

according to 1907/2006/EC, Article 31, (Commission Regulation (EU) 2020/878)

Trade name: **Epi-On**<sup>®</sup> Version: 10 Revision: 2023.11.27

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

1.1 Product identifier

Trade name Epi-On®

CAS number 1272659-40-1 (and) 7732-18-5 (and) 107-88-0

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

Recommended Use SU3 Industrial uses: Uses of substances as such or in

preparations at industrial sites

SU21 Consumer uses: Private household/general public/

consumers

SU22 Professional uses

Uses advised againstNot determinedProduct categoryNot determinedProcess categoryNot determined

#### 1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier

CORUM INC.

6FL., No.360, Ruei Guang Rd., Neihu Dist., Taipei 114729, Taiwan **Further information obtainable from** 

marketing@corum.com.tw

1.4 <u>Emergency telephone number</u>

Company phone number CORUM Tel. 886-2-8751-6060

Fax. 886-2-8751-6363

#### **SECTION 2: HAZARDS IDENTIFICATION**

#### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

This substance is not classified according to the CLP regulation.

#### 2.2 <u>Label elements</u>

Label according to Regulation (EC) No 1272/2008

Not applicable

#### 2.3 Other hazards

#### Results of PBT and vPvB assessment

PBT:

Based on available data, the ingredients of this mixture do not meet the PBT criteria (not PBT) according to (EC) 1907/2006, Annex XIII.

vPvB:

Based on available data, the ingredients of this mixture do not meet the vPvB criteria (not vPvB) according to (EC) 1907/2006, Annex XIII.

#### **Determination of endocrine-disrupting properties**

The product does not contain ingredients with endocrine-disrupting properties for humans.



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

#### 3.1 Substances

Not applicable

#### 3.2 Mixtures

Composition/information on ingredients

Name	Chemical name	Identification	Classification	SCLs, M-Factors	%
COMPONENT					
Azelamidopropyl Dimethyl Amine	-	(CAS No.) 1272659-40-1 (EC No.) -	-	-	48-52%
Water	-	(CAS No.) 7732-18-5 (EC No.) 231-791-2	Not Classified	-	35-40%
1,3-Butylene glycol	Butane-1,3-diol	(CAS No.) 107-88-0 (EC No.) 203-529-7	Not Classified	-	10-15%

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

4.1 Description of first aid measures

**General information** Remove contaminated clothing. Seek medical treatment.

After inhalation Supply fresh air; seek medical advice if symptoms persist.

After skin contact Immediately wash with soap and copious amounts of water.

If symptoms develop, seek medical attention.

After eye contact Check and remove any contact lenses. Rinse opened eye

for 15 minutes under running water. If symptoms persist, consult a doctor.

After swallowing Rinse mouth with water. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

**Symptoms** No further relevant information available.

4.3 <u>Indication of any immediate medical attention and special treatment needed</u>

**Note to physicians** No further relevant information available.

#### **SECTION 5: FIRE-FIGHTING MEASURES**

#### 5.1 Extinguishing media



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#### Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media

Not determined

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

No further relevant information available.

#### 5.3 Advice for firefighters

#### **Protective equipment:**

Wear self-contained breathing apparatus for firefighting if necessary.

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

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

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. For personal protection see section 8.

Avoid contact with skin, eyes and clothes.

#### 6.2 Environmental precautions

Do not allow product to reach sewage system or any water course.

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

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, and sawdust). Sweep up, place in a bag and hold for waste disposal.

#### 6.4 Reference to other sections

See Section 7 for information on safe handing.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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

#### 7.1 Precaution for safe handing

Advice on safe handling No special precautions are necessary if used correctly.

Avoid free fall and splashing. Prevent the risk of slipping.

Information about fire - and explosion protection:

No special measures required.

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

Storage conditions Protect from contacting with light, heat and moisture. Store in

tightly closed container at 25°C. It is best to use the entire

contents of the pack after opening.

Requirements to be met by storerooms and receptacles

No special measures required.

Information about storage in common storage facility

Not required

Further information about storage conditions

None

**Incompatible materials**None known based on information supplied.



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Storage class (VbF) No

**7.3** Specific end use(s) No further relevant information available.

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

#### 8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace

**Exposure limits**The product does not contain relevant quantities of materials

with critical values that have to be monitored at the workplace.

**PNEC** Not determined Not determined

**Additional information** The valid lists during this review were used as a basis.

8.2 Exposure controls

**Appropriate engineering controls** Ensure that eyewash and safety showers are in close

proximity to work location. Good general ventilation is recommended for handling the product. No further data; see

section 7.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures

Avoid contact with the eyes and skin. Wash hands before

breaks and at the end of work.

Personal protective equipment

**Respiration protection** Not necessary if room is well-ventilated.

es W

Hands protection Protective gloves

The glove material has to be impermeable and resistant to the product/the substance/the preparation. Due to missing tests no recommendation to the glove material can be given for the product/the preparation/the chemical mixture. Selection of the glove material on consideration of the penetration times,

rates of diffusion and the degradation

Material of gloves The selection of the suitable gloves does not only depend on

the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to

be checked prior to the application.

Penetration time of glove material The exact break through time has to be found out by the

manufacturer of the protective gloves and has to be observed.



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**Eye protection** Chemical safety goggles

**General protective measure** Avoid contact with the eyes and skin.

handing chemicals.

**Environmental exposure** 

**controls** No further relevant information available.

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

#### 9.1 <u>Information on basic physical and chemical properties</u>

Physical State Liquid
Appearance Liquid

Color Clear to yellow Odor Typical

Oder threshold Not determined

**Property** 

pH value (30% aq.) 5.0-7.0

Melting point/Melting rangeNot determinedBoiling point/Boiling rangeNot determinedFlash pointNot determinedFlammability (solid, gaseous)Not applicableIgnition temperatureNot determinedDecomposition temperatureNot determined

**Self-igniting** Product is not self-igniting.

**Danger of explosion** Product does not present an explosion hazard.

**Explosion limit** 

Lower Not determined Not determined Upper Oxidizing properties Not determined **Explosive properties** Not determined Vapor pressure Not determined Vapor density Not determined Relative density Not determined **Evaporation rate** Not determined Solubility Not determined

Partition coefficient

(n-octanol/water at 25 °C)Not determinedKinematic viscosityNot applicableDynamic viscosityNot determined

9.2 Other information

Surface tensionNot determinedDissociation constantNot determinedGranulometryNot determined

Information with regard to physical hazard classes

**Explosives** Not determined Flammable Gases and Chemically Unstable Gases

Not determined

Flammable Aerosols Not determined Oxidising Gases Not determined Gases Under Pressure Not determined



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Flammable Liquids Not determined Flammable Solids Not determined

**Self-reactive Substances and Mixtures** 

Not determined

Pyrophoric Liquids Not determined Pyrophoric Solids Not determined

**Self-heating Substances and Mixtures** 

Not determined

Substances and Mixtures which in contact with water emit flammable gases

Not determined

Oxidising LiquidsNot determinedOxidising SolidsNot determinedOrganic PeroxidesNot determined

**Substances and Mixtures corrosive to Metals** 

Not determined

Desensitized Explosives Not determined

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

#### 10.1 Reactivity

Not determined

#### 10.2 Chemical stability

The product is stable under ordinary condition.

#### Thermal decomposition/conditions to be avoided

No decomposition if used according to specifications.

#### 10.3 Possibility of hazardous reactions

No dangerous reactions known.

#### 10.4 Conditions to avoid

No further relevant information available

#### 10.5 Incompatible material

Strong oxidizing agents

Strong acids

Strong bases

#### 10.6 <u>Hazardous decomposition products</u>

No further relevant information available.

#### **SECTION 11: TOXICOLOGICAL INFORMATION**

### 11.1 <u>Information on toxicological effects</u>

Name	Azelamidopropyl Dimethyl Amine CAS:1272659-40-1	Water CAS:7732-18-5	1,3-Butylene glycol CAS:107-88-0
Acute toxicity	Not determined	Not Classified	Based on the available data, which indicate a low acute toxicity, and according to Regulation (EC) No 1272/2008 no



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			classification for acute
			toxicity is required.
Skin corrosion/irritation	Not determined	Not Classified	*No adverse effect observed (not irritating)
Serious eye damage/irritation	Non irritant (Epi-On® gel, 4% A.I.)	Not Classified	*No adverse effect observed (not irritating)
Respiratory tract	Not determined	Not Classified	Not determined
Respiratory/skin sensitization	Non irritant (Epi-On <sup>®</sup> )	Not Classified	Based on the available data and according to Regulation (EC) No 1272/2008 no classification for skin sensitisation is required. There are no data on respiratory sensitisation available.
Toxicokinetics, metabolism and distribution	Not determined	Not Classified	Not determined
Repeated dose toxicity	Not determined	Not Classified	The substance has not to be classified for toxicity after repeated exposure according to Regulation (EC) No 1272/2008, because no toxic effects were observed in a chronic study in rats (NOAEL 5000 mg/kg bw/day). Effects in a subchronic study in dogs were only observed at doses above 6000 mg/kg bw/day (NOAEL 6000 mg/kg bw/day).
Germ Cell mutagenicity	Non mutagenic/non pro-mutagenic (Epi-On®)	Not Classified	There are no in vitro studies available investigating genotoxicity of butane-1,3 -diol.
Carcinogenicity	Not determined	Not Classified	In the absence of carcinogenic effects in chronic studies with rats and dogs and the negative findings in the available mutagenicity assays 1,3 -butylene glycol has not to be classified as carcinogenic according to the criteria of Regulation (EC) No 1272/2008.
Reproductive toxicity	Not determined	Not Classified	Based on the available data it is concluded that 1,3 -butylene



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			glycol has not to be classified for toxicity on reproduction according to Regulation (EC) No 1272/2008.
STOT-single exposure	Not determined	Not Classified	Not determined
STOT-repeated exposure	Not determined	Not Classified	Not determined
Aspiration hazard	Not determined	Not Classified	Not determined

<sup>\*</sup>from ECHA webpage registration data

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

#### 11.2 Information on other hazards

Endocrine disrupting properties Cytotoxicity

Substance is not listed. Insignificant cytotoxicity.

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

Name	Azelamidopropyl Dimethyl Amine CAS:1272659-40-1	Water CAS:7732-18-5	1,3-Butylene glycol CAS:107-88-0
<b>12.1 Toxicity</b> Aquatic toxicity	No further relevant information available	No further relevant information available.	*Fish, LC50: (96H) > 100 mg/L (OECD 203) aquatic invertebrates, EC50: (48H) > 1000 mg/L (OECD 202) aquatic algae, ErC50: (72H) > 1,070 mg/L (mean measured concentrations, OECD 201) Aquatic algae, NOErC: (72H) > 1,070 mg/L (mean measured concentrations, OECD 201) Fish, Data waiving in accordance with column 2 of REACH Annex IX. Aquatic invertebrates, NOEC: (21D) > 85 mg/L (OECD 201) Microorganisms, EC50: (3H) > 100 mg/L (OECD 209) Microorganisms, EC50: (40H) > 18,035 mg/L (TETRATOX assay)
12.2 Persistence and degradability	No further relevant information available.	No further relevant information available.	*Biodegradation in water. The submission substance is readily



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			biodegradable as demonstrated in OECD TG 301 B.
12.3 Bioaccumulative potential	A worth-mentioning accumulation in organisms is not expected.	No further relevant information available.	*Based on a calculated log Pow of -0.29, the BCF was estimated to be 3.2 (log BCF = 0.5) (ECT, 2008). The potential for bioaccumulation in aquatic and benthic organisms is therefore expected to be very low.
12.4 Mobility in soil	No further relevant information available.	No further relevant information available.	No further relevant information available.
12.5 Results of PBT and vPvB assessment	PBT: Not applicable vPvB: Not applicable	PBT: Not applicable vPvB: Not applicable	PBT: Not applicable vPvB: Not applicable
12.6 Endocrine disrupting properties	The product does not contain substances with endocrine disrupting properties.	The product does not contain substances with endocrine disrupting properties.	The product does not contain substances with endocrine disrupting properties.
12.7 Other adverse effects	No further relevant information available.	No further relevant information available.	No further relevant information available.

<sup>\*</sup>from ECHA webpage registration data

#### **SECTION 13: DISPOSAL CONSIDERATIONS**

13.1 Waste treatment methods

**Recommendation** Observe community, national or regional regulations for waste

handling and treatment.

European waste catalogue Not applicable

13.2 Uncleaning packaging

**Recommendation** Disposal must be made according to official regulations.

Packaging may be reused or recycled after cleaning.

Packaging that may not be cleansed are to be disposed of in

the same manner as the product.

### **SECTION 14: TRANSPORT INFORMATION**

14.1 <u>UN number or ID number</u>

ADR/RID Not applicable
ADN Not applicable
IMDG Not applicable
IATA Not applicable

14.2 UN proper shipping name

ADR/RID Not applicable
ADN Not applicable
IMDG Not applicable
IATA Not applicable



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14.3 Transport hazard class(es)

ADR/RID

ADN

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

14.4 Packing group

ADR/RID Not applicable
ADN Not applicable
IMDG Not applicable
IATA Not applicable

14.5 Environmental hazard

Marine pollutant No

14.6 Special precautions for user

Special precaution for user Not applicable

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

14.8 ICAO/ IATA -DGR

Not regulated as a dangerous good

14.9 Maritime transport in bulk according to

IMO instruments Not applicable UN "Model Regulation" Not applicable

#### **SECTION 15: REGULATORY INFORMATION**

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

Name	Azelamidopropyl Dimethyl Amine CAS:1272659-40-1	Water CAS:7732-18-5	1,3-Butylene glycol CAS:107-88-0
Inventory - United States - Toxic Substances Control Act (TSCA)	N	Y	Υ
Inventory - Canada - Domestic Substances List (DSL)	N	Υ	Υ
Inventory - Canada - Non-Domestic Substances List (NDSL)	N	N	N
Inventory - Canada - Revised In Commerce List (R-ICL)	N	N	N
ECHA Inventory of substances	N	Y	Y
Japan Existing and New Chemical Substances (ENCS)	N	N	Υ
Inventory of Existing Chemical Substances in China (IECSC)	N	Y	Y
Korean Existing and Evaluated Chemical Substances (KECL)	N	Υ	Υ
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	N	Υ	Υ
Australian Inventory of Industrial Chemicals (AIIC)	N	Υ	Υ
New Zealand Inventory of Chemicals	N	Υ	Υ



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TCSI - Taiwan Chemical Substance Inventory	N	Υ	Y
OECD - List of High Production Volume Chemicals	N	Υ	Υ

Y: listed, N: not listed, E: exempted

Directive 2004/42/EC Seveso category

Substance is not listed.

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II

Substance is not listed.

Regulation (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

Substance is not listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

Substance is not listed.

Regulation (EC) No 273/2004 on drug precursors

Substance is not listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

Substance is not listed.

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer - ANNEX I (Ozone-depleting potential)

Substance is not listed.

National regulations

Other regulations, limitations and prohibitive regulations

Not determined

Substances of very high concern (SVHC) according to REACH, Article 59(10)

Substance is not listed.

#### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

#### **SECTION 16: OTHER INFORMATION**

This information is furnished without warranty, express or implied, except that it is accurate to the best knowledge of CORUM Inc. It relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process. CORUM Inc. assumes no legal responsibility for use of or reliance upon this information.

#### Abbreviations and acronyms

NOAEL: Non Observed Adverse Effect Level LOAEL: Lowest Observed Adverse Effect Level WAF: Water Accommodated Fraction NOEC: No Observed Effect Concentration

GHS: Globally Harmonized System of Classification and Labeling Chemicals



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EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstract Service (division of the American Chemical Society)

VbF: Ordinance on the storage of combustible liquids, Austria

DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent

STOT: Specific target organ toxicity

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

PBT: Persistent Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

#### **Sources**

Own data from manufacture

Chemical safety report according to REACH registration dossier