.com](http://www.kovaintl.com)

#### 1.4. Emergency Telephone Number

Emergency Number : 1-714-902-1700 (8:00 a.m. - 5:00 p.m., PST, Monday - Friday)

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1. Classification of the Substance or Mixture

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

Not classified

#### 2.2. Label Elements

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

EUH-statements : EUH210 - Safety data sheet available on request.

#### 2.3. Other Hazards

Other Hazards Not Contributing to the Classification : Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

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

The substance/mixture does not contain substance(s) equal to or greater than 0.1% by weight that are present in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or 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

### 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
Non-hazardous components	(CAS-No.) Not applicable	50,0082	Not classified
Water	(CAS-No.) 7732-18-5 (EC-No.) 231-791-2	49,44	Not classified
Phosphoric acid, disodium salt	(CAS-No.) 7558-79-4 (EC-No.) 231-448-7	0,25	Not classified
Gonadotropin, chorionic	(CAS-No.) 9002-61-3 (EC-No.) 232-660-2	0,12	Repr. 2, H361

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Name	Product Identifier	%	Classification According to Regulation (EC) No. 1272/2008
Phosphoric acid, potassium salt (1:1)	(CAS-No.) 7778-77-0 (EC-No.) 231-913-4	0,1	Not classified
Sodium hydroxide	(CAS-No.) 1310-73-2 (EC-No.) 215-185-5 (EC Index-No.) 011-002-00-6	< 0,1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Hydrochloric acid	(CAS-No.) 7647-01-0 (EC-No.) 231-595-7 (EC Index-No.) 017-002-00-2	< 0,1	Press. Gas Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335
4H-Imidazol-4-one, 2-amino-1,5-dihydro-1-methyl-	(CAS-No.) 60-27-5 (EC-No.) 200-466-7	0,055	Not classified
Gentamicin	(CAS-No.) 1403-66-3 (EC-No.) 215-765-8	0,016	Not classified
D-erythro-Hex-2-enonic acid, .gamma.-lactone	(CAS-No.) 89-65-6 (EC-No.) 201-928-0	0,01	Not classified

### Specific Concentration Limits:

Name	Product Identifier	Specific Concentration Limits
Sodium hydroxide	(CAS-No.) 1310-73-2 (EC-No.) 215-185-5 (EC Index-No.) 011-002-00-6	( 0,5 ≤ C < 2 ) Skin Irrit. 2, H315 ( 0,5 ≤ C < 2 ) Eye Irrit. 2, H319 ( 2 ≤ C < 5 ) Skin Corr. 1B, H314 ( 5 ≤ C < 100 ) Skin Corr. 1A, H314
Hydrochloric acid	(CAS-No.) 7647-01-0 (EC-No.) 231-595-7 (EC Index-No.) 017-002-00-2	( 0,1 ≤ C < 10 ) Met. Corr. 1, H290 ( 10 ≤ C < 25 ) Skin Irrit. 2, H315 ( 10 ≤ C < 25 ) Eye Irrit. 2, H319 ( 10 ≤ C < 25 ) STOT SE 3, H335 ( 10 ≤ C < 25 ) Met. Corr. 1, H290 ( 25 ≤ C < 100 ) Skin Corr. 1B, H314 ( 25 ≤ C < 100 ) STOT SE 3, H335 ( 25 ≤ C < 100 ) Met. Corr. 1, H290

Full text of H-statements: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First-aid Measures

- First-Aid Measures General** : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-Aid Measures After Inhalation** : When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.
- First-Aid Measures After Skin Contact** : Remove contaminated clothing. Obtain medical attention if irritation develops or persists. Drench affected area with water for at least 5 minutes.
- First-Aid Measures After Eye Contact** : Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.
- First-Aid Measures After Ingestion** : Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

### 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 known.

### 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

### 5.1. Extinguishing Media

- Suitable Extinguishing Media** : Water spray, fog, carbon dioxide (CO<sub>2</sub>), alcohol-resistant foam, or dry chemical.
- Unsuitable Extinguishing Media** : Do not use a heavy water stream. Use of heavy stream of water may spread fire.

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

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

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<b>Explosion Hazard</b>	: Product is not explosive.
<b>Reactivity</b>	: Hazardous reactions will not occur under normal conditions.
<b>Hazardous Combustion Products</b>	: Carbon oxides (CO, CO <sub>2</sub> ). Nitrogen oxides. Phosphorus oxides.
<b>5.3. Advice for Firefighters</b>	
<b>Precautionary Measures Fire</b>	: Exercise caution when fighting any chemical fire.
<b>Firefighting Instructions</b>	: Use water spray or fog for cooling exposed containers. Remove containers from fire area if this can be done without risk. Do not breathe fumes from fires or vapours from decomposition.
<b>Protection During Firefighting</b>	: Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

<b>General Measures</b>	: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).
<b>6.1.1. For Non-Emergency Personnel</b>	
<b>Protective Equipment</b>	: Use appropriate personal protective equipment (PPE).
<b>Emergency Procedures</b>	: Evacuate unnecessary personnel.
<b>6.1.2. For Emergency Responders</b>	
<b>Protective Equipment</b>	: Equip cleanup crew with proper protection.
<b>Emergency Procedures</b>	: Upon arrival at the scene, a first responder is expected to recognise the presence of 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.

### 6.3. Methods and Materials for Containment and Cleaning Up

<b>For Containment</b>	: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.
<b>Methods for Cleaning Up</b>	: 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.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

<b>Precautions for Safe Handling</b>	: Avoid breathing vapours, mist, spray. Avoid contact with eyes, skin and clothing.
<b>Hygiene Measures</b>	: Handle in accordance with good industrial hygiene and safety procedures. Wash contaminated clothing before reuse.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

<b>Technical Measures</b>	: Comply with applicable regulations.
<b>Storage Conditions</b>	: Store in accordance with applicable national storage class systems. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store in a dry, cool place.
<b>Incompatible Materials</b>	: Strong acids, strong bases, strong oxidisers.
<b>Storage Temperature</b>	: 2 – 8 °C (35.6 to 46.4 °F)

### 7.3. Specific End Use(s)

In vitro diagnostic use

## 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.

Gentamicin (1403-66-3)		
Bulgaria	OEL TWA (Legal Basis:Reg. No. 13/10)	0,1 mg/m <sup>3</sup>
Bulgaria	OEL STEL (Legal Basis:Reg. No. 13/10)	0,6 mg/m <sup>3</sup>
Sodium hydroxide (1310-73-2)		
Austria	OEL TWA (Legal Basis:BGBl. II Nr. 254/2018)	2 mg/m <sup>3</sup> (inhalable fraction)
Austria	OEL STEL (Legal Basis:BGBl. II Nr. 254/2018)	4 mg/m <sup>3</sup> (inhalable fraction)

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<b>Sodium hydroxide (1310-73-2)</b>		
Bulgaria	OEL TWA (Legal Basis:Reg. No. 13/10)	2 mg/m <sup>3</sup> (alkaline aerosols)
Croatia	OEL STEL (Legal Basis:OG No. 91/2018)	2 mg/m <sup>3</sup>
Czech Republic	OEL TWA (Legal Basis:Reg. 41/2020)	1 mg/m <sup>3</sup>
Denmark	OEL Ceiling (Legal Basis:BEK No. 698 of 28/05/2020)	2 mg/m <sup>3</sup>
Estonia	OEL TWA (Legal Basis:Regulation No. 105)	1 mg/m <sup>3</sup>
Estonia	OEL STEL (Legal Basis:Regulation No. 105)	2 mg/m <sup>3</sup>
Finland	OEL Ceiling (Legal Basis:HTP-ARVOT 2020)	2 mg/m <sup>3</sup>
France	OEL TWA (Legal Basis:INRS ED 984)	2 mg/m <sup>3</sup>
Greece	OEL TWA (Legal Basis:PWHS)	2 mg/m <sup>3</sup>
Greece	OEL STEL (Legal Basis:PWHS)	2 mg/m <sup>3</sup>
Hungary	OEL TWA (Legal Basis:Decree No. 05/2020)	1 mg/m <sup>3</sup>
Hungary	OEL STEL (Legal Basis:Decree No. 05/2020)	2 mg/m <sup>3</sup>
Ireland	OEL STEL (Legal Basis:2020 COP)	2 mg/m <sup>3</sup>
USA ACGIH	OEL Ceiling (Legal Basis:IMDFN1)	2 mg/m <sup>3</sup>
Latvia	OEL TWA (Legal Basis:Reg. No. 325)	0,5 mg/m <sup>3</sup>
Lithuania	OEL Ceiling (Legal Basis:HN 23:2011)	2 mg/m <sup>3</sup>
Norway	OEL Ceiling (Legal Basis:FOR-2020-04-06-695)	2 mg/m <sup>3</sup>
Poland	OEL TWA (Legal Basis:Dz. U. 2020 Nr. 61)	0,5 mg/m <sup>3</sup>
Poland	OEL TWA (Legal Basis:Dz. U. 2020 Nr. 61)	1 mg/m <sup>3</sup>
Portugal	OEL Ceiling (Legal Basis:Portuguese Norm NP 1796:2014)	2 mg/m <sup>3</sup>
Slovakia	OEL TWA (Legal Basis:Gov. Decree 33/2018)	2 mg/m <sup>3</sup>
Spain	OEL STEL (Legal Basis:OELCAIS)	2 mg/m <sup>3</sup>
Sweden	OEL TLV (Legal Basis:AFS 2018:1)	1 mg/m <sup>3</sup> (inhalable fraction)
Sweden	OEL STEL (Legal Basis:AFS 2018:1)	2 mg/m <sup>3</sup> (inhalable fraction)
Switzerland	OEL STEL (Legal Basis:OLVSNAIF)	2 mg/m <sup>3</sup> (inhalable dust)
Switzerland	OEL TWA (Legal Basis:OLVSNAIF)	2 mg/m <sup>3</sup> (inhalable dust)
<b>Hydrochloric acid (7647-01-0)</b>		
EU	IOELV TWA (Legal Basis:2019/1831 EU in accor. with 98/24/EC)	8 mg/m <sup>3</sup>
EU	IOELV TWA (Legal Basis:2019/1831 EU in accor. with 98/24/EC)	5 ppm
EU	IOELV STEL (Legal Basis:2019/1831 EU in accor. with 98/24/EC)	15 mg/m <sup>3</sup>
EU	IOELV STEL (Legal Basis:2019/1831 EU in accor. with 98/24/EC)	10 ppm
Austria	OEL TWA (Legal Basis:BGBl. II Nr. 254/2018)	8 mg/m <sup>3</sup>
Austria	OEL TWA (Legal Basis:BGBl. II Nr. 254/2018)	5 ppm
Austria	OEL STEL (Legal Basis:BGBl. II Nr. 254/2018)	15 mg/m <sup>3</sup>
Austria	OEL STEL (Legal Basis:BGBl. II Nr. 254/2018)	10 ppm
Belgium	OEL TWA (Legal Basis:Royal Decree 21/01/2020)	8 mg/m <sup>3</sup>
Belgium	OEL TWA (Legal Basis:Royal Decree 21/01/2020)	5 ppm
Belgium	OEL STEL (Legal Basis:Royal Decree 21/01/2020)	15 mg/m <sup>3</sup>
Belgium	OEL STEL (Legal Basis:Royal Decree 21/01/2020)	10 ppm
Bulgaria	OEL TWA (Legal Basis:Reg. No. 13/10)	8 mg/m <sup>3</sup>
Bulgaria	OEL TWA (Legal Basis:Reg. No. 13/10)	5 ppm
Bulgaria	OEL STEL (Legal Basis:Reg. No. 13/10)	15 mg/m <sup>3</sup>
Bulgaria	OEL STEL (Legal Basis:Reg. No. 13/10)	10 ppm
Croatia	OEL TWA (Legal Basis:OG No. 91/2018)	8 mg/m <sup>3</sup>
Croatia	OEL TWA (Legal Basis:OG No. 91/2018)	5 ppm
Croatia	OEL STEL (Legal Basis:OG No. 91/2018)	15 mg/m <sup>3</sup>
Croatia	OEL STEL (Legal Basis:OG No. 91/2018)	10 ppm
Cyprus	OEL TWA (Legal Basis:KDP 16/2019)	8 mg/m <sup>3</sup>
Cyprus	OEL TWA (Legal Basis:KDP 16/2019)	5 ppm
Cyprus	OEL STEL (Legal Basis:KDP 16/2019)	15 mg/m <sup>3</sup>
Cyprus	OEL STEL (Legal Basis:KDP 16/2019)	10 ppm
Czech Republic	OEL TWA (Legal Basis:Reg. 41/2020)	8 mg/m <sup>3</sup>
Denmark	OEL Ceiling (Legal Basis:BEK No. 698 of 28/05/2020)	8 mg/m <sup>3</sup>
Denmark	OEL Ceiling (Legal Basis:BEK No. 698 of 28/05/2020)	5 ppm
Estonia	OEL TWA (Legal Basis:Regulation No. 105)	8 mg/m <sup>3</sup>
Estonia	OEL TWA (Legal Basis:Regulation No. 105)	5 ppm
Estonia	OEL STEL (Legal Basis:Regulation No. 105)	15 mg/m <sup>3</sup>

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Hydrochloric acid (7647-01-0)		
Estonia	OEL STEL (Legal Basis:Regulation No. 105)	10 ppm
Finland	OEL STEL (Legal Basis:HTP-ARVOT 2020)	7,6 mg/m <sup>3</sup> (anhydrous and in solution)
Finland	OEL STEL (Legal Basis:HTP-ARVOT 2020)	5 ppm (anhydrous and in solution)
France	OEL STEL (Legal Basis:INRS ED 984)	7,6 mg/m <sup>3</sup> (restrictive limit)
France	OEL STEL (Legal Basis:INRS ED 984)	5 ppm (restrictive limit)
Germany	OEL TWA (Legal Basis:TRGS 900)	3 mg/m <sup>3</sup> (the risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed)
Germany	OEL TWA (Legal Basis:TRGS 900)	2 ppm (the risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed)
Gibraltar	OEL TWA (Legal Basis:LN. 2018/181)	8 mg/m <sup>3</sup>
Gibraltar	OEL TWA (Legal Basis:LN. 2018/181)	5 ppm
Gibraltar	OEL STEL (Legal Basis:LN. 2018/181)	15 mg/m <sup>3</sup>
Gibraltar	OEL STEL (Legal Basis:LN. 2018/181)	10 ppm
Greece	OEL TWA (Legal Basis:PWHSE)	7 mg/m <sup>3</sup>
Greece	OEL TWA (Legal Basis:PWHSE)	5 ppm
Greece	OEL STEL (Legal Basis:PWHSE)	7 mg/m <sup>3</sup>
Greece	OEL STEL (Legal Basis:PWHSE)	5 ppm
Hungary	OEL TWA (Legal Basis:Decree No. 05/2020)	8 mg/m <sup>3</sup>
Hungary	OEL STEL (Legal Basis:Decree No. 05/2020)	16 mg/m <sup>3</sup>
Ireland	OEL TWA (Legal Basis:2020 COP)	8 mg/m <sup>3</sup>
Ireland	OEL TWA (Legal Basis:2020 COP)	5 ppm
Ireland	OEL STEL (Legal Basis:2020 COP)	15 mg/m <sup>3</sup>
Ireland	OEL STEL (Legal Basis:2020 COP)	10 ppm
USA ACGIH	OEL Ceiling (Legal Basis:IMDFN1)	2 ppm
Italy	OEL TWA (Legal Basis:Decree 81)	8 mg/m <sup>3</sup>
Italy	OEL TWA (Legal Basis:Decree 81)	5 ppm
Italy	OEL STEL (Legal Basis:Decree 81)	15 mg/m <sup>3</sup>
Italy	OEL STEL (Legal Basis:Decree 81)	10 ppm
Latvia	OEL TWA (Legal Basis:Reg. No. 325)	8 mg/m <sup>3</sup>
Latvia	OEL TWA (Legal Basis:Reg. No. 325)	5 ppm
Lithuania	OEL TWA (Legal Basis:HN 23:2011)	8 mg/m <sup>3</sup>
Lithuania	OEL TWA (Legal Basis:HN 23:2011)	5 ppm
Lithuania	OEL STEL (Legal Basis:HN 23:2011)	15 mg/m <sup>3</sup>
Lithuania	OEL STEL (Legal Basis:A-N 684)	10 ppm
Luxembourg	OEL TWA (Legal Basis:A-N 684)	8 mg/m <sup>3</sup>
Luxembourg	OEL TWA (Legal Basis:A-N 684)	5 ppm
Luxembourg	OEL STEL (Legal Basis:A-N 684)	15 mg/m <sup>3</sup>
Luxembourg	OEL STEL (Legal Basis:A-N 684)	10 ppm
Malta	OEL TWA (Legal Basis:MOHSAA Ch. 424)	8 mg/m <sup>3</sup>
Malta	OEL TWA (Legal Basis:MOHSAA Ch. 424)	5 ppm
Malta	OEL STEL (Legal Basis:MOHSAA Ch. 424)	15 mg/m <sup>3</sup>
Malta	OEL STEL (Legal Basis:MOHSAA Ch. 424)	10 ppm
Netherlands	OEL TWA (Legal Basis:OWCRLV)	8 mg/m <sup>3</sup>
Netherlands	OEL STEL (Legal Basis:OWCRLV)	15 mg/m <sup>3</sup>
Norway	OEL Ceiling (Legal Basis:FOR-2020-04-06-695)	7 mg/m <sup>3</sup>
Norway	OEL Ceiling (Legal Basis:FOR-2020-04-06-695)	5 ppm
Poland	OEL TWA (Legal Basis:Dz. U. 2020 Nr. 61)	5 mg/m <sup>3</sup>
Poland	OEL TWA (Legal Basis:Dz. U. 2020 Nr. 61)	10 mg/m <sup>3</sup>
Portugal	OEL TWA (Legal Basis:Portuguese Norm NP 1796:2014)	8 mg/m <sup>3</sup> (indicative limit value)
Portugal	OEL TWA (Legal Basis:Portuguese Norm NP 1796:2014)	5 ppm (indicative limit value)
Portugal	OEL STEL (Legal Basis:Portuguese Norm NP 1796:2014)	15 mg/m <sup>3</sup> (indicative limit value)
Portugal	OEL STEL (Legal Basis:Portuguese Norm NP 1796:2014)	10 ppm (indicative limit value)
Portugal	OEL Ceiling (Legal Basis:Portuguese Norm NP 1796:2014)	2 ppm
Portugal	OEL Chemical Category (Legal Basis:Portuguese Norm NP 1796:2014)	A4 - Not Classifiable as a Human Carcinogen
Romania	OEL TWA (Legal Basis:Gov. Dec. No 1.218)	8 mg/m <sup>3</sup>
Romania	OEL TWA (Legal Basis:Gov. Dec. No 1.218)	5 ppm

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Romania	OEL STEL (Legal Basis:Gov. Dec. No 1.218)	15 mg/m <sup>3</sup>
Romania	OEL STEL (Legal Basis:Gov. Dec. No 1.218)	10 ppm
Slovakia	OEL TWA (Legal Basis:Gov. Decree 33/2018)	8 mg/m <sup>3</sup>
Slovakia	OEL TWA (Legal Basis:Gov. Decree 33/2018)	5 ppm
Slovakia	OEL STEL (Legal Basis:Gov. Decree 33/2018)	15 mg/m <sup>3</sup>
Slovenia	OEL TWA (Legal Basis:No. 79/19)	8 mg/m <sup>3</sup> (anhydrous)
Slovenia	OEL TWA (Legal Basis:No. 79/19)	5 ppm (anhydrous)
Slovenia	OEL STEL (Legal Basis:No. 79/19)	15 mg/m <sup>3</sup> (anhydrous)
Slovenia	OEL STEL (Legal Basis:No. 79/19)	10 ppm (anhydrous)
Spain	OEL TWA (Legal Basis:OELCAIS)	7,6 mg/m <sup>3</sup> (indicative limit value)
Spain	OEL TWA (Legal Basis:OELCAIS)	5 ppm (indicative limit value)
Spain	OEL STEL (Legal Basis:OELCAIS)	15 mg/m <sup>3</sup>
Spain	OEL STEL (Legal Basis:OELCAIS)	10 ppm
Sweden	OEL TLV (Legal Basis:AFS 2018:1)	3 mg/m <sup>3</sup>
Sweden	OEL TLV (Legal Basis:AFS 2018:1)	2 ppm
Sweden	OEL STEL (Legal Basis:AFS 2018:1)	6 mg/m <sup>3</sup>
Sweden	OEL STEL (Legal Basis:AFS 2018:1)	4 ppm
Switzerland	OEL STEL (Legal Basis:OLVSNAIF)	6 mg/m <sup>3</sup>
Switzerland	OEL STEL (Legal Basis:OLVSNAIF)	4 ppm
Switzerland	OEL TWA (Legal Basis:OLVSNAIF)	3 mg/m <sup>3</sup>
Switzerland	OEL TWA (Legal Basis:OLVSNAIF)	2 ppm

## 8.2. Exposure Controls

### Appropriate Engineering Controls

: 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. Insufficient ventilation: wear respiratory protection. 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.

### Eye Protection

: Chemical safety goggles.

### Skin and Body Protection

: Wear suitable protective clothing. In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

### 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
Colour, Appearance	: No data available
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: ≈ 0 °C (32 °F)
Freezing Point	: ≈ 0 °C (32 °F)
Boiling Point	: 100 °C (212 °F)

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Flash Point	: Not applicable
Auto-Ignition Temperature	: Not applicable
Decomposition Temperature	: No data available
Flammability	: Not applicable
Vapour Pressure	: No data available
Relative Vapour Density At 20 °C	: No data available
Relative Density	: ≈ 1 (water=1)
Solubility	: Water: Soluble
Partition Coefficient n-Octanol/Water	: No data available
Viscosity	: No data available
Explosive Properties	: No data available
Oxidising Properties	: No data available
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
Particle Dustiness	: Not applicable

### 9.2. Other Information

No additional information available

## 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

Not expected to decompose under ambient conditions.

## SECTION 11: TOXICOLOGICAL INFORMATION

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

Likely Routes of Exposure	: Dermal; Eye contact; Ingestion; Inhalation
Acute Toxicity (Oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute Toxicity (Dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute Toxicity (Inhalation)	: Not classified (Based on available data, the classification criteria are not met)

Gentamicin (1403-66-3)	
LD50 Oral Rat	6600 mg/kg
Phosphoric acid, disodium salt (7558-79-4)	
LD50 Oral Rat	17 g/kg
LD50 Dermal Rat	> 5000 mg/kg (50% solution)
Phosphoric acid, potassium salt (1:1) (7778-77-0)	
LD50 Oral Rat	> 2000 mg/kg (No deaths)
LD50 Dermal Rat	> 2000 mg/kg (No deaths)
LC50 Inhalation Rat	> 0,83 mg/l/4h (No deaths)
D-erythro-Hex-2-enonic acid, .gamma.-lactone (89-65-6)	
LD50 Oral Rat	18 g/kg
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 Oral	238 mg/kg
LD50 Dermal Rabbit	> 5010 mg/kg

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<b>Skin Corrosion/Irritation</b>	: Not classified (Based on available data, the classification criteria are not met)
<b>Eye Damage/Irritation</b>	: Not classified (Based on available data, the classification criteria are not met)
<b>Respiratory or Skin Sensitisation</b>	: Not classified (Based on available data, the classification criteria are not met)
<b>Germ Cell Mutagenicity</b>	: Not classified (Based on available data, the classification criteria are not met)
<b>Carcinogenicity</b>	: Not classified (Based on available data, the classification criteria are not met)
<b>Reproductive Toxicity</b>	: Not classified (Based on available data, the classification criteria are not met)
<b>Specific Target Organ Toxicity (Single Exposure)</b>	: Not classified (Based on available data, the classification criteria are not met)
<b>Specific Target Organ Toxicity (Repeated Exposure)</b>	: Not classified (Based on available data, the classification criteria are not met)
<b>Aspiration Hazard</b>	: Not classified (Based on available data, the classification criteria are not met)
<b>Symptoms/Injuries After Inhalation</b>	: Prolonged exposure may cause irritation.
<b>Symptoms/Injuries After Skin Contact</b>	: Prolonged exposure may cause skin irritation.
<b>Symptoms/Injuries After Eye Contact</b>	: May cause slight irritation to eyes.
<b>Symptoms/Injuries After Ingestion</b>	: Ingestion may cause adverse effects.
<b>Chronic Symptoms</b>	: None known.

### 11.2. Information On Other Hazards

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.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

<b>Hazardous To The Aquatic Environment, Short-Term (Acute)</b>	: Not classified (Based on available data, the classification criteria are not met)
<b>Hazardous To The Aquatic Environment, Long-Term (Chronic)</b>	: Not classified (Based on available data, the classification criteria are not met)

<b>Phosphoric acid, potassium salt (1:1) (7778-77-0)</b>	
LC50 - Fish	> 100 mg/l (Read across)
<b>Sodium hydroxide (1310-73-2)</b>	
LC50 - Fish	45,4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea	40 mg/l
<b>Hydrochloric acid (7647-01-0)</b>	
LC50 - Fish	7,45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)

### 12.2. Persistence and Degradability

<b>KOVA-Trol® III: (Normal)</b>	
Persistence and Degradability	Not established.

### 12.3. Bioaccumulative Potential

<b>KOVA-Trol® III: (Normal)</b>	
Bioaccumulative Potential	Not established.
<b>D-erythro-Hex-2-enonic acid, .gamma.-lactone (89-65-6)</b>	
Partition coefficient n-octanol/water (Log POW)	-1,69 at 25 °C (at pH 4)

### 12.4. Mobility in Soil

No additional information available

### 12.5. Results of PBT and vPvB Assessment

Does not contain any PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XVIII

### 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.

### 12.7. Other Adverse Effects

<b>Other Information</b>	: Avoid release to the environment.
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## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste Treatment Methods

<b>Product/Packaging Disposal Recommendations</b>	: Dispose of contents/container in accordance with local, regional, national, and international regulations.
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**Ecology - Waste Materials** : Avoid release to the environment.

### 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

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

### 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

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	Hydrochloric acid
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##### 15.1.1.2. REACH Candidate List Information

Contains no substance on the REACH candidate list

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

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

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

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

##### 15.1.1.5. REACH Annex XIV Information

Contains no REACH Annex XIV substances

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

No additional information available

##### 15.1.1.7. EC Inventory Information

<b>Gentamicin (1403-66-3)</b>
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
<b>Phosphoric acid, disodium salt (7558-79-4)</b>
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
<b>Phosphoric acid, potassium salt (1:1) (7778-77-0)</b>
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
<b>Water (7732-18-5)</b>
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
<b>D-erythro-Hex-2-enonic acid, .gamma.-lactone (89-65-6)</b>
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
<b>4H-Imidazol-4-one, 2-amino-1,5-dihydro-1-methyl- (60-27-5)</b>
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
<b>Gonadotropin, chorionic (9002-61-3)</b>
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
<b>Sodium hydroxide (1310-73-2)</b>
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
<b>Hydrochloric acid (7647-01-0)</b>
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

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### 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

#### Gentamicin (1403-66-3)

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 INSQ (Mexican National Inventory of Chemical Substances)  
Listed on the TCSI (Taiwan Chemical Substance Inventory)

#### Phosphoric acid, disodium salt (7558-79-4)

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 Chemicals Inventory)

#### Phosphoric acid, potassium salt (1:1) (7778-77-0)

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 Chemicals Inventory)

#### 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 Chemicals Inventory)

#### D-erythro-Hex-2-enonic acid, .gamma.-lactone (89-65-6)

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 Chemicals Inventory)

#### 4H-Imidazol-4-one, 2-amino-1,5-dihydro-1-methyl- (60-27-5)

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)

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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 Chemicals Inventory)

### Gonadotropin, chorionic (9002-61-3)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)  
Listed on NZIoC (New Zealand Inventory of Chemicals)  
Listed on the TCSI (Taiwan Chemical Substance Inventory)

### Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active  
Listed on the Canadian DSL (Domestic Substances List)  
Listed on the Canadian IDL (Ingredient Disclosure 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)  
Japanese Poisonous and Deleterious Substances Control 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 Chemicals Inventory)

### Hydrochloric acid (7647-01-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active  
Listed on the Canadian DSL (Domestic Substances List)  
Listed on the Canadian IDL (Ingredient Disclosure List)  
Listed on the United States SARA Section 302  
Subject to reporting requirements of United States SARA Section 313  
Listed on EPA Hazardous Air Pollutant (HAPS)  
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 Poisonous and Deleterious Substances Control 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 Chemicals Inventory)

## 15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out

## SECTION 16: OTHER INFORMATION

**Date of Preparation or Latest Revision** : 15/05/2023

**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-statements:

Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H361	Suspected of damaging fertility or the unborn child.
Met. Corr. 1	Corrosive to metals, Category 1
Press. Gas	Gases under pressure
Repr. 2	Reproductive toxicity, Category 2

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Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation

### Indication of Changes

No additional information available

### 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  
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

NDS - Najwyższe Dopuszczalne Stezenie  
NDSCh - Najwyższe Dopuszczalne Stezenie Chwilowe  
NDSP - Najwyższe 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  
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

### Limit Value Legal Basis\*

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

**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 - BGBl. 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) & BGBl. II No. 242/2006, BGBl. II No. 243/2007, lastly changed through BGBl. I Nr. 51/2011), BGBl. II Nr. 186/2015, BGBl. II Nr. 288/2017 amended by BGBl. II Nr. 254/2018.

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

**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

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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 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

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*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.*

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